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MANAGEMENT LIABILITY PRACTICE

Myths & Misconceptions of Biotech Securities Claims 5 Years Later:

An Updated Analysis of Motion to Dismiss Results, from 2005-2022

By Doug Greene, Genevieve York-Erwin, Michael Tomasulo,
Emily Baxter, and Alexandra Karambelas

EXECUTIVE SUMMARY

There is a common life cycle for the Directors and Officers Liability for a publicly-traded biotechnology company.

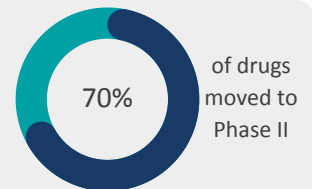
In the early stages, whether pre-clinical or Phase 1, there is more than adequate capacity in the marketplace and coverage can be attained rather competitively. As the company engages in Phase 2 studies, there are more questions asked, but still coverage is readily available. However, as a company engages in Phase 3 studies, the marketplace contracts dramatically leaving very few primary carriers willing to quote and a dramatic increase in pricing. In some cases, even a carrier that has been writing the account profitably for many years will suddenly non-renew as Phase 3 studies begin or, more importantly, if Phase 3 data will be provided during the policy period.

So why the sudden fear of Phase 3 and is it really warranted?

We embarked on a study five years ago to determine the real exposure to carriers on publicly traded pre-commercial biotech companies and attempted to discover if there was actual truth to a number of preconceived “red flags” regarding the risk profile, including: Phase 3 cases are expensive and risky, management that talks too highly about their drug or product leads to a serious settlement, and any insider stock sales by management are detrimental to the case. We have now updated this study to see if our original hypothesis has held up.

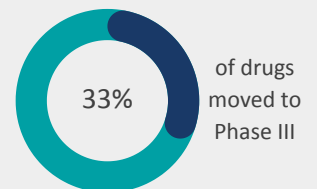
PHASE I

- Assesses the safety and effects of a drug
- Small study group of 20-100 healthy volunteers
- Studies typically last several months



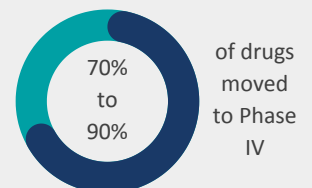
PHASE II

- Tests the efficacy and effectiveness of the drug
- A placebo is often introduced for comparative results
- Study group may include several hundred patients
- Studies may last several months to a couple years



PHASE III

- Randomized and blind testing occurs
- Study group may include several hundred to several thousand patients
- Once completed, FDA approval can be requested to sell to the public
- Allows for a more detailed understanding of the drug's benefits and risk



PHASE IV

- The drug is approved for consumer sale
- Monitors long-term effectiveness
- Compares drugs with others on the market
- Determines cost-effectiveness of new drug treatment compared to other traditional therapies

There is consensus that the biotech industry generates more securities claims than any other sector.

Over the past 3 years, roughly 25% of all securities claims were brought in the Healthcare space, and within the Healthcare sector, roughly 30% of claims are against pharmaceutical companies. There is undeniable frequency within this space, but does that necessarily equate to severity; and does claims frequency make it unprofitable business? The vast majority of claims brought against pre-commercial pharmaceutical or medical device companies are directly related to the drug or device not meeting set end points resulting in very negative news and a dramatic stock drop.

The question we wanted to answer was, given all the safe harbor language that a company provides from the pre-clinical stages of a new drug or device all the way through an NDA (New Drug Application) or PMA (Pre-Market Application) filing and the known public data from the FDA that states roughly only 16 of every 100 drugs that starts a Phase 1 trial gets to market, is there really a path to significant settlement? The short answer, we believe, is no. Five years ago, we reviewed 70 decisions on publicly traded biotech companies with negative trial data and we discovered that dismissal was the rule and not the exception. From 2005-2016, the overall dismissal rate was almost 70%. We have updated our findings with 44 additional cases from July 2017 through March 2022 and found that the dismissal rate is staying relatively flat at 68%, consistent with decisions dating back to 2005.

Taking this a step further, of the 114 decisions for bio-tech securities claims related to clinical trial issues, 78 of them were dismissed. When you consider the average retention amount of most of these policies has climbed to an average of \$5M with an average defense cost bill of only \$750-\$1M to get through dismissal, you are still looking at profitable accounts. Of the 14 cases that did get dismissed over the past 5 years, the average settlement was \$9.1M and the median settlement \$7.3M. When you look at the 10 cases that involved sub \$1B market cap companies, the average and median settlements dropped to \$5.2M and \$4.8M, respectively. In addition, the median settlement for the entire data set since 2005 is \$8.5M. So, while there is some frequency in this space - the dismissal rates are high, settlements are relatively low (especially in the under \$1B market cap segment) and the rates and retention rank among the highest in any industry. We continue to believe these risks are not nearly as caustic as they are treated and should be underwritten more favorably than they are.

Michael Tomasulo
Managing Partner, National Practice Leader
BRP Management Liability

INTRODUCTION

Five years ago, we surveyed a decade's worth of district court decisions on motions to dismiss securities claims brought against development-stage biotech companies to answer an important question:

Q Are these cases more likely to survive a motion to dismiss—and therefore riskier to insure against—than other securities class actions, as D&O insurers have traditionally assumed?

