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INTRODUCTION AND OVERVIEW

This year-in-review addresses developments in securities class actions brought against life sciences companies in 2017. We begin with an overview and analysis of trends in decisions involving life sciences companies with products at two distinct stages of development—pre- and post-FDA approval. We then provide summaries of the 35 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2017.

At the most basic level the cases analyzed share a common feature. In each, a life sciences company has suffered a setback that, when publicized, was followed first by a stock price decline and then by litigation initiated by shareholders seeking to recover investment losses. Such setbacks can, of course, occur at any stage of a company’s development, but in the life sciences sector—given particular issues relating to drug development, regulatory approval, and continued regulatory oversight of manufacturing, marketing and sales activities—the setbacks are clustered in a few obvious stages of a company’s life cycle.

We believe that analyzing legal developments by reference to the stage of drug or device development at which the setback occurs may yield useful insights and assist in risk mitigation. Accordingly, this year-in-review is structured with reference to the following stages:

Pre-Approval: Clinical Trials and Pre-Clinical Studies
Post-Approval: Launch and Marketing of the Product
PRE-APPROVAL: CLINICAL TRIALS AND PRECLINICAL STUDIES

PRECLINICAL DEVELOPMENT

CONDUCT OF PHASES 1-3
of clinical trials and analysis and report of trial results.

SUBMISSION OF APPLICATION FOR REGULATORY APPROVAL OF PRODUCT
for pharmaceutical products, the New Drug Application; for Class III medical devices, the Premarket Approval Application; and for non-exempt Class I or II medical devices, Premarket Notification under 510(k) of the Food, Drug and Cosmetic Act.

COMMERCIALIZATION AND LAUNCH OF THE NEW DRUG OR DEVICE

POST-APPROVAL: MATURE PRODUCT

LAUNCH STAGE

CONTINUED MONITORING BY AND INTERACTION WITH THE FDA
IN THE FOLLOWING AREAS:

Adverse Event Reporting — reporting of adverse events to the FDA as required by regulation; FDA response and further developments.

Inspection of Facilities — routine inspection by the FDA, followed by various communications should issues arise and not be resolved — Forms 483, Warning Letters, Complete Response Letters.

Marketing — Regulatory monitoring of marketing efforts, and the FDA or other government action if issues arise concerning off-label marketing, Medicare/ Medicaid fraud, Foreign Corrupt Practices Act or other statutory or regulatory violations.

Other Regulatory Issues — changes in label or product design that may trigger regulatory obligations.

NON-REGULATORY ISSUES

Sales and Sales Forecasting
Other Issues Not Specific to Life Sciences Companies

A setback at any stage will present disclosure issues, and a company will be required to determine when and how best to inform the financial markets of the negative development. Assuming a company’s stock price declines following the disclosure, members of the plaintiffs’ securities bar will review the company’s past statements relevant to the issue and will search for inconsistencies between past positive representations and the current negative development. Plaintiffs’ counsel will then seek to attribute any such inconsistencies to fraud. Given the heightened pleading standards of the Private Securities Litigation Reform Act, plaintiffs’ allegations will be tested at an early stage in the litigation. In nearly all cases, the company will move to dismiss, arguing that plaintiffs have failed to allege facts that create a “cogent” and “compelling” inference that the company made deliberately false statements.¹

In this section, we discuss trends in the reported federal decisions issued in securities actions at the pleading stage. Unless otherwise noted, these decisions concern class actions brought under Section 10(b) of the Securities Exchange Act of 1934. Companies have fared significantly worse in the district courts in 2017 than they did in the previous two years.

2015 Companies won dismissal in 18 of the 26 decisions issued by the district courts, or 69%
2016 Companies won dismissal in 25 of the 33 decisions issued by the district courts, or 76%
2017 Companies won dismissal in 13 of the 26 decisions issued by the district courts, or 50%

Losses for companies in 2017 came disproportionately from the post-approval context. Companies won dismissal in 63% of the pre-approval cases but in only 30% of the post-approval cases. Several of the post-approval cases in which companies were unsuccessful touched on recent scandals involving price-gouging and the opioid crisis—issues that are also at the heart of a substantial fraction of the new filings in 2017. Other post-approval decisions unfolded against an M&A background, which the courts considered relevant in assessing scienter.

Companies fared better in the appellate courts. The appellate courts affirmed dismissal in 4 of the 5 pre-approval cases and in 3 of the 4 post-approval cases. The activity in both the district and appellate courts is represented graphically on the following two pages. As we discuss more fully below, the volume of new filings has been increasing over the past three years:

2015 39 new complaints
2016 50 new complaints
2017 54 new complaints

The number of new decisions, however, has not kept pace. Indeed, the number of reported decisions fell from 41 in 2016 to 35 in 2017, suggesting that the cases are moving through the courts quite slowly.

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1 Under Section 10(b), life sciences companies and their officers may be liable for consciously false or misleading statements made in virtually any public context, including press releases, earnings calls, investor conferences and SEC filings. Defendants may also be liable for participating in a “scheme” to defraud; successful scheme claims, however, are rare. Several cases discussed in this review also include claims under Sections 11 and 12 of the Securities Act of 1933 as well as Section 10(b) claims. Sections 11 and 12 apply only to statements made in connection with new securities offerings—generally, statements in the prospectus and registration statement for an offering. In contrast with Section 10(b), Sections 11 and 12 do not have a scienter requirement.

2 In this section and throughout this review, we use the term “company” to refer collectively to the defendants in securities litigation—both the company and individual officers or directors.
DISTRICT COURT DECISIONS

10 DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

- 7 POST-Approval Decisions
  - Motion to Dismiss
  - DENIED

3 POST-Approval Decisions
- Motion to Dismiss
- DENIED

10 PRE-Approval Decisions
- Motion to Dismiss
- GRANTED

6 PRE-Approval Decisions
- Motion to Dismiss
- DENIED

16 DECISIONS RELATED TO PRE-APPROVAL DRUGS OR DEVICES
PRE-APPROVAL CASES

In 2017, as in the past two years, district court decisions in securities fraud actions involving pre-approval products broke in favor of defendants. The district courts granted defendants’ motions to dismiss in 10 cases and denied the motions in whole or in part in 6. Defendants also prevailed in 4 of the 5 pre-approval appellate decisions.

While the numbers are plainly good for life sciences companies, the development of the law has been somewhat uneven this year. Courts have generally continued to recognize institutional limitations in adjudicating disputes over science and medicine, but there have been some significant outliers. One district court took a deep dive into the parties’ dispute over the proper interpretation of a trial protocol and resolved the matter in plaintiffs’ favor. Two other district courts ruled against defendants on issues that could easily have been framed as matters of scientific dispute.

The 2017 decisions also illustrate the particular perils of commenting on interim results in ongoing trials. Three of the six cases in which companies were defeated at the pleading stage involved communications of this sort. While courts recognize that in some cases companies will simply not have access to relevant information during the course of a trial—a blinded trial is the classic example—the district court decisions taken together suggest that companies should exercise particular caution when discussing interim or preliminary trial results. They should be mindful of the risk that courts will find in such discussions a duty to update results as a trial continues, even if subsequent unfavorable data are short of conclusive.

On the other side of the ledger, life sciences companies have fared well in the 2017 cases in which plaintiffs challenged statements related to FDA communications or to prospects for approval. A company’s risk disclosures and other cautions can yield tangible dividends in this context. Courts are unlikely to conclude that plaintiffs have adequately alleged fraud as to statements about approval where a company warns the market that it cannot guarantee any particular action by regulators. Courts have also continued to recognize that companies have no standalone duty to disclose all interim communications with regulatory agencies.

Finally, 2017 saw new developments in the application of the Supreme Court’s 2015 Omnicare decision, which governs the analysis of challenged opinion statements. A pair of Ninth Circuit decisions exemplifies two distinct approaches, one favoring defendants and the other favoring plaintiffs. In Align Technology, the court affirmed dismissal where plaintiffs were able to show only that their methods of analysis would have yielded a different opinion—not that the company omitted material information about its own processes for deriving that opinion. The Align court’s focus on a company’s processes is particularly defendant-friendly. Plaintiffs will most often lack access to information about the process through which a company derives its opinions.

In Atossa, by contrast, the court was unconcerned with process and asked simply whether the information that plaintiffs claimed had been omitted—in that case, information about an FDA warning letter—“fairly aligned” with the company’s opinion that regulatory risks had been reduced. And the court concluded that the challenged opinion did not in fact fairly align with the omitted information, and accordingly reversed dismissal. Plaintiffs will clearly fare better in cases where a court is willing to weigh competing information relevant to an opinion statement than they will in cases where the court requires them to allege facts about a company’s processes.

We expand below on developments in these four areas—(1) scientific disputes, (2) communications about ongoing trials, (3) favorable statements about regulatory communications and prospects for approval, and (4) opinion statements under Omnicare. We identify categories of statements that may pose the greatest liability risk and suggest ways in which companies may be able to minimize that risk.

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3 Omnicare, Inc. v. Laborers District County Construction Industry Pension Fund, 135 S. Ct. 1318 (2015). Citation information for all 2017 decisions discussed in this section is provided in the table and summaries immediately following.
Scientific Disputes

As in past years, courts have largely continued to reject claims that can be characterized as direct or indirect challenges to the science underlying a company’s drug development program or trial design. Tetraphase (page 30) provides a good illustration. The company in that case, which was developing a synthetic antibiotic, reported favorable results from the lead-in portion of a Phase 3 trial. In the pivotal portion, however, the efficacy of the drug candidate proved to be inferior to that of the comparator drug, and the company’s stock price fell 80%. Plaintiffs claimed that the company must have known that its drug would not be effective, and they cited “scientific opinions” purportedly showing why, from a “chemical perspective,” that was the case. The company responded with competing arguments about expected efficacy. The court declined to adjudicate the dispute, holding that plaintiffs could not establish knowing misconduct where both sides could identify bases for their contradictory positions on matters of scientific analysis.

Kader v. Sarepta (page 29) similarly illustrates courts’ reluctance to enmesh themselves in scientific disputes. The company in that case had conducted rolling Phase 2 trials using a surrogate endpoint and had discussed the trials extensively with the FDA before submitting its NDA. After the company filed its application, the FDA released a briefing document including statements critical of certain of the company’s methods. Plaintiffs sought to amend a previously dismissed complaint to include the FDA’s unfavorable statements in challenging the company’s positive characterizations of the trials. The court rejected plaintiffs’ attempt, holding that “[d]isagreement with or criticism of drug study methodology is insufficient to state a claim for securities fraud.”

Plaintiffs in Northwest Biotherapeutics (page 30) similarly failed to state a claim in challenging statements related to specific features of trial design. The company there stated that it had designed its trial around a p-value of 0.02—a more rigorous confidence interval than the 0.05 p-value often employed in trials, and hence a “cushion” favoring approval. Plaintiffs claimed that this statement was misleading insofar as “the FDA does not consider a p-value of 0.05 to be the de facto measure of statistical significance.” The court rejected the claim, concluding that plaintiffs had “fail[ed] to move their Complaint from mere disagreement to actionable misrepresentation or omission.”

But not all courts have shared the general reluctance to adjudicate scientific disputes. The most striking decision on the other side of the ledger in 2017 is Clovis (page 34), in which the district court took a remarkably deep dive into the parties’ conflict over the correct interpretation of a Phase 1/2 trial protocol, and ended up siding with plaintiffs. Clovis was the developer of a lung cancer drug, and its Phase 1/2 trial involved measuring tumors for shrinkage at various points along a multi-cycle timeline. Clovis announced favorable initial response rates of 50-60% and continued to report results in that range as the trial progressed. Ultimately, however, after follow-up scans were performed to confirm the initial favorable results, the company announced that the response rate had dropped to 28-34%. Plaintiffs claimed that the company had engaged in fraud by continuing to report the favorable initial results long after the follow-up scans required by the protocol had shown that the initial results could not be confirmed or sustained. The parties’ dispute turned on when, according to the protocol, the confirmatory scans had to be performed and under what circumstances a less favorable follow-up scan superseded the initial favorable scan.

Resolving the dispute required not only careful analysis of the protocol but also interpretation of underlying industry guidelines and scientific literature. But far from expressing any reluctance to dive into these matters, the court analyzed in detail the parties’ competing arguments over what the protocol required and concluded that, at least at the pleading stage, plaintiffs had the better of the argument. Why the court was willing engage in this analysis is less clear. Perhaps the exercise of textual interpretation appeared to the court to be within its expertise. The court essentially needed to consult guidelines to determine when and under what circumstances one data point took precedence over another, and this may have appeared similar enough to the kinds of analysis judges and lawyers generally perform that the court was untroubled by issues of institutional expertise.

The court in PTC Therapeutics (page 36) similarly declined to dismiss claims simply because they might have been characterized as an attack on the science underlying the company’s trials and NDA. The company in that case had submitted an initial NDA following a Phase 2 trial that
failed to meet its endpoints. The company’s reason for doing so was that although efficacy could not be demonstrated as to the intent-to-treat population, efficacy could be shown with respect to a subset of sicker patients. After the FDA responded to the initial NDA with a Refuse to File letter, the company conducted a Phase 3 trial confined to sicker patients. The Phase 3 trial also failed to meet its endpoints but could be viewed as a success if further confined to a certain subgroup of patients in the study. The company discussed the Phase 3 results in positive terms and reported that based on a meta-analysis of the favorable portions of the Phase 2 and Phase 3 trials, it had demonstrated efficacy. The company then submitted a second NDA—and the FDA again responded with a Refuse to File letter.

Plaintiffs challenged the company’s positive statements following Phase 3 and the court denied the company’s motion to dismiss. Although the statement that a trial has demonstrated efficacy might be viewed as a classic matter of scientific judgment, the court did not see it in that light. Rather, the court held that plaintiffs had sufficiently pled that the company’s statements about efficacy were false or misleading. But the court did not reach that conclusion by means of the kind of elaborate independent inquiry seen in Clovis, and as a result, PTC Therapeutics is not as remarkable a decision as Clovis. At least implicitly, the PTC Therapeutics court viewed the parties’ dispute through the lens of the FDA’s actions. The FDA had not merely rejected the NDA, it had taken the more unusual step of issuing a Refuse to File letter. Against that background, the court concluded that the company had “misrepresented the sufficiency of [the trials] to meet even the most basic FDA review standards.”

In a third decision, Juno Therapeutics (page 34), the court again appeared to credit plaintiffs’ challenge to what could have been characterized as a matter of scientific dispute. After Juno reported favorable Phase 1 results, three patients died in Phase 2 trials. The company attributed the deaths to a chemotherapy drug that had been paired with the company’s own immunotherapy agent in Phase 2 but not in Phase 1. The chemotherapy drug was discontinued after the patients died—but then more patients died. Plaintiffs challenged the company’s initial explanation of the Phase 2 deaths. The court refused to dismiss the challenge, even though it could have been seen as a matter of scientific and medical opinion: Plaintiffs were essentially challenging the company’s conclusion that the chemo drug, rather than its own immunotherapy agent, was causing the deaths.