A The answer was a resounding no: our analysis showed that securities claims brought against small, clinical-stage biotech companies were actually more likely to be dismissed at an early stage than other types of securities class actions between 2005 and 2017. These companies have historically been considered attractive targets for securities actions given the inherent risks of the industry and the volatility of their stock prices, and, as a result, often have relatively limited D&O insurance options. But our study found the assumptions that have acted to limit their options to be incorrect—biotech startups do not, in fact, pose greater securities class action risk than other companies.

This spring we set out to analyze another 5 years' worth of data to see whether the patterns we observed in our prior study have held true in more recent years. Not surprisingly, they have. As described below, we surveyed all biotech securities class actions in the past five years to better understand how they have fared in the federal courts and, once again, found that they were actually more likely than other types of cases to be dismissed early in the litigation, saving defendants (and insurers) from the bulk of potential legal costs. This confirms many of the same insights we identified and discussed previously and again below, which can help biotech companies avoid and successfully defend against securities suits, and help insurers make better coverage decisions regarding these companies.

In short, biotech cases remain manageable risks if they are defended correctly, especially if biotech management takes proactive steps to manage its disclosures in a way that will further limit its risks. Below, we describe both the original study and the update we undertook and their results, in light of which we then identify 4 of the biggest myths that continue to surround biotech securities cases and explain why each is unfounded. Finally, we describe and analyze the real driving forces behind these decisions, and we explain how biotech companies, their attorneys, and insurers can use these insights to their greatest advantage.

STUDY METHODOLOGY & RESULTS

In 2017, we searched for and reviewed all of the district court decisions on motions to dismiss biotech securities cases within the previous twelve years to identify the subset of cases that concerned development-stage biotech companies' efforts to bring their first drug or device to market.[1] Only decisions that met all of the following criteria were included in our study set: final district court decisions[2] on motions to dismiss federal securities claims where the biotech company did not already have a drug or device on the market and its alleged false or misleading statements concerned clinical trials or the FDA approval process for its primary drug or device candidate.[3]

Of the 70 decisions in our study set that met these criteria for 2005-2017, 69% resulted in complete dismissals. Moreover, the dismissal rate appeared to have increased towards the end of that period: 76% of the decisions in the study set from 2012-2017 resulted in complete dismissals, compared with only 56% of decisions from 2005-2011. Interestingly, this shift occurred even as more securities class actions were being filed against small biotech companies: 45 decisions in the study set came from 2012-2017, versus only 25 decisions from the previous seven years.

For this update, we ran the same search for the time period July 11, 2017, through March 21, 2022, which yielded 44 additional cases that met our study criteria.[4] Of the 44 decisions in this update set, 68% resulted in complete dismissals. While this is lower than the 76% dismissal rate we observed for 2012-2017, it is nearly identical to the overall average in our original study (2005-2017). Moreover, we did not observe any consistent trends over time within the most recent set of decisions (i.e., there was not a sustained increase or decrease in the percentage of complete dismissals), and we believe 68% represents a fair average for these types of cases over the past five years.

[1] In our original study, we applied the following, over-inclusive search terms to all federal district court decisions from March 6, 2005 through July 10, 2017 in the Westlaw database: (pslra “private securities litigation reform”) & (FDA “food and drug administration” f.d.a.) /p (clinical medical bio! biotech! genom! gene genetic phase trial drug study therapy treatment) & “motion to dismiss.” This produced 332 results, only 70 of which met our study set criteria as described previously (additional cases met the same criteria except that they were brought against companies that already had at least one drug or device on the market).

[2] In each case, only the district court’s final decision on the defense’s motion(s) to dismiss was included in the study set. Any earlier dismissals, where plaintiffs were allowed to amend the complaint and the court then ruled on a subsequent motion to dismiss, were excluded so that sequential opinions in the same action were not double-counted. Likewise, cases that did not yet have a final decision on the motion to dismiss were excluded (e.g., if the court initially dismissed with leave to amend and a subsequent motion to dismiss was pending).

[3] Decisions where the securities fraud claims concerned something other than the clinical trial and FDA approval process for their primary drug or device candidate (e.g., alleged financial improprieties, marketing, sales, post-approval manufacturing issues, etc.) were not included in the study set.

[4] We conducted this search in two segments—from July 11, 2017, through September 6, 2019; and from September 7, 2019, through March 21, 2022—then combined the results for analysis.

As with our original study, and contrary to conventional wisdom, this analysis indicates that federal securities claims brought against biotech companies regarding the regulatory approval process actually are dismissed far more frequently than average at an early stage in the litigation.[5]

FOUR MYTHS ABOUT BIOTECH SECURITIES CASES

As discussed in our original article, these findings overturn several longstanding myths about this subset of securities class actions:

MYTH #1:

Cases against biotech companies for failed clinical trials or products that are not approved by the FDA are risky and expensive.

FACT:

These cases are less risky than the average securities class action. Our analysis shows that about two-thirds of these cases are dismissed in full. They also have structural elements that tend to make them less expensive to defend. There is typically one corrective disclosure—a negative clinical-trial or other FDA-approval development—so under loss-causation law, they can only be about that one thing. And the number of employees is typically quite small, which yields a relatively small number of witnesses and documents. All of this makes the motion to dismiss process simpler and, should the case survive, litigation through class certification, summary judgment, or even trial less cumbersome and expensive. Indeed, on the whole, because the issues and evidence are relatively streamlined, the merits relatively easy to comprehend and handicap, and the key witnesses often doctors and scientists who are trying to cure diseases and fix ailments, these cases can be excellent candidates for trials.[6]

[5] See Janeen McIntosh & Svetlana Starykh, NERA Economic Consulting, *Recent Trends in Securities Class Action Litigation: 2021 Full-Year Review*, at 14, [available here](#) (only 56% of the securities class action motions to dismiss that were decided between January 1, 2012, and December 31, 2021, were granted, with or without prejudice).

[6] See R. Hein & D. Greene, *A Free-Market Solution to Meritless Securities Litigation*, *PLUS Journal Vol XLI*, Fourth Quarter 2020, at 23.

MYTH #2:

Management puts the company at risk if it speaks too positively regarding its expectations of clinical trial results, FDA approval, or product commercialization.

FACT:

As discussed in more detail below, statements of opinion will be protected under the U.S. Supreme Court's decision in *Omnicare*,^[7] so long as they are genuinely held and not misleading when considered in their full context. Optimistic forward-looking statements will also generally be protected by the Private Securities Litigation Reform Act's ("Reform Act") safe harbor for forward-looking statements, provided they are accompanied by sufficiently specific cautionary language.^[8] Courts recognize the inherent uncertainty in the FDA approval process and understand that predictions sometimes will prove wrong; the important thing is for companies to make a meaningful effort to help investors understand these risks. Effective legal counsel can help companies manage their disclosures in a way that allows for optimistic statements while protecting against future litigation.

MYTH #3:

Once negative results become public, any positive spin given by management will be viewed as misleading.

FACT:

Even in the face of bad news, positive statements of opinion are not false or misleading if they are honestly held and are made within the proper context, especially where the company accurately discloses the underlying facts. Courts do not require companies to be pessimistic in assessing arguably negative results; they merely require that companies be honest in their statements and forthcoming with the relevant underlying facts. See, e.g., *Sarafin v. BioMimetic Therapeutics, Inc.*, 2013 WL 139521, at *13-14 (M.D. Tenn. Jan. 10, 2013) (dismissing where defendant characterized clinical trial results positively even though FDA had expressed concerns and contemporaneous news reports described the results as disappointing).

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

[8] The Reform Act provides a safe harbor for forward-looking statements that are identified as such and accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i).

MYTH #4:

Cases will not get dismissed if the company raises capital or insiders sell stock during the class period.

FACT:

These facts may contribute to an inference of scienter in some circumstances, but they are just factors in a holistic scienter analysis. Far more important is the overall story, and whether the alleged motivation to commit fraud makes sense in the context of this larger narrative. When courts are convinced that the defendants were trying their best for the company and were honest and forthright in their public statements, they tend not to be concerned about capital raising or insider sales during the class period. See, e.g., *Jun Shi v. Ampio Pharms., Inc.*, 2020 WL 5092910, at *5 (C.D. Cal. June 19, 2020) (dismissing; “Why would Defendants knowingly carry on a defective trial for the short-term purpose of obtaining non-dilutive financing, when this would inevitably result—after the FDA rejected the trial—in Defendants again needing more (likely dilutive) financing?”); *Brennan v. Zafgen, Inc.*, 2016 WL 4203413, at *2 (D. Mass. Aug. 9, 2016) (dismissing; “[T]he complaint’s circumstantial allegations concerning scienter—a patchwork of scientific literature and unsuspecting insider sales—are insufficient to support a strong inference of defendants’ conscious intent to defraud or high degree of recklessness.” (internal quotation marks omitted)); *In re MELA Sciences, Inc. Sec. Lit.*, 2012 WL 4466604, at *5 (S.D.N.Y. Sep. 19, 2012) (dismissing; “To the extent the [proposed amended complaint] relies on MELA’s capital raised during the Class Period, the court finds this inadequate to support an allegation of intent to commit fraud.”). But see *Gargiulo v. Isolagen, Inc.*, 527 F. Supp. 2d 384, 390 (E.D. Pa. 2007) (scienter was sufficiently pleaded based on several factors, including that defendants allegedly sold their respective securities at the time for “considerable gain”).

CASE TRENDS & PRACTICE TIPS

A careful review of the decisions in our original and updated study sets reveals important insights into how courts actually decide these cases and what companies and legal counsel can do to head off and defend against them. District court judges, like anyone else, are influenced by their overall impressions of the parties and the facts, even at the earliest stages in litigation. Motions to dismiss frequently turn on how the court chooses to characterize the pleadings, which leaves significant room for outcome-driven analysis.

This may seem obvious, but has important practice implications, as discussed below.

Decisions in our study set—both those that dismissed and those that did not—showed again and again that in applying the pleading standard and securities laws to young biotech companies, judges appeared to be swayed by their overall sense of whether or not company management had honestly been doing its best to bring a product to market and inform investors of significant developments in a timely manner. Where courts saw little indication of good faith, they rarely dismissed.

As one court put it:

[N]otwithstanding the defendants' contentions to the contrary, their allegedly misleading statements bear no hallmarks of good faith error. The defendants are sophisticated scientists running a regulated, publicly traded corporation; they are alleged to have misrepresented their regulator's feedback, misrepresented the legal context in which they operated, heralded scientific results, which they knew to be the product of empirically faulty procedures and manipulated statistical analysis, and claimed a level of external review that simply did not exist. If the defendants have good faith explanations for these misstatements, they do not emerge from the complaint.

Decisions are often driven by the court's overall feeling about whether or not the company was being forthright and dealing honestly.

Frater v. Hemispherx Bipharma, Inc., et al., 996 F. Supp.2d 335, 350 (E.D. Pa. 2014). See also, e.g., KB Partners I, L.P. v. Pain Therapeutics, Inc., 2015 WL 7760201, at *1 (W.D. Tex. Dec. 1, 2015) (refusing to dismiss where complaint plausibly alleged defendants intentionally concealed the nature and extent of problems with their drug candidate after its first NDA was rejected, and did so while lining their own pockets with “unjustifiable compensation packages”).