Like Clovis, Juno might appear to be a departure from the general principle that courts will not adjudicate scientific disputes. This would clearly be a setback for life sciences companies facing securities class actions. On the other hand, Juno may be sui generis. The court’s analysis was unusually perfunctory. In rejecting the company’s arguments, the court said little more than that plaintiffs had adequately specified the challenged statements and the reasons they were purportedly false—and that further inquiry needed to await factual discovery. It thus seems unlikely that Juno represents a significant analytical departure from the mainstream cases in which courts reject claims based on scientific disputes. Clovis remains an unusual decision against that background. Whether other courts will adopt its approach remains to be seen.

Communications About Ongoing Trials

Several of the cases just discussed—including both Clovis and Juno—illustrate a particular fact pattern that repeats in other 2017 cases. In three of the six pre-approval cases in which defendants failed to win dismissal, companies commented on results in the context of ongoing trials—that is, in a context in which the results were necessarily preliminary. This situation presents heightened perils for life sciences companies. Clovis provides the clearest illustration of the danger. The company there reported favorable rates of tumor response and continued to announce positive results as the trial moved forward. Plaintiffs do not appear to have disputed that the favorable statements were at one point true—that is, plaintiffs do not appear to have disputed that those results fairly reflected favorable initial responses. Instead, plaintiffs’ theory was that the mandatory follow-up scans were less favorable, and that the company misled investors by continuing to report the positive results when later data had overtaken them. The court, as noted, was receptive to this theory. One takeaway from Clovis is that when a company reports promising initial or preliminary results from an ongoing trial, it may unintentionally take on a duty to update those results as the trial continues. Labeling
the positive results “preliminary” or “interim” may not be enough to avoid such a duty. And the argument that the later negative results are not yet definitive may not carry the day either.

The latter problem surfaced not only in Clovis but also in Puma (page 36). The company there had completed Phase 3 trials but had not yet finished validating the Phase 3 data. In response to questions about safety, side effects and dropout rates, the company noted that it had not yet seen complete, validated results but anticipated that the results would be in line with those in earlier trials. Plaintiffs’ theory was that at the time of the statements, the company had already compiled top-line information that showed results less favorable than those in the earlier trials. The court credited plaintiffs’ theory—notwithstanding the company’s argument that the data were still being validated when it made the challenged statements. The court reasoned as follows:

Whether that data was still in preliminary form, or required further validation, isn’t really the point. Rather, [plaintiff] alleges that some form of reliable data was actually available, that [the company] knew that the current results weren’t in line with historical information they provided, and that they instead chose to mislead investors so that they could benefit from an increase in stock price. Defendants shouldn’t benefit by simply saying they “anticipated” success when, in fact, they had a reasonable belief that defeat was just around the corner.

Like Juno, the Puma decision is relatively thin analytically. But it nevertheless contains a significant warning. When trial results are still in preliminary form, the safest course may be to say nothing about them at all.

In some situations, a company will not have the luxury of deciding whether to comment on preliminary results. Several of the 2017 decisions involve patient deaths, which may alter the trial landscape in such a way that companies are left with no choice but to disclose interim data and events—particularly if the FDA has placed a hold on the trial. This was the case in Juno, where, as noted, the company attributed patient deaths to the second drug in the two-drug combination being evaluated in the trial, rather than to its own drug. In CytRx (page 31) too, the company made reassuring comments in the wake of patient deaths, telling investors that it did not expect the deaths or partial clinical hold to impact previously reported trial timelines. And in both cases, the courts held that plaintiffs had adequately pled that the statements were false or misleading (although the CytRx court then dismissed claims based on the challenged statements on scienter grounds). While it is difficult to generalize from these two decisions, they may show that securities plaintiffs will have an easier time sowing skepticism about company statements in judges’ minds in the wake of deaths or other adverse events.

Seattle Genetics (page 28) illustrates another problem for companies announcing patient deaths in the course of ongoing trials. In addition to challenging the announcement of a death and its consequences, plaintiffs may claim that earlier, positive statements can be shown to be false or misleading in light of the death. The company in Seattle Genetics made favorable statements about a drug’s safety profile based on partial Phase 1 trial results. Three weeks later, the company announced patient deaths in different ongoing trials. The court concluded that plaintiffs had adequately pled that the statement about Phase 1 was misleading in light of ongoing events in the other trials. (As in CytRx, however, the court dismissed the case without prejudice on scienter grounds—although it also signaled that plaintiffs might “easily” plead additional facts that would salvage their claim.) Much like Puma and Juno, Seattle Genetics shows that courts may look askance at even accurate reporting of earlier trial results if the challenged statements are made in the course of a later trial that plaintiffs can show was already beginning to yield less positive outcomes.

This is not to say that courts will invariably side with plaintiffs when a company’s commentary about previous trials or interim results is later undermined by final results. Plaintiffs will have a difficult time showing that positive statements made during ongoing trials are false—let alone knowingly false—where later negative results simply could not have been known at the time of the challenged statements. Blinded trials provide the classic illustration, and Xoma (page 31) is a good example of this. In Xoma’s Phase 3 trial, patients were treated with the drug (or a placebo) until the point of “exacerbation”—a worsening of their disease. Patients took longer to reach exacerbation than expected, and completion of the trial was accordingly delayed. The company characterized the situation as “encouraging,” but also cautioned the market that until the data were unblinded, there was no way of knowing whether the delayed exacerbations were occurring...
on the treatment arm, the control arm, or both. After unblinding, it turned out that there were no significant differences between the treatment and the control cohort; the trial was a failure and the company’s stock price dropped. But the court dismissed plaintiffs’ challenge to positive statements made during the course of the trial: Plaintiffs had pled no facts showing that the company knew before unblinding whether or not the “encouraging” delays could be attributed to its drug.

In Tetraphase (page 30) too, the court rejected a challenge to positive statements made during the course of a trial that ultimately failed. The Phase 3 trial at issue there was divided into a lead-in and a pivotal portion. The company announced positive results at the end of the lead-in portion. The pivotal portion, however, was not a success, and the stock price dropped after the company announced disappointing results. The court dismissed plaintiffs’ claims on scienter grounds. Plaintiffs had seized on the company’s statement that the pivotal portion of the trial was “nearing completion” to build a chronology designed to show that the company knew of the unfavorable pivotal results at the time of the challenged statements. That chronology, however, did not stand up to the facts in the record.

In a final case, Northwest Biotherapeutics (page 30), the court similarly rejected plaintiffs’ speculation about what the company must have known when it made positive statements in the course of an ongoing trial. The company there reported that after a pre-specified interim review of a Phase 3 trial, the Data Safety Monitoring Board had recommended that the trial continue. Plaintiffs hypothesized, with the assistance of an expert, that the interim review should also have revealed a failure as to efficacy. The court held that such speculation about what the data had shown and what the company had known during the course of an ongoing trial was insufficient to support a fraud claim.

Taken together, the 2017 cases in this area show that companies should exercise special caution in reporting preliminary results during an ongoing trial. Companies should think carefully about whether an initial favorable report could be seen as creating a duty to update when later unfavorable—but still non-final—data become available. Indeed, companies should exercise caution even when discussing favorable results from earlier completed trials during a later ongoing trial. If plaintiffs are able to show that a company already knew that the results in the later trial were inconsistent with those in the earlier trial, some courts will be receptive to the claim that repeated references to earlier favorable results may be misleading. The best course in this situation may be for a company to make as clear as possible to investors that positive results from earlier trials do not guarantee any particular results in later trials.

Notwithstanding the heightened risks in this sensitive area, it remains the case that courts will recognize the flaws in weak fraud claims. Where the context of an ongoing trial makes clear that a company has no knowledge of developing results, courts will generally dismiss challenges to positive statements as impermissibly speculative or based on hindsight.

**Regulatory Communications and Company Predictions About Regulatory Action**

When plaintiffs have challenged companies’ optimistic statements about approval—as opposed to their statements about interim trial results—companies have prevailed in the 2017 cases. Several factors have contributed to these victories. Risk disclosures and other cautionary statements can shield challenged statements under statutory safe harbors or otherwise provide context that negates an inference of fraud. And where plaintiffs fault companies for not disclosing all negative interim comments from regulators, courts will adhere to the principle that companies have no standalone duty to report regulatory communications that are less than definitive.

Both factors were present in Corban v. Sarepta (page 26). The company there intended to file an NDA based on Phase 2b trials using a surrogate endpoint. In a series of statements in 2013, the company told investors that the FDA was open to a filing based on the data it had seen to date. After a competitor’s Phase 2 trials failed, however, the FDA told Sarepta that an NDA based on current data would be premature, and the company’s stock price fell more than 60%. The district court rejected plaintiffs’ challenge to the company’s statements about its encouraging discussions with the FDA and the First Circuit affirmed. The appellate court noted that the company’s positive statements “came replete with caveats,” including the warning that
the FDA had not committed to the surrogate endpoint. The court also rejected plaintiffs’ claim that the company had breached a duty to disclose other negative comments made by the FDA: The company “had no legal obligation to loop the public into each detail of every communication with the FDA.” More generally, “[m]ere possession of...nonpublic information does not create a duty to disclose it...even when that information is ‘material.’” Sarepta was also the defendant in a second securities action, Kader v. Sarepta (page 29), in which plaintiffs challenged statements the company made in 2014, following the FDA’s earlier determination that an NDA would be premature. In the statements that gave rise to the second lawsuit, the company again characterized its interactions with the FDA in a positive way. Among other things, Sarepta told investors that after additional meetings with the agency, the company had concluded that an NDA was “fileable” based on current data. Following that statement, the FDA required the company to reassess its data before filing, and the company’s stock price again fell. The district court dismissed plaintiffs’ claims, noting that the company had consistently paired its “fileable” statement with the caveat that, based on the FDA’s expressions of concern, it intended to undertake additional analyses before filing. And as in Corban v. Sarepta, the court in Kader v. Sarepta noted that the company had no obligation to disclose all ongoing regulatory dialogue to investors.

The Third Circuit’s Amarin case (page 27), like the two Sarepta cases, arose from statements about a study based on a surrogate endpoint. In Amarin, the surrogate endpoint was triglyceride reduction; a clinical endpoint would have more directly tested cardiovascular health. After meeting with the FDA, Amarin told investors that it was optimistic about the agency’s acceptance of the surrogate endpoint. Subsequently, however, two competitors’ trials failed, and the FDA announced that it would no longer accept triglyceride reduction as a surrogate endpoint. As in the Sarepta cases, plaintiffs relied on FDA briefing documents that became available after the challenged statements were made; plaintiffs claimed that the company had misleadingly omitted the agency’s negative comments. And as in Sarepta, the court rejected the claim, holding that the FDA comments on which plaintiffs relied did not show that the agency had conclusively rejected the surrogate endpoint—and hence that the company had no obligation to report those comments to investors.

Both Amarin and the two Sarepta decisions fall into a pattern we have discussed in our annual reviews for 2015 and 2016. Over the past several years, the courts have increasingly viewed purportedly negative FDA comments within the context of regulatory give-and-take. The courts have recognized that regulators may change their position during the course of an approval process (or, indeed, during post-approval regulatory interactions), as companies provide additional information and the regulators undertake additional analysis. This recognition has spurred a substantial series of rulings that companies have no standalone duty to report negative but non-definitive agency communications. The company statements at issue in Amarin and Sarepta were relatively nuanced. But even where companies make more bullish or definitive statements about their expectations for approval, they may win dismissal at the pleading stage—particularly if the statements come within the safe harbor provisions of the Private Securities Litigation Reform Act. These provisions shield forward-looking statements if they are (1) identified as such and accompanied by meaningful cautionary language, or (2) made without actual knowledge of falsity. Both provisions were in play in Eagle Pharmaceuticals (page 32). The company’s business in that case was to develop already-approved drugs into easier-to-use formulations and then to seek approval through the Section 505(b)(2) regulatory pathway (which permits reliance on prior safety and efficacy findings). Eagle told investors that it expected approval of an anticoagulant drug it had reformulated from powder into liquid form. After the FDA denied the company’s application, investors sued, challenging the company’s statement that it expected approval. The court held that the statement came within both of the safe harbor provisions. The company had identified its statements as forward-looking

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4 It is worth noting that from a securities law perspective, companies need not disclose all details of even conclusive FDA communications. Liability to investors under the securities laws must generally be premised on a false or misleading statement, and unless omitted information can be shown to have rendered an affirmative statement misleading, the omission is not actionable. This is well illustrated by InVivo (page 26), in which plaintiffs faulted the company for not disclosing all of the conditions imposed in an FDA approval letter governing a feasibility study. Plaintiffs sought to tie the omission to the company’s positive statements about trial timelines; plaintiffs’ theory was that the company could not have satisfied the conditions and still have met the projected timelines. The First Circuit found no disconnect between the omitted conditions and the stated timelines and thus affirmed dismissal.
and had warned investors, among other things, that it could not ensure FDA approval of any product candidate. The challenged statement also came within the actual knowledge safe harbor: Plaintiffs had failed to plead facts showing that the company actually knew how the FDA would respond to its application.

TransEnterix (page 33) presents a similar fact pattern. The company there sought clearance of its robotic surgical device under Section 510(k), which provides for approval of devices substantially similar to those already on the market. The company predicted approval but the FDA initially required it to provide additional “human factors” information and ultimately denied the application. The court dismissed the complaint, relying, among other things, on the actual knowledge safe harbor. Plaintiffs had not shown that the company knew which course the FDA would take, and in the absence of conclusive agency communications, the most compelling inference was that the company had “simply misjudged the adequacy of [its] filing.” As in each of the cases discussed in this section, the court readily distinguished a company’s failure to accurately predict an agency’s actions from fraud on investors.

Opinion Statements Under Omnicare

Finally, the courts in 2017 have continued to work out the legacy of the 2015 Omnicare decision, in which the Supreme Court created a framework for analyzing opinion statements challenged under the securities laws. Securities class action plaintiffs suing life sciences companies often target opinion statements, and the past three years have seen broad application of Omnicare in life sciences cases, with mixed results for defendants.

To briefly recap the Omnicare decision itself: The Supreme Court there considered a challenge under Section 11 to legal compliance opinions in a company’s registration statement. The Supreme Court analyzed the challenge separately under Section 11’s false statement clause and Section 11’s omission clause. The Court held that an opinion statement may be actionable under the false statement clause if the speaker did not subjectively hold the belief expressed. An opinion statement may be actionable under the omission clause if a reasonable investor would be misled as a result of the omitted information. In practice, plaintiffs most often choose to proceed under the omission clause, given the difficulty of pleading subjective falsity. While Omnicare itself was confined to claims under Section 11—a strict liability statute for issuers—courts now largely apply it to Section 10(b) claims as well, notwithstanding the fact that Section 10(b) requires deliberate wrongdoing.

In some of the 2017 decisions, the application of Omnicare has been relatively straightforward. In the pre-approval setting, plaintiffs generally attack a company’s optimistically-phrased opinions about its chances of approval or its views of trial results. Proceeding under an omission theory, plaintiffs will seek to identify some undisclosed fact that does not, in the word of Omnicare, “fairly align” with the stated opinion. Plaintiffs will fail at the outset if the purportedly omitted fact was in reality disclosed, as was the case in Xoma. Plaintiffs there claimed that the company had not adequately informed investors that “encouraging” trials results could have come from the control rather than the treatment arm of a blinded trial—but in fact the company had very plainly stated just that. Plaintiffs will also fail if they cannot provide factual support for the claim that contradictory undisclosed facts existed and were known to defendants at the time of the challenged statements. That was the case in TransEnterix. Plaintiffs challenged the company’s optimistic statements about approval but pled no facts showing that the company knew that the FDA would reject its 510(k) application.