But when defendants presented a credible narrative evidencing good-faith, courts seemed inclined to run with it, absent specific, compelling allegations to the contrary. See Angelos v. Tokai Pharms., Inc., 494 F. Supp. 3d 39, at * 60 (D. Mass. 2020) (dismissing and noting “it is more likely that defendants believed, or at least sincerely hoped, that the Phase 3 trial would be successful than that they knew it would fail and concealed this fact from investors.”), appeal dismissed, 2021 WL 2206322 (1st Cir. Feb. 18, 2021); Jun Shi v. Ampio Pharms., Inc., 2020 WL 5092910, at *6 (C.D. Cal. Jun. 19, 2020) (dismissing and noting that plaintiffs’ scienter theory was “significantly less compelling than the opposing inference—that Defendants designed an inexpensive trial (because companies always have a desire to keep costs low), tried then best to ensure that the trial was well-controlled and adequate, but despite their best efforts, the FDA did not accept this trial for submission.”); In re Axonyx Sec. Lit., 2009 WL 812244, at *3 (S.D.N.Y. Mar. 27, 2009) (dismissing and noting that “[t]he idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly carry on a defective trial—so that any defects were not remedied—virtually defies reason, unless the company was bent on defrauding the FDA and the suffering people who might use the drug. Nothing of that sort is even suggested in the complaint.”); see also, e.g., Kovtun v. VIVUS, Inc., 2012 WL 4477647, at *3, 10 (N.D. Cal. Sep. 27, 2012) (dismissal influenced by fact that drug was approved after the class period, making alleged intentional misrepresentations re approvability improbable).

This seeming inclination to dismiss when presented with a convincing defense narrative appears to reflect two underlying beliefs that favor biotech defendants and may help drive the high dismissal rate in these cases:

- 1** That the research and development of new drugs and medical devices constitutes an important public good, and
- 2** That investment in development-stage companies, which have no existing revenue stream, is inherently particularly risky.

LET'S TAKE A LOOK AT WHAT COURTS HAVE EXPLICITLY NOTED...

There is a significant public interest in the development of life-saving drugs. For every drug that succeeds, others do not. Clinical trials are phased into stages: some drugs never make it past the first stage, others never make it past the second stage, and so on. The costs of failure are high, but the rewards for success are also high. The relationship and ratio between the two determines whether, as a matter of economics, the costs of experimentation are worth it. Publicly traded pharmaceutical companies have the same obligations as other publicly traded companies to comply with the securities laws, but they take on no special obligations by virtue of their commercial sector. It would indeed be unjust—and could lead to unfortunate consequences beyond a single lawsuit—if the securities laws become a tool to second guess how clinical trials are designed and managed. The law prevents such a result; the Court applies that law here, and thus dismisses these actions. *In re Keryx Biopharmas., Inc., Sec. Lit.*, 2014 WL 585658, at *1 (S.D.N.Y. 2014).

Ultimately, investments in experimental drugs are inherently speculative. Investors cannot, after failing in this risky endeavor, hedge their investment by initiating litigation attacking perfectly reasonable—if overly optimistic statements proved wrong only in hindsight. *In re Vical In. Sec. Lit.*, 2015 WL 1013827, at *8 (S.D. Cal. Mar. 9, 2015).

[I]nvesting in a start-up pharmaceutical company, like Adolor, involves a certain amount of risk on the part of investors. No matter how safe that risk may seem at the time, there are no guarantees, and Defendants never suggested otherwise. The fact that Plaintiffs now suffer from buyer's remorse does not entitle them to relief under Rule 10b-5. *In re Adolor Corp. Sec. Lit.*, 616 F. Supp. 2d 551, 570 (E.D. Pa. 2009).

Investors were well-warned of the risks of investing in a drug where studies were ongoing. Defendants' repeated cautionary statements would not cause a reasonable investor to conclude the opposite—that there were no risks associated and that the preliminary positive results would continue. Instead, the Risk Factors warned investors of the very risks Plaintiff claims were not disclosed. *Employees' Retirement Systems. Of City of Baton Rouge and Parish of East Baton Rouge v. Magrogenics, Inc.*, 2021 WL 4459218, at *12 (D. Md. Sept. 29, 2021).

Against this backdrop, biotech defendants are well positioned to secure early dismissals if they simply tell their stories and frame the facts in a manner that demonstrates their good faith. On the front end, this means companies will benefit from getting legal counseling on their disclosures, so that if trouble arises, the disclosures will show a pattern of being honest and forthright and avoid indications of fraud in the context of the company's particular situation (i.e., the state of its communications with the FDA, financing, stock sales, etc.).

Once biotech defendants have been sued, however, they should focus on selecting counsel who will tell their overall story in a way that emphasizes their honesty and does not just focus on a technical defense. Too many defense attorneys feel constrained to make narrow, technical arguments at the motion to dismiss stage—when a civil plaintiff’s factual pleadings usually are taken as true—rather than mounting a normative defense of their clients’ conduct.

This is a missed opportunity—as the decisions and results in our study set show.

Statements of opinion and forward-looking statements are generally safe, even more so after *Omnicare*.

The decision in *Omnicare* expressly allows, and even encourages defendants to tell their versions of the story by declaring that whether a statement of opinion (or, by clear implication, a statement of fact) was misleading “always depends on context.” 135 S. Ct. at 1330. Under this standard, courts are required to consider not only the challenged statements and the immediate contexts in which they were made, but also other statements made by the company and other publicly available information, including the customs and practices of the industry. In combination with the Supreme Court’s directive in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), to assess scienter based on not only the complaint’s allegations but also documents on which it relies or that are subject to judicial notice, *Omnicare* now clearly requires courts to consider a broad set of probative facts each time they decide a motion to dismiss federal securities claims. Effective defense counsel will take advantage of this mandate and continue to use the motion to dismiss to tell their client’s story in a way that frames the facts and issues favorably and helps the court feel comfortable dismissing the suit. Evaluating challenged statements in this broader context nearly always benefits defendants, since it helps courts better understand the statements and makes them seem fairer than they might on their own.

The sorts of forward-looking statements of opinion that biotech companies often most want to make about their flagship products are not actually likely to get them into trouble, so long as the statements are honestly believed and are accompanied by disclosures that acknowledge specific, relevant uncertainties.

This is so for two reasons:

1 Claims challenging statements of opinion—including optimistic predictions—are likely to be dismissed under the *Omnicare* standard.

Even before the Supreme Court’s decision in *Omnicare*, courts tended to find statements of opinion to be non-actionable on a variety of different theories (e.g., puffery, lack of falseness, immateriality, etc.). After all, “[p]unishing a corporation and its officers for expressing incorrect opinions does not comport with Rule 10b-5’s goals.” *In re Vical Inc. Secs. Lit.*, 2015 WL 1013827, at *8 (S.D. Cal. Mar. 9, 2015). So, for example, the court in *Shah v. GenVec, Inc.*, 2013 WL 5348133 (D. Md. Sep. 20, 2013), found the defendants’ positive characterizations of interim data to be immaterial “puffery” and, therefore, non-actionable:

Plaintiffs properly characterize their challenge as Defendants placing ‘an unjustifiably positive spin on the data available at the time of the [first interim analysis] by using terms like “encouraging” and “bullish[.]”’ Such vague and general statements of optimism constitute no more than puffery and are understood by reasonable investors as such. Accordingly, they are immaterial and not actionable under § 10(b).

Id. at *15 (internal citations omitted). See also, e.g., *Oklahoma Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, 2020 WL 3268531, at *12 (S.D.N.Y. June 17, 2020) (statements “that the [FDA approval] process was ‘on track’ and making continued ‘progress,’ or declar[ing defendants’] belief that they were ‘moving through the approval process in a timely manner,’ constitute inactionable puffery”); *Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *11 (N.D. Cal. Sep. 27, 2012) (“[S]tatements referring to [the drug candidate’s] ‘excellent’ or ‘compelling’ risk/benefit profile, or statements to the effect that the trials had shown ‘remarkable’ safety and efficacy, . . . are simply vague assertions of corporate optimism and therefore are not actionable”); *In re MELA Sciences, Inc. Sec. Lit.*, 2012 WL 4466604, at *13 (S.D.N.Y. Sep. 19, 2012) (characterizing positive statements about clinical results as opinions and dismissing because “Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial.”).

The decision in *Omnicare*, however, as discussed above, established a clear, unified, and even more defendant-friendly standard for assessing statements of opinion in securities cases:

An opinion is only false if the speaker does not believe it, and it is only misleading if it omits facts that make it misleading to a reasonable investor when viewed in its full, broadly understood context. See *id.* at 1328-30. Thus, a company’s statements of opinion, including optimistic projections about clinical results or FDA approval, are not actionable as long as the company actually believed them at the time and they were not misleading in their full context.

FOR EXAMPLE:

Applying this standard in *Gillis v. QRX Pharma Ltd.*, 2016 WL 3685095 (S.D.N.Y. July 6, 2016), the court concluded that the defendants’ optimistic statements that it was “encouraged” by FDA feedback and was “confident that [its drug candidate would] receive approval” were opinions, and plaintiffs had failed sufficiently to allege that defendants did not believe them or that they were misleading in context. *Id.* at *21-23. See also, e.g., *Leavitt v. Alnylam Pharms., Inc.*, 451 F. Supp. 3d 176, 184 (D. Mass. 2020) (“Although the FDA interpreted trial results differently and defendants’ opinions may have been erroneous, those facts alone do not render the statements fraudulent or misleading. Without specific allegations of falsity, opinions interpreting the results of a clinical study are not actionable.”); *Corban v. Sarepta*, 2015 WL 1505693, at *8 (D. Mass. Sep. 30, 2015) (“[T]he company’s statements that it was encouraged by the feedback and believed its data would be sufficient for a filing constituted an expression of opinion,” which the court found not to be actionable).

Both the district court (before *Omnicare*) and the Second Circuit (after *Omnicare*) came to the same conclusion regarding the optimistic predictions at issue in *In re Sanofi Securities Litigation*.^[9] There, plaintiffs alleged that the defendants’ optimistic statements concerning a drug candidate’s likelihood of approval and its clinical results were misleading where they failed to disclose that the FDA repeatedly had expressed concerns about the company’s use of single-blind studies. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 517 (S.D.N.Y. 2015). Applying the Second Circuit’s pre-*Omnicare* standard, the district court concluded that the challenged statements all were statements of opinion, and dismissed because plaintiffs had not established either that the opinions were not honestly held or that they were “objectively false.” *Id.* at 531-33. The Second Circuit affirmed, but took the opportunity to apply the Supreme Court’s then-recent *Omnicare* standard to the facts at hand, emphasizing in particular the larger context in which the challenged statements were made:

Plaintiffs are sophisticated investors, no doubt aware that projections provided by issuers are synthesized from a wide variety of information, and that some of the underlying facts may be in tension with the ultimate projection set forth by the issuer... These sophisticated investors, well accustomed to the “customs and practices of the relevant industry,” would fully expect that Defendants and the FDA were engaged in a dialogue, as they were here, about the sufficiency of various aspects of the clinical trials and that, inherent in the nature of a dialogue, are differing views.