The analysis becomes more complicated where plaintiffs are able to identify significant omitted facts that appear to undermine the challenged opinion. Two Ninth Circuit decisions illustrate the range of approaches and outcomes in this area. The first is Align Technology (page 41), in which the challenged opinion statement was the valuation of goodwill associated with a recent corporate acquisition. Align wrote off $77 million in goodwill within two years of the acquisition, and plaintiffs challenged the original goodwill valuation. In analyzing the claim, the Ninth Circuit jettisoned a pre-Omnicare test for evaluating opinion statements—a test under which plaintiffs could state a claim if they showed that a challenged opinion was not supported

5 We discuss the pre-approval and post-approval cases involving Omnicare issues together in this section. Align was a company with mature products.
by a “reasonable basis.” The Align court explained that plaintiffs may attack the basis for a challenged opinion only if (1) they can show that defendants omitted material information about the basis of their opinion, and (2) that information was contrary to what a reasonable investor would have believed to be the case in light of the challenged statement.

The Align court then applied Omnicare’s ruling that the omitted fact must relate to the company’s “inquiry into or knowledge concerning” the opinion statement. Plaintiffs in Align had offered goodwill calculations of their own in an effort to show that the company’s goodwill estimate was not supportable. The Ninth Circuit rejected that approach as fundamentally mistaken. The court held that it was irrelevant that plaintiffs had arrived at a different valuation after conducting their own goodwill analysis. Only the company’s goodwill calculations were relevant. And because plaintiffs had pled no facts about the assumptions or methods underlying the company’s calculations, they had also failed to plead any actionable omission concerning goodwill. The court’s focus on the process a company uses in reaching an opinion appears to impose substantial obstacles in the way of securities plaintiffs. In most cases, plaintiffs will not have access to information about a company’s processes.

Align, however, was not the Ninth Circuit’s last word on opinion statements in 2017. Three months after it decided Align, the court reversed a defense victory on a motion to dismiss in Atossa (page 28), and did so by means of an application of Omnicare that appears far more plaintiff-friendly than that in Align. Atossa manufactured two components of a system for breast cancer screening. The first component had received FDA clearance but the second apparently had not. The company nevertheless referred to the second component as “FDA cleared.” The FDA issued a warning letter in which it stated, among other things, that these references, which appeared on product labels, were false or misleading. Plaintiffs in turn challenged the company’s statements to investors, including the statement that “FDA clearance risk has been achieved.” The Ninth Circuit held that this was an opinion rather than a factual statement: Saying that a risk has been “achieved,” the court explained, is different from saying that a product has received clearance, or even that clearance risk has been eliminated. After categorizing the statement as an opinion, however, the court held that plaintiffs had satisfied Omnicare’s requirements. At the time of the challenged statement, Atossa had received the warning letter and hence knew that the FDA’s position was that the company’s references to FDA clearance were false or misleading. The opinion statement did not, in the Ninth Circuit’s view, “fairly align” with the existence of the warning letter. Significantly, the Ninth Circuit did not require plaintiffs to allege facts relating to the company’s processes of evaluating regulatory risk or determining that risk had been “achieved.” The court simply considered the contradictory facts identified by plaintiffs and determined that because those facts did not fairly align with the challenged opinion, plaintiffs had pled an actionable omission. While the conclusion the Atossa court reached does not appear surprising in light of the warning letter, the approach the court employed—weighing information to test its “alignment” with the challenged statement—appears far more favorable to plaintiffs than the approach used in Align.

This difference in approach may relate to differences in the subject matter of the opinions challenged in the two cases. The opinion at issue in Align was a single number—an estimate that reflected the end product of a series of calculations. It may be difficult to undermine an opinion of this sort without some reference to the process by which it was derived. In Atossa, by contrast, the opinion related in effect to regulatory compliance; as the court explained, “saying that FDA clearance risk has been achieved is another way of expressing a belief that Atossa’s conduct mostly complies with the FDA rules.” It may be possible to undermine an opinion of this sort simply by reference to the regulatory landscape as it existed at the time of the challenged statements, without needing to recreate the process by which the company arrived at its opinion. In order to obtain the more favorable treatment represented by Align, companies should try, to the extent possible, to characterize opinions as the end product of an evaluative process.
POST-APPROVAL CASES

Decisions in cases involving post-approval products were significantly less favorable than the pre-approval decisions in 2017. Companies fared poorly in the district courts, winning complete dismissal in only 3 of 10 cases. The appellate decisions were more favorable: Companies prevailed in 3 cases and lost in only one.

In three of the district court cases (Insys, Valeant, Intuitive Surgical), plaintiffs succeeded in leveraging regulatory setbacks or government investigations into securities fraud claims. In two other cases related to unfavorable regulatory developments, however (GNC and Cardiovascular Systems), companies won dismissal.

Three additional district court decisions illustrate a different factual scenario. In Concordia, Alere and Rubinstein, plaintiffs succeeded asserting Section 10(b) claims based on statements made by companies on the cusp of a merger or acquisition. The M&A context created unique circumstances and unique motivations for defendants, and the courts drew on those circumstances in holding that plaintiffs had adequately pled scienter.

Companies fared better in defending against challenges to revenue projections. In two of the favorable appellate decisions (Biogen and Globus), the courts affirmed dismissal of claims arising from missed guidance. We further discuss themes relating to these three distinct factual scenarios immediately below.

Securities Litigation Related to Adverse Regulatory Proceedings

A number of the 2017 post-approval cases fall into a familiar pattern. A company is investigated by federal or state authorities for potentially improper conduct. The company discloses the investigation, and its stock price falls. As the investigation proceeds, matters may deteriorate further. Media accounts may add details and additional government actors may begin new inquiries. In the worst cases, investigations culminate in criminal charges against the company or its executives.

Even catastrophic events of this sort are not in themselves a sufficient basis for securities fraud claims. Under the securities laws, the basic unit of a company’s liability to stock purchasers is generally a false or misleading statement, and unless plaintiffs can link the purportedly wrongful conduct to a company’s statements, they will not have stated a claim. But not all courts apply that principle with equal discipline. Two of the 2017 decisions arising from catastrophic setbacks, Insys (page 44) and Valeant (page 44), illustrate the range of results that can follow.

The company in Insys sold an oral fentanyl product approved for breakthrough cancer pain. Between 2014 and 2016, state and federal authorities investigated the company for off-label marketing and kickbacks to physicians. These investigations culminated in December 2016 with the arrest and indictment of former company executives. Further charges rolled out after the period covered by the securities complaint, including actions by numerous state regulators and the indictment of the company’s founder on federal racketeering charges.

In seeking to turn the company’s regulatory downturn into a securities fraud action, plaintiffs challenged dozens of statements related generally to the company’s product, its business, and its interactions with insurers, pharmacies and physicians. As the court characterized the complaint, “[f]or most of [the challenged statements], Plaintiff contends they are false or misleading because they were spoken against the background of Insys’s ongoing criminal fraud.” And the court rejected that theory, holding that it was foreclosed by the Ninth Circuit’s 2008 Metzler decision. This part of the court’s analysis is an important reinforcement of the principle that allegedly unlawful underlying conduct does not automatically equate to securities fraud.

The Insys court also went further, however, and carefully parsed the challenged statements one by one. Although the court concluded that plaintiffs had failed to plead falsity as to nearly all of the statements, it permitted the case to move forward with respect to two. This holding too is important. In the two statements that survived dismissal, the company spoke of its efforts

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to market its drug to oncologists—the only specialists likely to be treating patients within the label. Plaintiffs were able to show that the company had instructed sales representatives to avoid oncologists and instead to seek other specialists, including specialists whose patients could be expected to live longer than cancer patients. In light of these allegations, the court concluded that plaintiffs had adequately pled fraud.

Significantly, the court rejected two arguments in which the company relied on its disclosure of unfavorable information to contend that the challenged statements could not have misled investors. The company pointed out, first, that it had disclosed the ongoing investigations. But the court held that this was not enough. While the company may not have had a standalone duty to disclose unlawful practices, it could not rely on descriptions of the investigations—as opposed to descriptions of the practices themselves—to show that the market was not misled by favorable statements contradicted by those practices. The company also pointed to its risk disclosures, and in particular to its warning that employees might engage in off-label marketing. But the court found these disclosures insufficient too: In disclosing only risks, the company had stopped short of telling investors that it was actually engaged in the forbidden practices.

In Valeant, as in Insys, the company was beset by scandal. Beginning in 2015, Valeant was the subject of congressional investigations into price-gouging. During the same period, media pieces raised questions about Valeant’s use of Philidor, a pharmacy that the company controlled and that was accused of using improper tactics to generate prescriptions. The company announced in October 2015 that it was closing Philidor. In 2016, the company reported that its 10-K would be delayed in light of issues related to revenue recognition, and the SEC launched an investigation into those issues. Later, former Valeant and Philidor executives were arrested and indicted.

As the company spiraled down, securities plaintiffs, much as in Insys, challenged a broad range of statements spanning several years. But the Valeant court, unlike the Insys court, largely skipped any particularized analysis of the challenged statements, instead proceeding directly to the questions of whether the statements were material and whether plaintiffs had sufficiently pled scienter—and answering “yes” in both instances. The court then permitted plaintiffs to proceed with claims based on all of the challenged statements. Notably, this included Section 10(b) claims not only against management but also against outside directors. The court found that plaintiffs had sufficiently pled that the directors were the “makers” of challenged statements in press releases—as required by the Supreme Court’s Janus decision—insofar as the press releases referred to reviews undertaken by the company’s audit committee or the full board.7

As in Insys and Valeant, plaintiffs in Intuitive Surgical succeeded in turning regulatory setbacks into securities claims. Following reports of adverse events involving its surgical devices, Intuitive Surgical provided physicians with revised instructions for using those products. The company did not inform the FDA that it had communicated with physicians, and the agency held that this violated applicable regulations. The FDA also met with the company to discuss possible underreporting of adverse events, and the company thereafter began to submit reports at an increased rate. This spurred an FDA safety probe, and when the probe was announced, the company’s stock price fell. The court held in a 2014 decision that plaintiffs had successfully pled fraud with respect to the company’s statements that it believed in the safety of its products. In 2017, the court re-analyzed the challenged opinion statements under the Supreme Court’s intervening Omnicare decision—and once again held that plaintiffs had adequately pled fraud. But not all regulatory setbacks—not even all scandals—give rise to securities claims capable of withstanding a motion to dismiss. The corporate defendant in KaloBios (page 33) was a development-stage company that hired a CEO with prior experience at a company with mature products. That CEO was Martin Shkreli, and KaloBios’ stock plunged after Shkreli was arrested in late 2015 for wrongdoing at his previous company, Retrophin. Plaintiffs challenged KaloBios’ statements about Shkreli’s qualifications, arguing that the statements were misleading in light of the company’s failure to disclose Shkreli’s misconduct at Retrophin. The court dismissed the claims based on the “truth on the market” defense. That defense, which is rarely successful on a motion to dismiss, permits a company to show that investors could not have been misled even by concededly false or misleading company statements because other sources available to investors made revealed the truth. In the case of KaloBios, those other sources were media pieces detailing

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Shkreli’s wrongdoing at Retrophin and his other professional and personal shortcomings. The KaloBios court concluded that in light of the truth disseminated by the media pieces, investors could not have reasonably been misled by the company’s statements about Shkreli’s qualifications.

Having reached that conclusion, the KaloBios court did not need to determine whether the company had an obligation to disclose Shkreli’s past conduct. The court nevertheless touched on key principles distinguishing unlawful conduct generally from securities fraud:

It merits noting that courts have been skeptical toward theories of liability based on broad duties to disclose allegations of misconduct, especially when the connection between the liability sought and the alleged misconduct is attenuated... [It is not the law that] a corporation or senior executive is liable whenever that executive is involved in misconduct that might lead to his or her resignation, regardless of the nature of that misconduct, unless the conduct is disclosed... For an omission to be actionable, there must be a duty to disclose the underlying noncompliance or misconduct... [The] securities laws do not impose a general duty to disclose corporate mismanagement or uncharged criminal conduct.

Other principles have also enabled companies facing adverse regulatory developments to extract themselves from securities litigation in the 2017 cases. Positive statements may turn out to be false in light of regulatory developments, but unless plaintiffs can also show that the statements were knowingly false, they will not have pled fraud. This was the case in GNC Holdings (page 42), where the company was the subject of a state attorney general action challenging the sale of a dietary supplement containing two substances that did not qualify as dietary ingredients. Plaintiffs challenged the company’s statements that it was successfully managing regulatory risk and that it had made a successful transition away from a previous problematic ingredient replaced by the two ingredients at issue. The court held that plaintiffs had adequately alleged that these statements were false or misleading. But the court then dismissed the complaint on scienter grounds, holding that plaintiffs had failed to show that the company knew about the problems with the ingredients.

A company may also succeed in dismissing securities litigation by contesting the claim that conduct underlying an adverse regulatory development was actually improper. That was the case in Cardiovascular Systems (page 42), where the company had paid $8 million to settle a qui tam action in which plaintiffs alleged off-label marketing and physician kickbacks. Rather than seeking to determine whether the company had a duty to disclose that conduct, the court asked whether plaintiffs had sufficiently shown that the conduct was wrongful in the first place. And the court concluded in relatively short order that plaintiffs had not done so. Plaintiffs had failed to show that the uses for which the company was accused of marketing its device were in fact off-label, and had likewise failed to show that any company payments amounted to improper kickbacks. The court’s approach in this case—resolving the merits of allegations of illegality on a motion to dismiss—is somewhat unusual, but may provide support for companies that believe strongly that they have the better of the argument on questions of illegality.

Challenged Communications in the Shadow of Mergers or Acquisitions

Three of the post-approval cases involve allegations of fraud against an M&A background. In all three, this background was relevant to the analysis of scienter and contributed to rulings unfavorable to defendants.

In Concordia (page 45), after private equity firms had expressed their interest in acquiring the company, the company solicited bids. Plaintiffs claimed that Concordia improperly failed to disclose several adverse developments during the bidding process—among other things, the loss of coverage for a significant drug and the layoff of the sales force contracted to sell that drug. In ruling that plaintiffs had adequately established scienter, the court gave significant weight to motives created by the bidding process. While allegations that company executives are motivated to maintain high stock prices generally are insufficient to establish scienter—such allegations could sweep in nearly every executive in the country—motive allegations have more force in the context of an acquisition. The Concordia court held that against the background of bid solicitation, plaintiffs had identified a “motivat[ion] to inflate company stock
prices as a means to effectuate a specific acquisition that would not otherwise be possible.” And that, in the court’s view, supported the required inference of scienter.

A second case, Alere (page 45), also played out against an M&A background. The company there had agreed to be acquired by Abbott Laboratories for $56/share, which represented a premium of nearly 30%. Unfavorable information of various sorts came to light before the deal closed, and the two companies sued one another over the terms of the transaction. The acquisition was eventually consummated at $51/share. Securities plaintiffs then alleged that the company had made false or misleading statements relating to, among other things, internal controls, Medicare eligibility, FCPA compliance and a looming product recall. The court concluded that plaintiffs had adequately alleged falsity as to the product recall (though not as to the other issues). And in holding that plaintiffs had sufficiently pled scienter, the court pointed, among other things, to the timing of the Abbott acquisition and to the large change-of-control payments Alere’s executives would receive on consummation of the deal.

In Concordia and Alere, the M&A context informed the courts’ views of defendants’ motives. In a third case, Rubinstein v. Gonzalez (page 46), the M&A context bore on the scienter analysis in a more direct way. The corporate defendant in Rubinstein was AbbVie, a US company that had agreed to merge with Shire, an Irish company. AbbVie told investors that it had decided to merge for strategic reasons rather than for tax advantages. The IRS subsequently issued a notice regarding the application of a critical tax rule, the consequence of which was that AbbVie would no longer receive a tax benefit from the merger. AbbVie subsequently pulled out of the merger agreement and was required to pay a $1.64 billion breakup fee. Securities plaintiffs challenged various statements the company had made about the merger. The court dismissed the claims with respect to the company’s statements about its motivation but concluded that plaintiffs had adequately pled falsity with respect to a single statement the company made after the IRS issued its notice. In that statement, which was addressed to the Shire shareholders, AbbVie said that it was “more energized than ever” about the merger and “more confident than ever” about the combined companies’ potential. In holding that plaintiffs had adequately pled that the company spoke with a reckless disregard for the truth—which qualifies as scienter under Section 10(b)—the court looked to the circumstances of the merger itself. The court noted that “given the fast paced nature of mergers and acquisitions, one could expect AbbVie to have given immediate consideration to any legal changes that would or might impact any of the deal’s strategic rationale[s]—and, in view of the size of the potential transaction and termination fee, to have devoted considerable resources to the issue.” Against the background of such expected scrutiny, the court held, plaintiffs had sufficiently established that the company was reckless in continuing to express its commitment to the merger.

Missed Guidance Cases

Finally, two appellate decisions show the difficulty plaintiffs face when asserting claims based on missed or revised revenue guidance. In Biogen (page 40), the company issued revised guidance after learning that a patient death and resulting label change had taken a greater toll on prescriptions than anticipated. In Globus (page 40), the company issued revised guidance after the termination of a distributor drove down sales. In both cases, the appellate courts affirmed dismissal. Guidance is, of course, forward-looking by nature, and in Globus, the Third Circuit held that both of the PSLRA safe harbors applied. The company had issued meaningful cautionary statements and plaintiffs had failed to show that the company actually knew at the time it made the challenged forecasts that it would fall short of guidance. Issues of knowledge and timing also doomed the claims in Biogen. While plaintiffs there had assembled facts that purportedly showed management’s awareness of the impact of a patient death, plaintiffs’ theory suffered from a critical timing problem. The facts at issue had emerged only after the company made the challenged statements.
In this section (pages 20-24), we provide very brief summaries of each of the decisions issued in 2017, organized by stage of a product’s or company’s life cycle. We have grouped the 35 decisions according to outcome, with those in which companies prevailed listed first.

As noted above, life sciences companies largely fared well in securities litigation involving pre-approval drugs and devices in 2017, winning dismissal in 10 out of 16 cases in the district courts and affirmance in 4 out of 5 cases on appeal. Companies were far less successful in the post-approval context, winning dismissal in only 3 out of 10 cases in the district courts and affirmance in 3 out of 4 cases on appeal.

The page numbers in this section refer to more detailed summaries of the same decisions included in the following sections (pages 25-47).
DECISSIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

APPELLATE DECISIONS

Ganem v. InVivo Therapeutics Holdings Corp., 845 F.3d 447 (1st Cir. 2017) ......................26
After FDA approves medical device feasibility study with certain conditions, company reports favorable timelines for commencement and completion of the study but does not disclose FDA’s conditions; the timelines are later extended and the company’s stock price falls; appellate court affirms dismissal, holding that plaintiffs failed to allege facts showing that, at the time of the challenged statements, the FDA’s conditions prevented completion within the stated timelines.

Corban v. Sarepta Therapeutics, Inc., 868 F.3d 31 (1st Cir. 2017) ........................................26
Company makes optimistic statements about FDA’s acceptance of proposed NDA based on surrogate endpoint, but after a competitor’s drug with a similar mechanism fails, FDA advises company that NDA would be premature; court affirms dismissal, holding that company adequately qualified its optimistic characterizations and appropriately cautioned investors that the FDA’s acceptance of the surrogate endpoint could not be guaranteed.

Brennan v. Zafgen, Inc., 853 F.3d 606 (1st Cir. 2017) ..............................................................27
Company discloses serious but not superficial adverse events from Phase 2 trial; after patient dies in Phase 3 trial, FDA imposes clinical hold; court affirms dismissal, holding that scientific articles cited by plaintiffs did not show that the company knew that its omission of the superficial events made its statements misleading, and that the company’s forthright disclosure of the serious adverse events undermined any inference of fraud.

In re Amarin Corporation PLC Securities Litigation, 689 Fed. App’x 124 (3d Cir. 2017) ...27
FDA approves Phase 3 trial using surrogate endpoint (lower triglycerides), which succeeds, but competitor’s trials testing clinical endpoint (increased cardiovascular health) later fail, leading to denial of NDA; appellate court affirms dismissal, concluding that company’s description of its trials and it hopes for approval were accurate when made.

In re Atossa Genetics, Inc. Sec. Litig., 868 F.3d 784 (9th Cir. 2017) ......................................28
Although only one of the company’s two linked breast cancer screening products had received premarket clearance, company publicly refers to both products as “FDA-cleared” and later receives FDA warning letter relating to this and other issues; appellate court reverses dismissal, holding that plaintiffs adequately alleged falsity with respect to the term “FDA-cleared” and further pled an actionable omission insofar as company’s public description of warning letter disclosed only one of three issues identified by the FDA.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

In describing Phase 1 trial of successor to earlier drug withdrawn due to toxicity issues, the company says successor drug is “well tolerated”; following adverse events including patient deaths, however, FDA imposes partial clinical hold; court concludes that plaintiffs have adequately pled falsity but dismisses on scienter grounds because plaintiffs have not shown through their confidential witness that executives knew of toxicity issue at the time of the challenged statements.

Six months after informing investors that an NDA would be “fileable” on current data, the company reports that on the basis of further FDA feedback, it will gather additional data and reassess existing data before submitting the NDA; court grants motions to dismiss successive complaints, holding that the company did not misrepresent the nature of its communications with the FDA and that plaintiffs’ claims amounted to an impermissible critique of trial designs.


Company makes optimistic statements about Phase 2 and Phase 3 trials, but faces criticism from an outside researcher and later a clinical hold; court dismisses action, characterizing plaintiffs’ claims as disagreements over trial design, over the correct interpretation of trial results and over matters of scientific judgment.


Company reports positive results after lead-in portion of Phase 3 trial, but pivotal portion of trial is unsuccessful; court dismisses complaint, holding that plaintiffs fail to plead falsity with respect to company’s “scientific opinion” interpreting its lead-in phase and that plaintiffs fail to create strong inference of scienter given company’s heavy expenditures in the trial, and notwithstanding executive resignations and stock sales under trading plans.


Company reports that delay in completing Phase 3 trial of antibody is “encouraging” insofar as completion depends on patients’ condition worsening, but also cautions that results remain blinded; after unblinding, it turns out that delay occurred equally on treatment and control arms and trial fails; court dismisses on both falsity and scienter grounds, as plaintiffs plead no facts showing that company knew what results would be at the time of the challenged statements.


Partial clinical hold of Phase 3 trial following patient death is eventually lifted but company experiences timing issues, with possible impact on ultimate success of trial; court concludes that plaintiffs have adequately pled falsity with respect to company’s statements that the hold would not affect trial timelines but have failed to plead that the company knew of that impact.


Company expresses optimism that its “ready-to-use” version of existing compounded drug will easily receive approval, but FDA rejects NDA and requires more information about product and possible further trials; court dismisses complaint, holding that the FDA’s rejection does not show that the company’s description of product or expressions of optimism were false or misleading when made.

**In re Dynavax Sec. Litig., 2017 WL 4005584 (N.D. Cal. Sept. 12, 2017)**

Company reports low rate of “Adverse Events of Special Interest” during Phase 3 trial but FDA later rejects its Biologics License Application, citing among other things concerns about adverse cardiac events; court dismisses complaint, explaining that plaintiffs’ premise that cardiac events constituted “Adverse Events of Special Interest” is contrary to definitions in the trial protocol.


Company announces expectation that FDA will approve its 510(k) application for robotically enhanced surgical device, but FDA rejects application in climate of increased scrutiny of such devices; court dismisses complaint, holding that the company’s optimistic statements are protected by Omnicare and the PSLRA safe harbor, and that plaintiffs have failed to show that company knew its application would be rejected.
Investors sue company headed by Martin Shkreli for misleading them about Shkreli’s credentials and background; court dismisses complaint, holding that Shkreli’s reputation was widely known before investors purchased shares.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED

After patient dies in Phase 2 trial, company makes positive statements about Phase 1 results, and after two more patients die, attributes deaths to the combination of the company’s drug with another drug in Phase 2; after fourth and fifth deaths, however, company halts trial; court denies motion to dismiss, holding that plaintiffs have adequately pled that statement about Phase 1 results was misleadingly incomplete and declining to delve further into the facts.

Medina vs. Clovis Oncology, 215 F.Supp.3d 1094 (D. Colo. 2017).................................34
Company reports favorable results in ongoing trial but later discloses that those results had not yet been “confirmed” in the way required by trial protocol, and that the confirmed results are less favorable; company also subsequently reveals negative safety information and withdraws NDA; court denies motion to dismiss after detailed analysis of company’s argument that its disclosures were not misleading in light of its interpretation of the trial protocol.

In ruling on motion to dismiss complaint amended after the ruling in Crihfield v. CytRx (above), court concludes that plaintiffs have adequately pled falsity and scienter with respect to statements that the company adhered to the terms of the Special Protocol Assessment for Phase 3 trial.

Although company states that all study results have been positive, rat study raised FDA concerns about carcinogenicity; after Ninth Circuit reverses dismissal on scienter grounds in 2016 decision, district court holds on remand that as a matter of logic, plaintiffs have also adequately alleged falsity.

After completion of Phase 3 trial but before data are fully validated, company states that safety information and drop-out rates are not yet available but that it anticipates they will be in line with favorable results from earlier studies; later, however, data turn out to be less favorable; court denies motion to dismiss, holding that company had sufficient (if not fully validated) data at the time of the challenged statements to render its statements about what it anticipated misleading.

After receiving Refuse to File letter in connection with NDA based on Phase 2b trial that failed to meet its endpoint, company files second NDA based on combined Phase 2b and Phase 3 data and largely supported by post-hoc analysis, and NDA again responds with Refuse to File letter; court permits plaintiffs to proceed with challenge to company’s statements that the “totality” of trial data supports a finding of clinical benefit.
DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

APPELLATE DECISIONS

In re Biogen Inc. Securities Litigation, 857 F.3d 34 (1st Cir. 2017) ........................................ 40
Patient death and resulting label change slow sales growth and company revises revenue guidance; court affirms dismissal on scienter grounds, largely because the facts on which plaintiffs relied to show company’s knowledge that sales would decline post-dated the challenged statements.

Williams v. Globus Medical, Inc., 869 F.3d 235 (3d Cir. 2017) .................................................... 40
Company reduces revenue forecast in part because sales of spinal implants decreased after company’s previously undisclosed termination of relationship with third-party distributor; appellate court affirms dismissal, ruling that company’s risk disclosure was not misleading and that its revenue guidance was forward-looking and plausibly accounted for termination of distributor.

City of Dearborn Heights Police and Fire Ret. Sys. v. Align Technology, Inc., 856 F.3d 605 (9th Cir. 2017) ......................................................................................................................... 41
After corporate acquisition, company determines that goodwill in business unit formed from acquired company’s assets is impaired, and eventually writes off goodwill entirely; court affirms dismissal, holding that challenged goodwill valuations are opinion statements under Omnicare and that plaintiffs, having failed to show how the company reached its opinions, have also failed to show that the company omitted material facts that would have undermined those opinions.

Cooper v. Thoratec Corporation, 698 F. App’x 516 (9th Cir. Oct. 4, 2017) ................................. 41
Company markets heart pump as having low rates of thrombosis, notwithstanding data showing increased numbers of serious adverse events; district court dismisses, finding that increased numbers of SAEs do not establish higher rates of SAEs; appellate court reverses with little explanation.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

Manufacturer of devices used in the treatment of arterial disease is accused by sales manager of off-label marketing and making kickbacks to physicians, and when the matter is settled for $8 million, company’s stock price drops; court dismisses securities claims, holding that plaintiffs failed to allege unlawful conduct with the necessary particularity.

In re Intrexon Corp. Securities Litigation, 2017 WL 732952 (N.D. Cal. February 24, 2017) ................................................................. 42
Short-seller publishes article criticizing company’s technology and revenue recognition practices; court dismisses complaint, holding that article does not contradict company’s generalized characterizations of its technology and in any event is based on outdated information already in the public realm.

After FDA bans ingredients in company’s dietary supplement, company substitutes a product containing alternative ingredients, but the FDA later determines that those ingredients too are improper, and the company is sued by state regulators; court
concludes that plaintiffs have adequately pled falsity but dismisses complaint on scienter grounds, holding that plaintiffs have failed to show that the company knew the replacement ingredients would be deemed improper.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED

*In re Intuitive Surgical Sec. Litig.*, 2017 WL 4355072 (N.D. Cal. Sept. 29, 2017) ..................43
Manufacturer of surgical devices receives medical device reports when its products are used in procedures that result in adverse events but forwards only some such reports to the FDA and seeks to rectify issues in other instances with communications to physicians; court denies motion to dismiss, holding that plaintiffs have adequately alleged under *Omnicare* that company omitted information about reports that did not fairly align with its stated beliefs in product safety.

Company accused of paying kickbacks and marketing fentanyl-based cancer pain drug off-label attributes its success to superior product and marketing strategy; court dismisses complaint in part on falsity grounds but permits plaintiffs to proceed with challenge to statements that company was focused on marketing on-label, given particularized facts showing that employees were told to avoid oncologists and market to other specialists.

Company’s stock price falls after government and media inquiries into price gouging and the creation of captive pharmacies to raise prices and manipulate revenue; court denies motion to dismiss, holding that plaintiffs adequately alleged that company improperly concealed its relationship with the captive pharmacies and misstated revenue received from them.

Company acquires rights to potentially lucrative drug but fails to disclose insurers’ decision to stop covering drug and company’s layoff of sales force dedicated to the drug; court denies motion to dismiss with respect to omission of developments related to insurance coverage and sales force layoffs but grants motion as to challenged statements regarding company’s debt and liquidity position.