[9] This district court dismissal was excluded from our primary study set because, although it otherwise met our study criteria, Sanofi is a well-established pharmaceutical company with numerous drugs already on the market.

Tongue v. Sanofi, 816 F.3d 199, 211 (2d Cir. 2016). As previously discussed, this highly contextual analysis favors defendants, and makes it even more likely that claims challenging defendants' statements of opinion—including optimistic predictions concerning FDA approval or interpretations of clinical results—will be dismissed, provided the defendants genuinely held those opinions.

Of course, even statements of opinion can be false if they're not genuinely believed; making an optimistic projection about FDA approval when a company has specific reason to believe the drug will not in fact be approved is likely to get it into trouble.

So, for example, in *In re Pozen Sec. Lit.*, 386 F. Supp. 2d 641 (M.D. N. Car. 2005), the court refused to dismiss claims regarding optimistic statements by the defendant touting its drug candidates' effectiveness and implying their approvability, where the company knew at the time that it was applying a statistical analysis different from what it had agreed to with the FDA and knew that the drugs had failed in part to meet a critical clinical measure it had specifically agreed upon with the FDA ahead of time. *Id.* at 646-47. The court noted that the defendants might well have had other reasons to believe their own expressions of optimism at the time, which would make these statements of opinion not false, but it found the allegations sufficient to survive a motion to dismiss. *Id.*

2 Predictions of clinical trial success or FDA approval usually are also protected forward-looking statements

Not only are most optimistic projections statements of opinion, subject to Omnicare's rigorous standard, they also tend to be forward-looking statements protected under the Reform Act's safe harbor. See *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 354-55 (2d Cir. 2022) (affirming dismissal in part because predictions regarding likelihood of clinical trial's success and drug candidate's speed to market were protected forward-looking statements).

Courts in the study set usually found expressions of optimism regarding clinical trial results or the likelihood of FDA approval to be forward-looking statements protected under the Reform Act's safe harbor where the statements were accompanied by specific cautionary language that warned investors of the most significant risks.

As one court explained:

Projections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the company's plan for its product, and, as such, fall under the PSLRA's safe harbor rule. Each VIVUS press release or other public statement cited by plaintiff included warnings about the uncertainties of forward-looking statements, and also referred to VIVUS' SEC filings. Those filings, in turn, were replete with discussion of risk factors, including potential difficulties with obtaining FDA clearances and approval; the known side-effects of Qnexa's two components, and the possibility of FDA required labeling restrictions; the risk that the FDA might require additional, expensive trials; and concerns regarding Qnexa's association with Fen-Phen.

Kovtun v. VIVUS, Inc. 2012 WL 4477647, at *12 (N.D. Cal. Sep. 27, 2012) (dismissing); see also, e.g., Hackel v. AVEO Pharmaceuticals, Inc., 474 F. Supp. 3d 468, 478 (D. Mass. 2020) (dismissing in part because predictions about the timing of topline results were protected forward-looking statements; "In addition to the use of language such as 'expect' and 'anticipate,' which signals looking forward, the Company was in the midst of a clinical trial with endpoints that were by their very nature unknown and . . ."); Gillis v. QRX Pharma Ltd., 2016 WL 3685095, at *23 (S.D.N.Y. July 6, 2016) ("QRX's statement that it was 'confident that MOXDUO will receive approval,'... is, separately, shielded by the PSLRA safe harbor.").

In fact, some courts found optimistic projections to be protected even where the cautionary language was fairly minimal. For example, in *Oppenheim v. Encysive Pharms., Inc.*, 2007 WL2720074 (S.D. Tex. Sep. 18, 2007), the court concluded that statements by the defendant (1) that it had a “good shot” at receiving priority review from the FDA (but where it had clearly acknowledged that it was “an FDA decision of course”), and (2) that it did not expect the FDA to require additional clinical trials (but where it had stated “you never know what’s going to happen when you get into a regulatory process”), were protected under the safe harbor. *Id.* at *3.

3 Challenges to clinical methodology and analysis are generally rejected, as long as the defendants do not appear to have been manipulating data.

Courts also routinely dismiss challenges to a company’s clinical methodology or analysis.

Statements interpreting clinical trial results often are found to be true and not misleading expressions of opinion. See, e.g., *Tongue v. Sanofi*, 816 F.3d 199, 214-15 (2d Cir. 2016) (affirming dismissal; “Defendants’ statements about the effectiveness of Lemtrada cannot be misleading merely because the FDA disagreed with the conclusion... At bottom, Plaintiffs’ allegations regarding Defendants’ stated opinion about the [] trial results are little more than a dispute about the proper interpretation of data, a dispute this Court rejected as a basis for liability in [*Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013)].”); *In re Karyopharm Therapeutics Inc. Sec. Litig.*, 552 F. Supp. 3d 77, 89 (D. Mass. 2021) (dismissing; “Although the FDA interpreted the... study results differently... and defendants’ view of the data may have been erroneous, those facts alone do not render their opinions actionable.”); *Employees’ Retirement Sys. Of City of Baton Rouge and Parish of East Baton Rouge v. Magrogenics, Inc.*, 2021 WL 4459218, at *12 (D. Md. Sept. 29, 2021) (“Defendants are not required to adopt [plaintiff’s view of the data]. [They] may take issue with Defendants’ researchers and scientists, but where a defendant’s competing analysis or interpretation of data is itself reasonable, there is no false statement.”); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 543 (S.D.N.Y. 2015) (“Courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.”); *Corban v. Sarepta*, 2015 WL 1505693, at *6 (D. Mass. Sep. 30, 2015) (applying pre-Omnicare standard and dismissing claims re statements touting the strength of clinical trial results in part because “many of the challenged statements consist of interpretations of the company’s data,” which the court found to be nonactionable expressions of opinion).