After announcing profitable merger agreement, company discloses product recall as well as internal control, billing and FCPA issues, all of which results in lower acquisition price; court dismisses challenge to statements related to product recall, holding that plaintiffs have adequately alleged that the company anticipated the recall, but grants motion with respect to statements relating to other issues on scienter grounds.

*In re Akorn, Inc., Sec. Litig.*, 240 F.Supp.3d 802 (N.D. Ill. 2017).................................46
After firing auditors who found material weaknesses in internal controls, company restates its financial statements multiple times; court denies motion to dismiss, ruling that plaintiffs have adequately pled falsity and scienter notwithstanding company’s disclosure of the control issues in its 10-Ks.

U.S. company plans merger with Irish company but withdraws after Treasury Department issues notice that would deprive company of tax benefits arising from the merger; court grants motion to dismiss as to challenged statements regarding company’s motivation for merger but denies motion as to company’s statement, after Treasury Department notice, that it is “more confident than ever” in planned merger.
DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 26-37), we provide detailed summaries of decisions in cases arising from setbacks life sciences companies experience at the pre-approval stage. As discussed in the “Trends and Analysis” section above, companies have fared relatively well in these cases, winning dismissal in roughly 60% of the cases in the district courts and winning affirmance in 80% of the cases in the appellate courts.

At the same time, however, the development of the law in the cases taken as a whole has not always been favorable to defendants. While courts have generally continued to recognize their lack of expertise in resolving disputes over science and medicine, there have been some significant exceptions. And several decisions illustrate particular dangers for companies commenting on favorable preliminary or interim results during the course of ongoing trials.

Companies have done better where securities plaintiffs challenge optimistic statements about FDA approval. Courts recognize that companies cannot predict regulators’ actions and have no duty to disclose all interim regulatory communications.

Finally, the 2017 decisions have continued to develop the Supreme Court’s Omnicare framework for the analysis of challenged opinion statements. In one leading decision, the appellate court focused on the process the company used to develop the challenged opinion—an approach quite favorable to securities defendants. In another decision, however, the same court was willing to weigh evidence that allegedly contradicted the challenged opinion—a less favorable approach for defendants.
**APPELLATE DECISIONS**

**Ganem v. InVivo Therapeutics Holdings Corp.**, 845 F.3d 447 (1st Cir. 2017), affirming dismissal.  
**Feasibility study**

InVivo, which developed a biopolymer scaffolding to treat spinal cord injuries, informed investors that it would seek an Investigational Device Exception (IDE) from the FDA in order to conduct a feasibility study. The FDA approved the proposed IDE, but with conditions: InVivo had to correct the study’s consent form, obtain approvals from the Institutional Review Boards of proposed testing sites, modify the study design to anticipate a larger follow-on study, and identify stages over a fifteen month period at which FDA approval would be required. InVivo issued a press release that stated that the FDA had approved the IDE and that a study would commence in the “next few months” and would last fifteen months. The company did not disclose any of the FDA’s conditions. InVivo’s stock price rose in response to the press release. A month later, InVivo issued a second press release predicting that the study would begin within the year. The stock price remained unchanged. Several months later, InVivo issued a third press release stating that the study would be delayed until the following year. The company’s stock lost approximately half its value over the next four trading days.

Investors sued, the district court granted the company’s motion to dismiss, and the First Circuit affirmed dismissal. The appellate court held that the omission of the FDA’s conditions did not render the optimistic statements about timing false or misleading. Plaintiffs failed to allege facts showing that, at the time of the challenged statements, the FDA’s conditions prevented completion of the study within the stated timelines. In the absence of such facts, plaintiffs were left with the assertion that because the company was ultimately required to adjust its chronological projections, the original timeline “must always have been impossible to achieve”—and such hindsight inferences are insufficient to support a fraud claim.

**Corban v. Sarepta Therapeutics, Inc.**, 868 F.3d 31 (1st Cir. 2017), affirming dismissal.  
**Phase 2(b)**

Sarepta developed eteplirsen for the treatment of Duchenne muscular dystrophy. After conducting Phase 2(b) trials, the company met with the FDA in March 2013 and again in July 2013 to discuss submitting an NDA using a surrogate endpoint. Eteplirsen enables a patient’s cells to produce a form of dystrophin, a protein necessary for muscle function. The surrogate endpoint measured the production of dystrophin; a clinical endpoint would have measured a patient’s ability to walk. The company reported favorably on its meeting with the FDA and described its data set as “compelling and favorable.” The company projected submitting an NDA in the first half of 2014, although it also cautioned investors that questions remained about the use of the surrogate endpoint. In September 2013, a competitor’s drug whose mechanism was in certain ways similar to that of eteplirsen failed Phase 3 trials. In November 2013, the FDA advised the company that in light of the competitor’s failure, filing an NDA for eteplirsen would be premature. The company’s stock price dropped 64%. After additional setbacks in 2014 (described below in connection with the **Kader v. Sarepta** case), the company submitted an NDA in June 2015 and the drug was approved in September 2016.

Investors sued on the basis of the November 2013 stock price drop, challenging Sarepta’s statements that the FDA was open to submission of an NDA on the basis of the surrogate endpoint data. Plaintiffs’ theory was that Sarepta had misleadingly omitted the fact that the FDA had expressed strong reservations about the proposed NDA. The district court dismissed plaintiffs’ claims and the First Circuit affirmed. The court concluded that the challenged statements about the FDA’s position “convey[ed] opinion more than fact,” and in any event were not misleading in light of the company’s repeated cautions that the FDA had not committed to the surrogate endpoint. The court further rejected plaintiffs’ challenge to two specific statements about the FDA’s request for additional tissue biopsies: Plaintiffs were overlooking the relevant chronology, in which the company was submitting information on a rolling basis and meeting certain concerns the FDA had identified as it proceeded. The court also made a key distinction between the FDA’s stated concerns about the *reliability* of data—which could be addressed through independent testing—and purported concerns about the company’s *methodology*—which plaintiffs failed to support with facts. As to plaintiffs’
accusation that the company did not disclose all of the negative statements made at the FDA meetings, the court emphasized that companies have “no legal obligation to loop the public into each detail of every communication with the FDA.” As long as the company accurately reported the gist of its interaction with the agency—which it did—it could not be faulted for omitting particular details. Finally, the court held that plaintiffs failed to establish scienter. The disclosures the company did make weighed against any inference of deliberate fraud, and allegations about financial motivation did not outbalance that.

Brennan v. Zafgen, Inc., 853 F.3d 606 (1st Cir. 2017), affirming dismissal. Phase 2/3
Zafgen developed Beloranib, an anti-obesity drug. In a Phase 2 trial, two patients suffered serious blood-clotting events, and two suffered superficial clotting events. Third-party clinical investigators did not link the events to Beloranib. Zafgen reported the serious but not the superficial events to investors and noted that the events had not been linked to the drug. A patient later died during a Phase 3 trial. The FDA put the drug on partial clinical hold and Zafgen disclosed the two superficial clotting events. The company’s stock price fell 50%.

Investors sued, challenging the company’s statements that Beloranib did not increase cardiovascular risk and that no serious adverse events in the Phase 2 trial were connected to Beloranib. Plaintiffs’ theory was that it was misleading for the company to omit the two superficial clotting events, which they claimed would have signaled to investors a higher likelihood of failure in Phase 3. Plaintiffs also alleged that the company knew or should have known of scientific articles purportedly linking Beloranib to clotting events, and that insider stock sales and compensation incentives further supported a strong inference of scienter. The district court dismissed the action and the First Circuit affirmed on both falsity and scienter grounds. The court rejected the theory that the omission of the superficial events showed fraud: That theory was undercut by the facts that (1) Zafgen forthrightly disclosed the two serious events; (2) the third-party clinical investigators never linked Beloranib to any adverse events; (3) even the serious events took on significance only after the patient’s death in Phase 3; and (4) Zafgen had clearly informed investors that it would not report all adverse events as they occurred. The court noted that under the Supreme Court’s 2011 Matrixx decision, companies may be required to disclose even adverse events that are not statistically significant. The court nevertheless concluded that disclosure was not required in this case, given, among other things, the fact that the FDA’s own rules do not require real-time reporting of superficial events in the clinical trial setting. The court also carefully reviewed the scientific articles cited by plaintiffs and concluded that they did not show links between Beloranib and clotting at doses relevant in Zafgen’s trials. As to scienter, the court noted that the officers had retained the vast majority of their stock holdings and that insider sales in any event cannot in themselves support a strong inference of scienter.

Amarin sought FDA approval of its drug Vascepa to treat high triglycerides. In 2008, Amarin met with FDA officials to determine whether a 12-week Phase 3 study on triglyceride reduction could serve as a surrogate endpoint for increased cardiovascular health. The FDA agreed, but told the company that it would need to have a long-term outcome trial well under way by the time of NDA review. The FDA also noted that two of Amarin’s competitors were conducting long-term studies on the effect of lowered triglycerides on cardiovascular health—a clinical endpoint—and told Amarin that the outcomes of those trials could affect approval of Vascepa. Amarin then informed investors that it was “optimistic” that the surrogate endpoint would be acceptable and that a completed outcome trial would not be required for an NDA. The company did not disclose other details of its communications with the FDA. In 2011, Amarin’s study was successful—but the two competitors’ studies were not. After commencing its long-term outcome trials as agreed, the company submitted an NDA in 2013. The FDA rejected the NDA in light of the failure of the competitors’ studies, stating that triglyceride reduction was no longer a valid surrogate endpoint for cardiovascular health. The company’s stock price fell.

Investors sued, alleging that once the competitors’ studies failed in 2011, it became “certain” that the FDA would reject Amarin’s surrogate endpoint and that the agency would require a completed
outcome trial before approving an NDA. The Third Circuit affirmed the district court’s dismissal of the complaint, holding that the challenged statements of optimism were accurate when made and that Amarin was under no duty to disclose details of FDA communications that were less than definitive. The court also cited the company’s risk disclosures, noting that they clearly warned investors that the FDA could always require additional studies or data before approval.

In re Atossa Genetics, Inc. Sec. Litig., 868 F.3d 784 (9th Cir. 2017). S10(k) Premarket Clearance
In 2012, Atossa received premarket clearance under Section 510(k) for its MASCT product, a device that collects breast cells for pre-cancer screening. Atossa later combined the product with a screening test called ForeCYTE, which had not received FDA clearance. The company nevertheless referred to ForeCYTE as “FDA-cleared” in an SEC filing. In February 2013, the company received an FDA warning letter stating that (1) the MASCT product had been modified and therefore required a new 510(k) clearance, (2) the ForeCYTE test required independent clearance, and (3) statements on the company’s website and labels that referred to the products as FDA-approved or cleared were false or misleading. The company disclosed the first issue to investors but not the second or third. Over the next several months, the company stated in various contexts that the products had progressed through the clearance process or that risks associated with clearance had been “achieved.” In October 2013, the company announced that it was recalling both MASCT and ForeCYTE. The company’s stock price fell 46% over three days.

Investors sued, the company moved to dismiss and the district court granted the motion on the ground that plaintiffs had failed to identify a false or misleading statement. The Ninth Circuit reversed in part. The court held that plaintiffs had adequately pled falsity with respect to the company’s statement that ForeCYTE was FDA-cleared. The court rejected the company’s argument that more nuanced statements in other SEC filings showed that the test had not been cleared; the court concluded that the nuanced statements did not in fact provide investors with that information, and that in any event, where plaintiffs plead direct reliance on a challenged statement, defendants cannot escape liability by pointing to corrective information in other documents. The court also held that plaintiffs had sufficiently pled that the company’s description of the warning letter was misleading by way of omission; the company disclosed only one of the three issues in the letter, and investors could reasonably conclude that this was a complete description of the issues raised. As to the company’s statement that clearance risk had been “achieved,” the court categorized this as an opinion under Omnicare, but held that the company’s failure to identify all issues in the warning letter rendered the opinion statement actionable under an omission theory. The court affirmed the district court’s dismissal as to statements of generalized optimism (“reasonably confident in responses to the FDA”) and statements that the MASCT system had been approved for unspecified uses.

DISTRICT COURT DECISIONS

Motions to Dismiss Granted


Seattle Genetics developed a drug for the treatment of acute myeloid leukemia, known by the shorthand name 33A. 33A was the successor of a drug earlier developed by Pfizer and approved by the FDA but withdrawn after studies revealed a rate of treatment-related toxicity higher than that in comparator therapies. In developing the successor drug, Seattle Genetics worked to reduce the toxicities that had led to the withdrawal of the predecessor drug. Seattle Genetics then conducted several trials simultaneously, including a Phase 1/2 trial for stem cell transplant patients and a Phase 1 trial in which 33A was given in combination with other drugs. In discussing the latter trial, the company described 33A as “well tolerated” and said that it did not add significantly to the toxicity of the combination treatment. After six patients in the trials were found to be suffering from liver toxicities and four patients died, the FDA placed
a full clinical hold on the Phase 1/2 trial and a partial hold on the Phase 1 trial. The company’s stock price fell 15%. Several months later, the company announced that it was abandoning the Phase 1/2 trial but had adopted risk mitigation measures for the Phase 1 trial, and that with those measures in place, the FDA had removed the partial hold.

Investors sued, challenging the company’s positive statements about toxicity. The investors relied in large part on statements made by a confidential witness who claimed to have brought concerns about toxicity to his superiors but did not purport to have communicated those concerns to the company’s executives. The court concluded that the investors had adequately pled that the challenged statements were false but had failed to plead scienter. On the element of falsity, the court rejected the company’s arguments that the challenged statements referred only to a part of the study in which no adverse events had occurred. The court drew on the Ninth Circuit’s 2016 Arena decision, and in particular on the principle that a company that announces positive information to the market is “bound to do so in a manner that wouldn’t mislead investors, including disclosing adverse information that cuts against the positive information.” On the element of scienter, the court agreed with the company that plaintiffs had failed to plead specific facts showing when and how company executives had learned about the information known to the confidential witness. In granting leave to amend, the court noted that plaintiffs “could easily allege consistent facts” that cured the pleading defect.


Sarepta developed eteplirsen for the treatment of Duchenne muscular dystrophy. Sarepta told investors that if it was able to produce sufficiently robust tissue biopsy results showing that the drug enables cells to produce a protein necessary for muscle function, the FDA would be receptive to an NDA based on those results as a surrogate endpoint, rather than requiring a clinical endpoint (which would be measured by patients’ ability to walk). In April 2014, Sarepta announced that with the data it currently had, it believed an NDA was “fileable,” but that because the FDA had expressed concerns and some skepticism about the data, the company planned to gather additional data over the next six to eight months and to file an NDA thereafter. The company repeated this two-part message over the next several months. In October 2014, Sarepta announced that the FDA had provided updated guidance requiring additional and reassessed data, and that in light of this, the company was delaying its projected NDA. The company’s stock price dropped. The company then filed an NDA in June 2015. In a January 2016 briefing document, the FDA again expressed concern about the biopsy data and indicated that in 2013, it had strongly encouraged the company to obtain independent laboratory verification of those results. In September 2016, the FDA approved the drug.

Investors sued based on the October 2014 stock price drop, claiming that Sarepta had misled the market when it stated in April 2014 and thereafter that an NDA was fileable. The court granted the company’s motion to dismiss in a 2016 decision, rejecting plaintiffs’ central premise that the FDA had told the company that it would not accept an NDA based on the existing data. Plaintiffs had pled no facts showing any such definitive communication from the FDA; meanwhile, the company had repeatedly disclosed that the FDA had expressed enough skepticism that the company had concluded that filing without additional data would be unwise. After dismissal, plaintiffs sought leave to file an amended complaint in which they added references to the January 2016 briefing document. The court denied the motion, holding, among other things, that amendment would be futile. Plaintiffs’ attack, the court held, amounted to a critique of trial design, and such critiques cannot serve as the basis of a fraud claim. The company’s conduct, moreover, indicated that it had confidence in the strength of its data, and the ultimate approval of the drug further undercut any argument that the company had “disregarded FDA requirements while indicating otherwise to the public.” The company had properly informed investors of the FDA’s “questions and concerns” about the trial, had included appropriate risk disclosures, and was under no duty to disclose its entire “ongoing dialogue” with the agency.

Northwest developed dendritic cell cancer immunotherapies. In 2012-2014, the company was engaged in Phase 3 trials for DCVax-L and Phase 1/2 trials for DCVax-Direct, a newer immunotherapy in which the drug is injected directly into tumors. The company reported that in a pre-specified interim review of the Phase 3 trial, the Data Safety Monitoring Board recommended that the study continue. The company also reported favorable results in the Phase 1/2 trials, including results from a compassionate use “information arm.” In April 2014, an article appeared in TheStreet.com, in which a vice president of clinical research at MD Anderson Cancer Center criticized both the science behind the DCVax-Direct trials and the company’s statements about the treatment. The company’s stock price fell 20%. In July 2014, Seeking Alpha published an article in which the company was accused of engaging in an improper stock promotion scheme and the stock fell 6%. In August 2015, the FDA put a clinical hold on enrolling new patients in the Phase 3 trial for DCVax-L and the stock fell 22%.

Plaintiffs sued, challenging several categories of statements related to both the Phase 3 and the Phase 1/2 trials. The court granted the company’s motion to dismiss with respect to all statements. Plaintiffs’ critique of the ongoing Phase 1/2 results reported by the company amounted to the difference between two permissible judgments and in any event was based on a distortion of the MD Anderson doctor’s comments. Plaintiffs’ attack on the company’s positive description of certain features of its Phase 3 trials was similarly grounded in differences of opinion about trial design. Plaintiffs also criticized the company’s report of the DSMB’s interim safety check, relying on an expert who claimed that the company could have ascertained efficacy on the basis of the interim review and therefore must have been concealing unfavorable results. The court rejected this theory too, finding it impermissibly speculative. The court also rejected plaintiffs’ challenge to statements that data arising from the compassionate use arm were “encouraging”; the company had no obligation to report all information that cut the other way or to adopt a pessimistic view. Finally, the court held that plaintiffs had failed to create a strong inference of scienter, and distinguished cases in which life sciences companies had made unequivocal promises of efficacy or had concealed adverse FDA recommendations.


Tetraphase developed eravacycline, a synthetic antibiotic. The development program consisted of two Phase 3 trials, the second of which had a lead-in portion and a pivotal portion. The lead-in portion was completed in September 2014, and Tetraphase reported that the results were “positive” compared to those of a competing antibiotic, and that a lower dose of eravacycline was even more effective than a higher dose. In the following months, Tetraphase made additional positive statements about the drug’s predicted efficacy. In September 2015, however, Tetraphase reported that the pivotal portion of the study had failed to meet its endpoints, and the company’s stock dropped 80%.

Investors sued, challenging 75 statements on subjects ranging from efficacy and the favorable early results to market potential to internal controls. Plaintiffs’ theory was that aspects of the lead-in data (including the dose-response results) indicated that the pivotal portion would not be a success. Plaintiffs also claimed, pointing to statements about when enrollment would be completed and how long data analysis would take, that the company knew the results of the pivotal stage months before it reported them. The court dismissed the complaint, largely on scienter grounds. The court rejected the theory that the company knew and concealed results for months, finding the alleged timeline on which plaintiffs relied unsupported. The court also rejected plaintiffs’ claim that executive resignations and stock sales under trading plans showed scienter, and held that the company’s continued investment in the drug undercut an inference of scienter. As to plaintiffs’ challenge to favorable statements about efficacy, the court characterized this as a matter of “scientific opinion” and relied on pre-Omnicare law to conclude that plaintiffs had not established falsity. The court also held that many of the challenged statements were forward-looking, were accompanied by robust and particularized risk disclosures, and thus came within the PSLRA’s cautionary statement safe harbor.
**Markette v. XOMA Corp.**, 2017 WL 4310759 (N.D. Cal. Sept. 28, 2017), motion to dismiss granted without prejudice. **Phase 3**

XOMA partnered with another company to develop an antibody called gevokizumab, for the treatment of inflammatory eye disease. The Phase 3 trial compared the time that patients on the drug and patients on the placebo reached the point of “exacerbation,” or a worsening of their condition. The company initially told investors that unblinding would occur in June 2014, but at that time only 75% of the target exacerbations had occurred. The company continued to update the market over the next year, explaining that in the case of some patients, exacerbations had not occurred because doctors had departed from the protocol and performed “rescues.” Data from patients who had been “rescued” could not be used in the study. With respect to those patients who were not “rescued,” the company explained that the delay in reaching exacerbation was encouraging and consistent with the expected treatment effect of the drug. At the same time, the company repeatedly cautioned the market that until the study was unblinded, it had no way of knowing whether the delayed exacerbations were occurring on the treatment arm or the control arm. When the study was unblinded a year later than originally expected, it turned out that there was no significant difference between the treatment and the control cohorts, and the company’s stock price fell.

Investors sued, challenging a series of statements in which the company had characterized the delay in reaching exacerbation as encouraging. The court granted the company’s motion to dismiss. The court concluded that most of the challenged statements were opinion statements with respect to which plaintiffs failed to satisfy the standards of Omnicare and the Ninth Circuit’s 2017 decision in **Align Technology**. Plaintiffs pled no facts suggesting that the company did not genuinely believe the results were encouraging; nor did plaintiffs show that any embedded factual statements were false. And plaintiffs’ omission theory failed in light of the company’s repeated cautions that the data remained masked (“It could be great news, or it could mean nothing. We won’t know until the data are unblinded”). Plaintiffs also failed to raise a strong inference of scienter, particularly as they had not established that the company actually knew what the unblinded data would show at the time of the challenged statements.

**Crihfield v. CytRx Corp.**, 2017 WL 2819834 (C.D. Cal. June 14, 2017), motion to dismiss granted without prejudice. **Phase 3**

In January 2014, CytRx announced that it would be conducting a single pivotal Phase 3 trial of its lead candidate, the cancer drug aldoxorubicin, under a Special Protocol Assessment. The trial would compare progression-free survival (PFS) on treatment and control arms. The company expected that a total of 191 “PFS events” would demonstrate an effect sufficient for approval under the SPA. The SPA incorporated the assumptions that patients would go through an 18-month accrual period and a 15-month follow-up period after enrollment. In November 2014, the company announced that the FDA had imposed a partial clinical hold on the trial following a patient death from metabolic acidosis. Under the partial hold, no new patients could be enrolled but existing patients could continue treatment. In December 2014, the company announced that in keeping with recommendations in the third-party “Edison Report,” existing patients would be given the drug only after they had cleared additional screening for acidosis risk. In January 2015, the company announced that the hold had been lifted in its entirety and that it expected that the trial timelines, including the timelines for unblinding and analyzing data, would remain unchanged. The trial reached 191 PFS events on schedule in April 2016. In July 2016, the company announced disappointing results: There were no significant differences between the treatment and control arms. In explaining that result, the company referred to the partial clinical hold in November 2014, stating that as a result of the interruption in enrollment, nearly half of the participating patients were excluded because they had not yet received sufficient follow-up evaluation. The company’s stock price fell 59% and fell an additional 10% over the next two days.

Investors sued, challenging statements both before and after the December 2014 announcement of the Edison Report. The court granted the company’s motion to dismiss. With respect to the pre-Edison Report statements, the court concluded that plaintiffs had adequately pled that the challenged statements were misleading by way of omission insofar as the company had failed to describe the risk that acidosis screening might lead to delay or even failure of the trial. The court nevertheless dismissed the claims based on pre-December 2014 statements on scienter grounds,
finding it implausible to infer that the company knew that delays would have a negative effect on the trial. As to the post-Edison Report statements, the court rejected plaintiffs’ theory that by departing from the 18-month and 15-month timeline assumptions in the SPA, the company was violating the terms of the SPA or misleading investors by stating that it was conducting the trial pursuant to those terms. The court concluded that the balance of the statements were forward-looking and protected under the PSLRA’s safe harbors. On the elements of both falsity and scienter, the court distinguished the Ninth Circuit’s 2016 Arena decision, holding that the company did not make the kind of affirmatively misleading statement of universally positive results at issue in that case.

_Bauer vs. Eagle Pharmaceuticals, Inc.,_ 2017 WL 2213147 (D.N.J. May 19, 2017), motion to dismiss granted without prejudice. **NDA**

Eagle developed a “ready-to-use” liquid version of an approved anticoagulant (bivalirudin) that normally needs to be compounded into liquid before use. The company sought approval through the Section 505(b)(2) regulatory pathway, which permits a developer to rely, in part, on the FDA’s prior findings of safety and efficacy for an existing drug. Eagle announced the filing of its NDA to investors with the “expectation,” based on dialogue with the FDA, that “we’ll get approval.” The FDA, however, issued a Complete Response Letter advising the company that it would not approve the product in its present form. Eagle informed investors of the Complete Response Letter, stating that the FDA had requested “further characterization of the bivalirudin-related substances in the drug product.” Eagle also told investors that it was discussing a possible human trial with the FDA. The company’s stock price fell 19%.

Investors sued, challenging the company’s statements that (1) the only difference between its product and the approved drug was that its product was a liquid rather than a powder, and (2) the company expected approval based on its dialogue with the FDA. The court rejected both challenges. Plaintiffs’ attack on the company’s description of its drug was based on the premise that if the drug had in fact been equivalent to the approved product, the FDA would not have denied approval or requested human trials. The court held that this theory was impermissibly speculative, and established neither falsity nor scienter. The optimistic statements about approval, meanwhile, came within both of the PSLRA’s safe harbors for forward-looking statements: The statements were accompanied by cautionary language and plaintiffs had failed to plead facts showing that the company had actual knowledge of their purported falsity. The court also held that plaintiffs had failed to raise a strong inference of scienter, rejecting plaintiffs’ argument that the challenged statements came within the company’s “core operations.”

_In re Dynavax Sec. Litig.,_ 2017 WL 4005584 (N.D. Cal. Sept. 12, 2017), motion to dismiss granted without prejudice. **BLA**

Dynavax’s lead product candidate was a hepatitis vaccine. The FDA rejected a Biologics License Application that the company had submitted in 2012, explaining that the company needed to perform a larger safety study to assess the possibility of rare autoimmune side effects. In response, the company designed and performed additional Phase 3 trials. The company and the agency agreed on a defined list of Adverse Events of Special Interest, or AESIs for this trial; those events were related solely to potential autoimmune and inflammatory disorders. The company submitted a new BLA in March 2016 and spoke favorably about the low rate of AESIs. In September 2016, the FDA canceled a scheduled advisory committee meeting, and the company’s stock price dropped 30%. Two months later, the company announced that it had received a Complete Response Letter evaluating its BLA and that the FDA had expressed concerns about issues including the rate of adverse cardiac events in the Phase 3 trial. The company’s stock price dropped 64%. Several months later, the company announced a restructuring, a suspension of launch activities, and the layoff of 40% of its workforce.

Investors sued, alleging that the company made false or misleading statements when it spoke favorably about the low rate of AESIs without disclosing the adverse cardiac events. The court granted the company’s motion to dismiss. Plaintiffs’ theory was based on a fatally flawed factual premise. AESIs, as defined for purposes of the Phase 3 trial, included only events related to autoimmune and inflammatory disorders—not all adverse events, and not cardiac events.
**TransEnterix Investor Group v. TransEnterix, Inc.,** 272 F.Supp.3d 740 (E.D. N.C. 2017), motion to dismiss granted without prejudice. **510(k) application**

TransEnterix manufactures robotics for use in surgeries. In June 2015, the company submitted a Section 510(k) application for the SurgiBot, a robotically enhanced surgical device. While the 510(k) application was pending, the FDA announced generally that it would increase scrutiny of robotically assisted devices like the Surgibot, and that it expected manufacturers of such devices to support their 510(k) applications with human-factors data. The FDA then requested additional information from TransEnterix specifically, including human-factors data. The company responded with an additional submission of over 11,000 pages in an attempt to address the FDA’s concerns about human-factors issues. Thereafter, the company repeatedly stated that it anticipated FDA clearance for the SurgiBot and included such statements in the registration statement and prospectus for a new securities offering. The FDA ultimately rejected the 510(k) application, and the company’s stock price fell more than 50%.

Investors sued, challenging the company’s optimistic statements about approval and asserting Section 10(b) claims as well as 1933 Act claims based on statements in the offering documents. The court granted the company’s motion to dismiss as to all claims. The court held that plaintiffs had failed to adequately allege falsity. The challenged statements were opinions, and plaintiffs had neither satisfied the requirements of Omnicare nor shown that the company had failed to submit the human-factors data requested by the FDA. The statements were also forward-looking and hence protected by the PSLRA’s actual knowledge safe harbor. Plaintiffs additionally failed to create a strong inference of scienter, as the more likely inference was that the company had simply misjudged the adequacy of its supplemental submission. The company’s investment of resources in alternative products did not support a contrary inference, and neither did insider stock purchases following the announcement of bad news. Finally, plaintiffs lacked standing to assert their 1933 Act claims, having failed to allege facts showing that their purchases could be traced to the challenged offering or offering documents.

**In Re KaloBios Pharmaceuticals Inc. Securities Litigation,** 258 F.Supp.3d 999 (N.D. Cal. 2017), motion to dismiss granted without prejudice. **Corporate leadership**

KaloBios Pharmaceuticals was a development stage biopharmaceutical company. Throughout 2015, KaloBios repeatedly reported financial difficulties and funding shortages. In early November 2015, it announced plans to cancel further drug trials, wind down operations, and liquidate its assets. Its stock price dwindled to near zero. That month, Martin Shkreli purchased the majority of KaloBios’ shares on the open market, prompting talk of KaloBios’ continued viability. Just prior to Shkreli’s purchases, several national news outlets had begun reporting on criminal securities investigations into Shkreli’s activities and his termination as CEO and manager of other biopharmaceutical and investment enterprises. Nevertheless, in late November KaloBios’ board accepted Shkreli’s financing proposal and named him CEO. Shkreli publicly expressed optimism about his qualifications as CEO, pledged to provide the company with sufficient funding to continue its drug trials, and praised the company’s potential. The stock price rose. In December 2015, however, Shkreli was indicted on federal securities charges. KaloBios’ stock again dropped, and the company was eventually delisted.