Likewise, courts tend to dismiss suits where plaintiffs' theory boils down to a mere disagreement with the company's clinical trial methodology. See, e.g., *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013); *Davison v. Ventrus Biosciences, Inc.*, 2014 WL 1805242, at *7 (S.D.N.Y. May 5, 2014) (dismissing claims that optimistic statements were misleading because they failed to disclose that the small sample size allegedly distorted results, and noting that "[t]he Second Circuit has emphasized that in scrutinizing a Section 10(b) claim, a court does not judge the methodology of a drug trial, but whether a defendant's statements about that study were false and misleading"); *In re Keryx Biopharmas., Inc.*, 2014 WL 585658, at *10-12 (S.D.N.Y. Feb. 14, 2014) (dismissing claims based on statements re clinical results that plaintiffs allege were misleading due to extensive methodological flaws); *Abely v. Aeterna Zentaris, Inc.*, 2013 WL 2399869, at *6 10 (S.D.N.Y. May 29, 2013) (dismissing claims because plaintiff's allegations "merely amount to a competing view of how the trial should have been designed" and "[p]ublic statements about clinical studies need not incorporate all potentially relevant information or findings, or even adhere to the highest research standards, provided that its findings and methods are described accurately"); see also *Immanuel Lake v. Zogenix Inc.*, 2020 WL 3820424, at *9 (N.D. Cal. Jan. 27, 2020) (dismissing claim based on defendants' failure to disclose that certain information was not included in the NDA; "[W]ere plaintiffs' version of falsity the law... [p]otential plaintiffs could merely parrot any deficiency identified by the FDA rejection letter and then claim the company concealed from the market that it failed to include this 'necessary' piece of information in its application.").

As long as a biotech company describes its clinical and interpretive methodologies accurately, courts generally will not pass judgment on the soundness of those approaches.

See *Abely*, 2013 WL 2399869, at *6 ("The Second Circuit and other tribunals have concluded that the securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors." (emphasis added)).

Where plaintiffs put forth specific, credible allegations indicating that defendants were intentionally misrepresenting or manipulating data, however, courts often allow these cases to go forward. See, e.g., *Voulgaris v. Array Biopharma Inc.*, 2020 WL 8367829 at *10 (D. Col. Nov. 24, 2020) (declining to dismiss where plaintiffs credibly alleged that “Defendants concealed material, negative data that directly contradicted the impression they created in terms of [the drug’s] supposed ‘clinical benefit.’”); *In re Delcath Systems, Inc. Sec. Lit.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014) (dismissing claims re optimistic projections concerning drug approval, but allowing claims re alleged misrepresentations and omissions concerning clinical results because “[t]he allegations here do not involve differing interpretations of disclosed data, but rather data that was not disclosed”); *In re Immune Response Sec. Lit.*, 375 F. Supp. 2d 983, 1018-22 (S.D. Cal. 2005) (refusing to dismiss claims alleging that defendants continuously misrepresented clinical results that they knew were incomplete and flawed, where complaint included specific corroborating details suggesting intentional misconduct); *In re Vicuron Pharms. Inc. Sec. Lit.*, 2005 WL 2989674, at *6 (E.D. Pa. July 1, 2005) (allowing claims re positive statements about Phase III clinical results to move forward where court seemed convinced by allegations that defendant actually knew clinical results were problematic and approval was unlikely).

Other than cases where companies appear to have made false statements of fact, the riskiest areas for companies are disclosures made relative to FDA feedback.

Thus, it is best for biotech companies accurately to disclose the details of their clinical trial methodology and underlying data along with the company’s interpretation of that data, in order to avoid plausible claims of subterfuge later on.

One category of statements sticks out in the study set as particularly troublesome for defendants: alleged misrepresentations concerning feedback from or interactions with the FDA.

On the one hand,

[N]umerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology. Indeed, such courts frequently reason that interim FDA feedback is not material because dialogue between the FDA and pharmaceutical companies remain ongoing throughout the licensing process, rendering such criticism subject to change and not binding in regards to ultimate licensing approval.

Vallabhaneni v. Endocyte, Inc., 2016 WL 51260, at *12 (S.D. Ind. Jan. 4, 2016) (dismissing claims that defendant misled investors by touting Phase II results without disclosing that the FDA had questioned how efficacy was determined in the study, because FDA concerns expressed were not so severe as to suggest the drug could not be approved, and the FDA subsequently allowed Phase III to move forward). See also Tongue v. Sanofi, 815 F.3d 199, 214 (2d Cir. 2016) (affirming dismissal; “Reasonable investors understand that dialogue with the FDA is an integral part of the drug approval process, and no sophisticated investor familiar with standard FDA practice would expect that every view of the data taken by Defendants was shared by the FDA.”).