Plaintiffs who purchased KaloBios stock during its brief resurgence sued, alleging that Shkreli misled investors about his reputation and qualifications as well as about the brightening prospects of KaloBios. The court dismissed the complaint. Plaintiffs failed to plead that they reasonably relied on the challenged statements about Shkreli’s reputation and qualification, given the negative information on the subject already in the market at the time of their purchases. Shkreli’s later arrest did not redeem the claim, as it did not correct any previous statements. The court parenthetically noted that courts have declined to adopt a broad-based duty to disclose uncharged criminal conduct. As to statements about the company’s own prospects—that a particular drug had promise and that Shkreli would contribute funding—plaintiffs failed to allege facts showing that the challenged representations were false when made. Plaintiffs’ argument that the company’s plans were too “unrealistic” to succeed was simply too vague and speculative to support a fraud claim.
DISTRICT COURT DECISIONS
Motions to Dismiss Denied

In re Juno Therapeutics, Inc., 2017 WL 2574009 (W.D. Wash. June 14, 2017), motion to dismiss denied. Phase 1/2

Juno developed a drug, JCAR015, for the treatment of acute lymphoblastic leukemia. Treatment with the drug involves the patient with genetically modified T-cells, called chimeric antigen receptor, or “Car-T” cells. Other companies were also developing Car-T products, and Juno adopted a “fast-to-market” strategy. The company conducted Phase 1 and Phase 2 trials simultaneously. In the Phase 2 trials, the company’s drug was combined with another drug, fludarabine, which destroyed patients’ existing T-cells. After a single patient died in the Phase 2 trial, the company made positive statements about the Phase 1 trial. In July 2016, after two more patients had died in the Phase 2 trial, the company announced that the FDA had instructed it to halt that trial. The company also explained that it believed it was the combination of its drug with fludarabine that had caused the three deaths. After the FDA permitted the company to resume the Phase 2 trial, another two patients died, for a total of five. In November 2016, the company announced that it had placed a voluntary hold on the trial. The company’s stock price dropped 30% following the July 2016 announcement and 25% following the November 2016 announcement.

Investors sued, challenging both the positive statements about the Phase 1 trial and the statements following the initial three deaths in which the company had attributed those events to the combination with fludarabine. The court denied the company’s motion to dismiss. On the issue of falsity, the court agreed with plaintiffs that it was at least arguably misleading to describe the positive Phase 1 results without also disclosing the initial death in the Phase 2 trial. The court relied on the Ninth Circuit’s 2016 Arena decision, quoting the principle that defendants who make positive statements must “do so in a manner that wouldn’t mislead investors, including disclosing adverse information that cuts against the positive information.” The court acknowledged the company’s argument that the challenged representations were statements of opinion that fell short of Omnicare’s standard, but then left the argument largely unanalyzed. On scienter, the court again drew on Arena, as well as on the “core operations doctrine” (under which important transactions are assumed to be known to a company’s executives) and the fact that the company was competing with others to develop a Car-T drug. On both falsity and scienter, the court’s approach differs notably from the detailed and methodical analysis typical under the PSLRA and Tellabs: The court showed a marked impatience with the sifting of facts and weighing of inferences generally required under the heightened pleading regime. (For example: “Based on the undeveloped record currently before the Court, there are simply too many questions of fact to dismiss this case”; “despite Defendants’ arguments to the contrary, Plaintiffs need not prove these claims to survive this Motion”; “[the parties] are attempting to conduct a trial by paper. The Court does not appreciate being flooded with hundreds of pages of evidence”).

Medina v. Clovis Oncology, 215 F.Supp.3d 1094 (D. Colo. 2017), motion to dismiss denied in part. Phase 1/2

Clovis developed rociletnib, a drug for the large fraction of lung cancer patients who develop resistance to the first-line treatment, tyrosine kinase inhibitors. A competitor was developing a rival drug at the same time. Clovis began Phase 1 and 2 trials with the intent of submitting its NDA on a rolling basis. The trials tested for clinically meaningful tumor shrinkage, which was measured by the objective response rate. The trial protocol required that the ORR yielded by an initial scan be “confirmed” through follow-up tumor scans. From mid-2014 through November 2015, Clovis told investors that it was adhering to the protocol, that rociletnib’s ORRs were between 53% and 67% (depending on dosage), and that rociletnib’s only side effect was easily-managed hyperglycemia. In November 2015—after the competitor’s drug was approved—Clovis announced that previously-reported ORR data had been based on a mix of unconfirmed and confirmed responses, and that confirmed ORRs were as low as 28%. The stock price fell 70%. Over the next several months, the company stated that while rociletnib’s efficacy
might be less than that of the now-approved rival drug, rociletinib’s favorable safety profile could still make it marketable. In April 2016, however, the company and FDA released safety data showing severe cardiac events and high discontinuation rates in the trial, and the stock fell an additional 17%. The advisory committee reviewing the drug subsequently recommended that the FDA delay action, and the company withdrew its NDA.

Investors sued, challenging the company’s statements reporting ORRs of 53-67%. The investors’ theory was that at the time the company reported those figures, the data yielded by follow-up scans had already undermined the original favorable responses. The court denied the company’s motion to dismiss with respect to these statements, undertaking a remarkably deep dive into the protocol and governing medical literature. The company had argued that the protocol did not require it to update initial positive ORRs as soon as new data from follow-up screens became available; the court, however, after analyzing the protocol and related literature at length, rejected the company’s argument. The court also denied the company’s motion to dismiss challenges to its statements about safety, holding that objectively verifiable terms such as “safe” and “well tolerated” are actionable. (On the other hand, the court rejected plaintiffs’ challenge to statements that the drug was “promising,” “impressive,” and “encouraging”). As to scienter, the court concluded that plaintiffs had adequately alleged that confirmed and unconfirmed response rates differed at the time of the challenged statements and that the company had access to all relevant data. The court then considered what it called “Tellabs’ battle of the motives,” and credited plaintiffs’ argument that the company acted in the hope that known negative results from early follow-up scans would later be overtaken by positive results from subsequent follow-up scans—and that this was improper. Plaintiffs also brought 1933 Act claims against underwriters and venture capital parties based on a stock offering that took place during the class period. The court denied the company’s motion to dismiss plaintiffs’ Section 11 claims on the same basis as it denied the Section 10(b) claims. The court granted the motion to dismiss the Section 12 claims on privity grounds and dismissed the claims against the venture capitalists because plaintiffs had failed to show that they were controlling persons.


Following the district court’s order in Crihfield v. CytRx discussed on page 31, above, plaintiffs filed an amended complaint, the company again moved to dismiss, and the court issued a second order. In this second order, the court dismissed without leave to amend plaintiffs’ challenge to statements about trial progress and timelines. But the court denied the motion with respect to plaintiffs’ challenge to statements that the company was conducting the trial according to a Special Protocol Assessment. The court concluded that plaintiffs had adequately pled that any departure from the assumption in the SPA that patients would be followed for 15 months negated the FDA’s obligations under the SPA and increased the chance that the trial would yield immature results. The court also concluded that plaintiffs had adequately pled that the company knew about the adverse effects of deviating from the 15-month assumption.


In an important 2016 decision, the Ninth Circuit reversed a district court dismissal of investors’ claims against Arena, the developer of a weight loss drug. Arena had stated that all studies had yielded positive results, notwithstanding the fact that rats in an animal study had developed cancer and the FDA had raised concerns about this. The company had argued that the statements were not knowingly false or misleading because company executives believed that the rat results were susceptible to a benign explanation, and one that had no implications for human health. The Ninth Circuit rejected that argument, holding that by affirmatively stating that all results were positive, the company took on a duty to disclose the unfavorable rat results, notwithstanding its belief that the results did not show risks to humans.

On remand to the district court, the company moved to dismiss on the ground that the challenged opinion statements were not false or misleading; the Ninth Circuit had ruled solely on scienter grounds, and not on the element of falsity. The district court denied the company’s motion,
finding that as a matter of logic, the Ninth Circuit’s holding that the company acted with scienter foreclosed the company’s argument that the statements at issue were not false or misleading.


Puma developed neratinib, a breast cancer drug. After a Phase 3 trial had been completed, but before results were fully validated, the company hosted an analyst call. In response to a question about whether the disease-free survival rate for the placebo was around “86% or so,” the CEO stated that he was “comfortable” with that figure. The company also stated it was still in the process of analyzing safety results and dropout rates but anticipated that data would be comparable to positive data that in earlier trials. When complete Phase 3 results were reported, however, they proved disappointing, and the company’s stock price fell.

Investors sued, and in a 2016 decision, the court permitted them to move forward with a challenge to the statement that the disease-free survival rate on the placebo arm was approximately 86%; plaintiffs alleged it was 91.6%. After discovery, plaintiffs amended to add new challenges to the company’s statements about safety and dropout rates. Plaintiffs’ theory was that at the time it made the statements, the company knew enough about unfavorable data that it was misleading to state that it anticipated that results would be similar to those in earlier trials. The company moved to dismiss these new challenges, and the court again denied the motion. The court rejected the company’s argument that the challenged statements came within the PSLRA’s safe harbor for forward-looking statements, holding that plaintiffs had adequately alleged that the company knew that results would be unfavorable. While the company argued that “fully validated data” had not yet been compiled at the time, the court concluded that “some form of reliable data” was available and that this showed the company’s knowledge. The court also held that plaintiffs had adequately pled scienter, explaining that new allegations about executives’ incentives to increase the likelihood of an acquisition served to buttress rather than undercut the allegations the court had previously found sufficient.


PTC developed Translarna, a drug designed to treat Duchene muscular dystrophy. Because the disease is rare, the drug was given fast track designation, which allowed the company to submit its NDA on a rolling basis. Although the Phase 2b trial failed to meet its endpoints, the company determined that when younger, healthier patients were excluded from the data set, the trial demonstrated statistically significant results. The company accordingly filed an NDA based on the Phase 2b data for older, sicker patients. In response, the FDA issued a Refuse to File letter, rejecting the company’s post-hoc analysis. The company then conducted a Phase 3 trial restricted to older, sicker patients. The Phase 3 trial yielded results worse than the Phase 2b trial, save with respect to one of the two subgroups the company had earlier identified as key to the trial. In reporting the trial results, the company stated that the results were positive with respect to the pre-identified subgroup and that the positive results were further supported by a “pre-specified meta-analysis” combining the favorable Phase 2b data with data from the successful sub-group in Phase 3. The company also told investors that the “totality of the data” confirmed the clinical benefit of the drug; the company did not, however, disclose that 60% of the Phase 3 patients reported no clinically meaningful benefit. The company filed a second NDA based on its meta-analysis and additional post-hoc analysis but again received a Refuse to File letter. The company’s stock price fell 62%.

Investors sued, challenging statements about the Phase 3 trial data and the FDA’s timeline for reviewing the second NDA. The court dismissed the claims with respect to positive statements made before the company had access to the Phase 3 data, holding that plaintiffs failed to show that the company’s statements about expected Phase 3 results were false when made. But the court allowed plaintiffs to proceed with their challenge to the company’s statements about the actual results of the Phase 3 trial and the meta-analysis. Plaintiffs had adequately alleged that the company’s statements about the “totality of the data” were false or misleading, given the omission of information about the majority of patients who had experienced no benefit, as well
as the omission of the fact that the trial had failed with respect to one of the two pre-specified subgroups. Once the company made its statements about the totality of the data, the court held, it took on a duty to disclose the negative information. The court also concluded that plaintiffs had adequately alleged that the company misleadingly suggested that its meta-analysis had been pre-approved by the FDA; in fact it had not been. And plaintiff had adequately pled scienter, the court held, by reference to the company’s knowledge that the FDA typically requires two successful trials for approval, and to the fact that the only favorable results from the Phase 3 trial were based on the same kind of post-hoc meta-analysis the FDA had rejected in connection with the company’s first failed NDA.
DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 40-47), we provide detailed summaries of decisions in cases arising from developments at the post-approval stage. As discussed in the “Trends and Analysis” section above, companies fared poorly in the cases at the district court level, winning motions to dismiss in only 3 of the 10 cases. Companies did better at the appellate level, winning affirmance in 3 out of 4 cases.

Courts ruled against defendants in whole or in part in cases arising from price-gouging and opioid scandals, although the principle remains that alleged regulatory violations do not in themselves constitute viable claims for securities fraud. Companies also failed to win dismissal in three cases that unfolded against the background of mergers or acquisitions. The M&A setting contributed to courts’ conclusion that plaintiffs had adequately pled scienter.

Two of the three appellate decisions in which companies prevailed arose involved claims arising from revised revenue guidance. In both decisions, the courts held that plaintiffs had failed to plead facts showing that the companies knew their predictions would turn out to be wrong.
APPELLATE DECISIONS

In re Biogen Inc. Securities Litigation, 857 F.3d 34 (1st Cir. 2017), affirming dismissal. Adverse events/label change

In 2013, the FDA approved Tecfidera, Biogen’s multiple sclerosis drug. In October 2014, Biogen reported increasing revenues from Tecfidera, but also announced on an earnings call that a patient had died while taking it. In November 2014, the FDA issued a public warning about the death, and Biogen updated Tecfidera’s label to include a warning of the risk of death. In January 2015, Biogen issued annual revenue guidance projecting 14%-16% growth. Also during January-February 2015, however, the company publicly acknowledged fewer new Tecfidera prescriptions and cited the death and updated label as one cause. In April 2015, Biogen reported weaker-than-expected first quarter earnings, but expressed “optimism” for the future. In July 2015, Biogen issued revised revenue guidance of 6%-8% growth and stated that the death had led to greater caution among physicians. The company’s stock price dropped 22%. In October 2015, Biogen executives again confirmed that the death and new labeling had impacted prescription rates.

Investors sued, alleging that the company concealed, in statements made between December 2014 and July 2015, the true effect of the patient death on Tecfidera sales. The First Circuit affirmed the district court’s dismissal of the complaint on scienter grounds alone. Plaintiffs relied on confidential witnesses and purported admissions by company officers, but all of these allegations suffered from a fatal timing problem. They showed at most that the purportedly concealed information about declining prescriptions was available after the company made the challenged statements. The court rejected plaintiffs’ “core operations” theory on similar chronological grounds: Whether or not the purportedly concealed information was so central to the company that its executives would have known of it, that information post-dated the challenged statements. The court also rejected plaintiffs’ argument that they should have been permitted to amend the complaint to add new allegations. The information they sought to add showed only that one medical center had stopped prescribing the drug due to concerns about side effects generally, not that physicians had stopped prescribing in response to the patient death.

Williams v. Globus Medical, Inc., 869 F.3d 235 (3d Cir. 2017), affirming dismissal. Revenue guidance

Globus develops and commercializes spinal implants, which it sells using both in-house sales representatives and independent distributors. As part of its overall strategy to increase reliance on in-house sales representatives, the company terminated its relationship with a distributor named Vortex. Although the company warned in its 10-K risk disclosures that its sales could be adversely affected if independent distributors ceased to work with the company, it did not state that it had ended its relationship with Vortex. After the Vortex termination, Globus revised its revenue guidance, attributing the lower numbers in part to the decision not to renew its Vortex contract. The company’s stock price dropped 18% after it revised guidance. Ultimately, however, the company came close to meeting its original revenue guidance and exceeded its original earnings guidance.