On the other hand, claims concerning statements or omissions about interactions with the FDA seem to survive motions to dismiss more often than other types of statements in biotech cases, particularly where companies appear to have cherry-picked the FDA feedback they choose to disclose.

In assessing these sorts of claims, courts carefully distinguish between optimistic projections regarding approval, which tend to be opinions and protected forward-looking statements, and statements regarding past FDA interactions or feedback, which pertain to verifiable historical facts. For example, in *In re Mannkind Sec. Actions*, 835 F. Supp. 2d 797 (C.D. Cal. 2011), the court refused to dismiss claims regarding defendants’ repeated assurances that the FDA had “blessed,” “approved,” “accepted,” and “agreed to” the company’s methodological approach in its clinical trials, when it later became clear that the FDA had done no such thing:

Courts must of course be careful to distinguish between forward-looking statements later deemed to be unduly optimistic, and statements of historical fact later shown to be false when made... [S]tatements touting the merits of the bioequivalency studies, can be fairly read as misguided opinion or ‘corporate optimism,’ [but] it is harder to escape the conclusion that Defendants’ statements concerning the FDA cross the line from exaggeration and ‘corporate optimism’ into outright misstatement of historical fact.”

Id. at 809-11 (emphasis in original); see also *Skiadas v. Acer Therapeutics Inc.*, 2020 WL3268495, at *10 (S.D.N.Y. June 16, 2020) (similar).

Likewise, in *In re Cell Therapeutics, Inc. Class Action Lit.*, 2011 WL 444676 (W.D. Wa. Feb. 4, 2011), the court dismissed claims challenging the defendants’ optimistic statements about the drug candidate’s progress in clinical trials and the company’s hopes for FDA approval because these were forward-looking statements accompanied by sufficient cautionary language. *Id.* at *7-8. At the same time, however, the court allowed claims to move forward regarding defendants’ repeated statements indicating that its Special Protocol Assessment (“SPA”)—an agreement with the FDA that the drug would be approved if the company followed the agreed-upon protocol and the drug proved effective[10]—was still in effect even after defendants knew that they had invalidated the SPA. *Id.*; see also, e.g., *Tomaszewski v. Trevena, Inc.*, 482 F. Supp. 3d 317, 333 (E.D. Pa. 2020) (declining to dismiss claims premised on omission of specific negative FDA feedback where defendant subsequently represented that the FDA “approved” of the study design); *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014) (declining to dismiss claims re statements that allegedly mischaracterized FDA feedback by:

1. Omitting FDA statements indicating that it probably would not be receptive to company’s intended clinical approach, AND
2. Incorrectly stating that the FDA had withdrawn its request for a new clinical trial as part of a resubmitted New Drug Application).

In light of these cases, how does a company decide what to disclose when it is in constant communications with the FDA? This is a prime area where a company can mitigate its risk by getting expert disclosure advice.

[10] As the court explained: “[A]n SPA can only be modified by written agreement between the FDA and the sponsor and then only if it is intended to improve the study. Failure to follow the agreed-upon protocol constitutes an understanding that the SPA is no longer binding.” *In re Cell Therapeutics*, 2011 WL 444676, at *1.

In light of these cases, how does a company decide what to disclose when it is in constant communications with the FDA? This is a prime area where a company can mitigate its risk by getting expert disclosure advice.

As a starting point, review of our case study set suggests the following:



Context and clarity are important.

Omnicare will protect statements of opinion so long as they are genuinely held and not misleading in their full context. If a company wants to express an opinion regarding its interactions with the FDA, it can protect itself by accurately and clearly disclosing the important underlying facts (positive and negative) regarding that interaction, as well. Moreover, if a company wants to make optimistic projections regarding the approval process more generally, it should keep in mind that any negative feedback from the FDA, whether disclosed or not, will be part of the overall context in which those statements of opinion are judged.



Companies need to be careful not to mislead.

Selective disclosure of some facts but not others can create difficulties and must be done with care and transparency. If a company chooses to disclose interim FDA feedback, it should do so fairly, reporting both positive and significant negative components of that feedback at the same time. With expert guidance, it is possible to emphasize the positive while acknowledging the negative in a way that will not leave the company open to challenge at a later date.



Companies should be careful not to overstate or misconstrue FDA opinions.

These can later be contradicted by the agency when an approval decision is made, opening the company up to allegations that it intentionally misrepresented the interim feedback it received. A biotech company most often will be best served by couching any optimism it wants to express in terms of the company's opinions and expectations, rather than positively characterizing the FDA's feelings or intentions, and sticking to accurate, factual accounts of FDA feedback.

CONCLUSION

Both our original study and this updated analysis show that, contrary to popular belief, development-stage biotech companies actually have less to fear from federal securities cases than do many other types of corporate defendants that have a far easier time securing insurance coverage.

Over the last decade and a half, these cases have been dismissed at a high rate early in the litigation process. Biotech startups may well end up being sued if and when their flagship products are not approved by the FDA, but courts are sympathetic to the inherent risks of the industry and seem primed to dismiss these suits when defendants can present a credible narrative of good faith conduct. By getting expert disclosure advice before making important announcements, and by hiring litigation counsel who will affirmatively tell the company's story at the motion to dismiss stage, small biotech companies and their insurers can guard against litigation and give the company an excellent shot at early dismissal in any securities suits that are ultimately brought against them.

Insurance products offered through one or more licensed insurance agency affiliates of Baldwin Risk Partners, LLC

**To learn more about Biotech Securities Claims,
contact our team:**

ManagementLiability@BaldwinRiskPartners.com