Investors sued, challenging both the risk disclosure and the original revenue guidance and alleging that the company breached a duty to disclose its intention to terminate the Vortex relationship. The district court dismissed the action and the Third Circuit affirmed. Plaintiffs’ theory with respect to the challenged risk factor was that it was misleading to state that the loss of a distributor like Vortex could negatively impact sales when the risk at issue had already come to pass. The Third Circuit rejected the theory. The only risk that had come to pass at the time of the challenged statement was that the distributor relationship had ended—not that sales had declined. The Third Circuit also rejected plaintiffs’ attack on the company’s revenue guidance. First, the guidance came within the PSLRA’s “actual knowledge” safe harbor, which renders forward-looking statements inactionable save when plaintiffs can plead facts showing that defendants actually knew their statements were false when made. Plaintiffs had pled no such facts. Second, plaintiffs failed to alleged facts showing that the company had not factored the end of the Vortex relationship into the challenged revenue projection; if anything, the facts plaintiffs alleged showed the opposite.
City of Dearborn Heights Police and Fire Ret. Sys. v. Align Technology, Inc., 856 F.3d 605 (9th Cir. 2017), affirming dismissal. **Corporate acquisition/accounting for goodwill**

Align, which manufactures the Invisalign system for straightening teeth, acquired Cadent in April 2011. Cadent manufactures 3D digital products, including intra-oral scanners used by dentists and orthodontists. Align allocated $136 million of the $188 million purchase price to goodwill; $77 million was allocated to the combined companies’ “SCCS unit.” The SCCS unit performed below projections, and in October 2012, Align announced that it was conducting an interim goodwill impairment test for the SCCS goodwill. Align's stock price fell 20%, and over the next six months, the company wrote off the entirety of the $77 million SCCS goodwill.

Investors sued, challenging the company’s statements about its goodwill valuation and claiming that facts known to Align indicated the need to test for goodwill impairment a year before the company did so in October 2012. The district court dismissed plaintiffs’ claims and the appellate court affirmed. In its first substantial application of Omnicare to challenged opinion statements, the Ninth Circuit made two significant holdings. First, the court held that while Omnicare itself involved 1933 Act claims based in strict liability or negligence, the Omnicare standards apply equally to scienter-based Section 10(b) claims. Second, the court expressly rejected a Ninth Circuit pre-Omnicare standard in which plaintiffs were permitted to establish falsity by showing that defendants lacked a reasonable basis for opinion statements. The Align court explained that plaintiffs may challenge the basis of a speaker’s opinion only under an omission theory, and only (in the words of Omnicare) where they can allege “facts going to the basis for the [defendant’s] opinion...whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.” The court then concluded that plaintiffs had failed to satisfy Omnicare's standards. Most fundamentally, plaintiffs failed to allege facts about how the company arrived at the challenged opinions. While plaintiffs argued that particular data points and assumptions should have led the company to form a contrary opinion, those arguments were irrelevant in the absence of information about the assumptions the company actually employed and the calculations it actually made. The court also affirmed dismissal on scienter grounds, explaining that even if it were to credit plaintiffs’ allegations that the company knew certain negative facts bearing on goodwill, this would not show that the company’s conclusions about goodwill were anything other than permissible judgments.

Cooper v. Thoratec Corporation, 698 F. App’x 516 (9th Cir. Oct. 4, 2017), reversing dismissal. **Adverse events**

Thoratec manufactures the HeartMate II, a heart pump used to support heart function and blood flow in patients with heart failure. When the FDA approved the device, it published data showing a 2% rate of thrombosis (a complication in which blood clots form in a vessel). After approval, the number of serious adverse events involving thrombosis reported to the Manufacturer and User Facility Experience database increased, and studies in medical journals reported increased rates of thrombosis related to the HeartMate II. Thoratec continued to market the device as having low thrombosis rates.

Investors sued, claiming that the company’s statements regarding the low rates of thrombosis were false and misleading, and alleging that the company failed to disclose that thrombosis rates were increasing. The district court rejected these assertions, finding that the MAUDE data could not be used to establish the rates of SAEs. The court noted that the 2% rate of thrombosis was expressed in patient years, which reflect the number of years that the devices have been in place, not just the number of devices implanted—and that plaintiffs had failed to account for this. A reasonable investor, in the court’s view, would calculate a change in rates using the same formula used to calculate the baseline rate. The court also concluded that certain challenged statements did not refer to thrombosis rates at all, and that other statements downplaying the seriousness of the problem had not been shown to be false or misleading. The Ninth Circuit reversed in a single-paragraph order, stating simply that plaintiffs had cited facts suggesting that the rate of thrombosis was higher than “advertised,” that the company’s affirmative statements had downplayed that fact, and that this was sufficient to establish falsity.
DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED


CSI developed and manufactured devices used to treat arterial disease. A former sales manager filed a sealed qui tam action, i.e., an action purportedly on behalf of the government. The sales manager alleged that the company engaged in off-label marketing (for use of the device on with blood vessels other than those for which use was approved), improper discounts, and kickbacks in the form of free travel to desirable locations. When the company settled the qui tam action for $8 million and the matter was unsealed, the company’s stock price dropped.

Investors sued, alleging that the company had misled them by falsely attributing its sales growth to legitimate practices, by certifying its financial reporting as required by Sarbanes-Oxley, and by stating that it was in compliance with legal and regulatory obligations. In addition to incorporating the allegations made in the qui tam complaint, plaintiffs relied on the purported statements of 14 confidential witnesses. The court granted the company’s motion to dismiss. The court largely discounted the confidential witness allegations, holding that plaintiffs had failed to plead facts showing that the information provided by the witnesses was reliable. The court then rejected as legal conclusions plaintiffs’ claims that the uses for which the product was marketed were in fact off-label. The court also concluded that plaintiffs failed to allege facts showing that the discounts were improper, noting that buy-some-get-some-free arrangements may be lawful if disclosed. Similarly, plaintiffs failed to show violation of anti-kickback laws, as they had not established that the company remunerated persons who could refer patients or buy devices. In the court’s view, plaintiffs’ claim failed because it was based on the premise that the company was engaged in illegal conduct and plaintiffs had not shown this to be the case.

In re Intrexon Corp. Securities Litigation, 2017 WL 732952 (N.D. Cal. February 24, 2017). Motion to dismiss granted without prejudice. Value of technology

Intrexon acquired and built a group of technologies that modify DNA sequences and then licensed the technologies to collaborators developing products in various industries. In April 2016, an anonymous short-seller published a research report claiming that Intrexon’s suite of technologies was overvalued and that its work with Car-T cells in particular was based on a flawed technology long ago abandoned by its original developer. The short seller also claimed that the company’s reported revenue was inflated by the inclusion of transactions with insiders and affiliated companies. Intrexon’s stock price fell after the report was published.

Investors sued, challenging the company’s optimistic characterization of its technology and claiming that the short-seller’s report showed that the company’s statements were false. The court granted the company’s motion to dismiss. The court held that the short-seller’s attack on particular technologies did not show that the company’s generalized characterizations were untrue, particularly as the attacks were based on dated information. The challenge to the company’s Car-T technologies was also based on aging information that did not bear on the current value or functionality of the technologies. The challenge to reported revenue failed because the company fully disclosed its revenue recognition policies and plaintiffs did not allege that it had violated them. The court also held that plaintiffs had failed to establish a strong inference of scienter; plaintiffs’ reliance on the “core operations” doctrine did not outweigh the inference that Intrexon and its executives believed in the value of the technology. Finally, the court held that plaintiffs had failed to plead loss causation: Because the short-seller’s report was based entirely on information already in the public realm, it did not constitute a corrective disclosure revealing any previously concealed truth.
Regulation of dietary supplements

GNC sells health and wellness products, including dietary supplements manufactured by third-party vendors. After the FDA banned dimethylamylamine (DMAA), the company sold replacement products, also manufactured by third parties, that had been reformulated with two other ingredients: picamilon and ß-Methylphenethylamine (BMPEA). The FDA eventually determined that neither picamilon nor BMPEA qualified as a dietary ingredient, and GNC stopped selling products with those ingredients. In October 2015, the Oregon Attorney General filed a civil action against the company for selling products with picamilon and BMPEA. The company’s stock fell 15% the same day. A week later, the company reduced its earnings forecast and its stock price dropped another 20%.

Investors sued, alleging that the company made false or misleading statements about the purity of its products, its ability to manage regulatory risk, and its ability to offset losses related to the removal of DMAA from its products. The court granted the company’s motion to dismiss without prejudice. On the issue of falsity, the court agreed with plaintiffs, concluding that they had sufficiently pled that the company was not in fact able to manage regulatory risk and that it had not offset sales of DMAA products with FDA-compliant replacement products. But the court rejected plaintiffs’ allegations of scienter, which were based on statements from confidential witnesses. The court held that plaintiffs had failed to establish that the witnesses were knowledgeable, reliable, or had communicated with management, and hence that it was plausible to infer that the company did not know about issues with picamilon or BMPEA until the FDA determined they did not qualify as dietary supplement ingredients. The court also held that plaintiffs had failed to establish loss causation. The Oregon AG’s complaint did not constitute a corrective disclosure, and plaintiffs did not allege that the company’s reduced earnings forecast a week later was related to picamilon or BMPEA.

DITRRICT COURT DECISIONS: MOTION TO DISMISS DENIED

Intuitive Surgical manufactured and sold the Da Vinci System, a robotic system in which laparoscopic surgery is performed through very small incisions. The company received numerous medical device reports, which hospitals are required to submit to manufacturers if they believe that an adverse event may be linked to a medical device. Manufacturers are required to forward medical device reports to the FDA if the reports reasonably suggest that a device may have contributed to the adverse event. Intuitive Surgical did not forward all of the reports it received to the FDA. In some instances, the company sent letters to hospitals containing additional instructions for the safe use and inspection of the product. The company did not notify the FDA of these letters, and the agency ultimately deemed this to be a regulatory violation. When the company began filing increased numbers of medical device reports, the FDA began a safety probe, and when the probe became public, the company’s stock price fell 11%, followed by additional drops as the story remained in the news. Before and during this time, the company made various statements expressing its belief in the safety and efficacy of its systems, particularly as compared to the alternative of open surgery.

Investors sued and the court denied the company’s initial motion to dismiss in 2014. After plaintiffs filed an amended complaint to conform to evidence obtained in discovery, the company moved to dismiss again, arguing that the challenged statements were statements of opinion and that plaintiffs had failed to comply with the pleading requirements imposed by the Supreme Court’s intervening Omnicare decision. The court again denied the motion. The court credited plaintiffs’ allegations that the company had misclassified medical device reports and had failed to convey the reports to the FDA as required. This information, the court held, did not “fairly align” with the company’s statements of belief in the safety and efficacy of its products, and the omission of the information thus rendered the challenged statements actionably misleading under Omnicare. The court also held that plaintiffs had adequately alleged scienter by means
of detailed allegations about the executives’ knowledge of medical device reports and the underlying adverse events and alleged product defects. Allegations of insider selling and the company’s entry into tolling agreements with potential personal injury plaintiffs added to the inference of scienter.


Virtually all of Insys’ revenue came from Subsys, an oral fentanyl spray approved to treat breakthrough cancer pain. Because of the addictive dangers of fentanyl, the FDA monitored prescribing oncologists and confined distribution to specialty pharmacies. Other applicable regulations required that coverage decisions be made by pharmacy benefits managers within insurance companies. Meanwhile, federal anti-kickback laws prohibited remuneration to physicians for prescribing drugs. The company spoke favorably of its compliance programs and attributed Subsys’ performance to the “superior product” and the company’s success in marketing to oncologists and working with benefits managers. Between late 2014 and early 2016, however, the national media published articles stating that Insys was bribing non-oncologists to prescribe Subsys off-label, and that its in-house reimbursement unit was falsifying patient records to increase reimbursement. The company’s stock price dropped following a number of these reports, in amounts ranging from 5% to 20%. State and federal investigations were ongoing throughout this period, and they culminated in late 2016, with the indictments of physicians and company executives. The company’s stock price then fell an additional 12%, ending at less than 25% of its 2014 price.

Investors sued, challenging a broad range of statements, including statements about the company’s compliance program, statements about why patients liked the drug, statements about coverage, and statements that Subsys was a superior product promoted through a successful marketing strategy. The court rejected plaintiffs’ challenges to all of these statements, holding that some were too vague to be actionable and that with respect to the others, the purportedly contradictory facts plaintiffs alleged did not show falsity. The court emphasized that securities defendants have no affirmative duty to disclose that they are engaging in purportedly illegal conduct. At the same time, however, the court permitted plaintiffs to move forward with respect to two challenged statements, both attesting to the company’s on-label marketing to oncologists. The court held that plaintiffs had adequately alleged facts showing that the company instructed sales representatives to avoid oncologists and to seek out (and bribe) other doctors to make off-label prescriptions. The court also concluded that plaintiffs had raised a strong inference of scienter with respect to these statements. Plaintiffs had pled facts showing that the management knew of the improper conduct, and in any event, under the “core operations” doctrine, it would have been “absurd” for Insys’ officers to believe that the drug’s high profits were not driven by fraud. Finally, the court held that plaintiffs adequately pled loss causation by means of the apparent link between the unfavorable articles and indictments and subsequent stock price declines; plaintiffs did not do so, however, with respect to a stock price drop following an unfavorable earnings announcement.


Valeant grew in 2013-2015 by acquiring approved drugs from other companies and in some cases raising drug prices thereafter. In September 2015, Congress began investigating Valeant for price gouging, and media outlets reported that the company was turning neglected drugs into expensive specialty products. In October 2015, the company stated on an earnings call that price increases accounted for 60% of its growth in 2014-15. The same month, commentators questioned Valeant’s use of captive pharmacies and suggested that the company was inappropriately concealing its relationship with them. Following additional unfavorable media coverage, the company announced that one of the captive pharmacies, Philidor, would close. The next several months brought management changes, the withdrawal of earnings and revenue guidance and the delay of the company’s 10-K following a finding of revenue misstatements. The company’s stock price fell during this period.
Investors sued the company and its officer and directors, as well as banks that had underwritten securities offerings during the relevant period and the company’s independent auditor. Plaintiffs challenged statements in 2013 related to drug pricing, internal controls and the sustainability of the company’s business model. Plaintiffs also challenged the company’s responses in October 2015 to unfavorable public coverage. All defendants moved to dismiss and the court largely denied the motions. The court held that plaintiffs had sufficiently alleged that the company had concealed its relationships with captive pharmacies, inaccurately reported revenues derived from those pharmacies, and falsely certified that it had effective internal controls over financial reporting. Significantly, the court permitted plaintiffs to move forward with claims against outside directors under Section 10(b), holding that the directors qualified as “makers” of the challenged statements insofar as the company referred to findings made by the audit committee and full board in certain press releases. The court also permitted plaintiffs to proceed with claims against the company’s auditor, holding that plaintiffs had satisfied Omnicare’s requirements in connection with the auditor’s opinion statements. Defendants’ sole victory was related to certain claims under Section 12(a)(2) of the 1933 Act. Those claims arose from private placements under Rule 144A, and the court adopted the majority position that such sales are not public offerings and hence fall outside the scope of Section 12.


Concordia acquired the rights to sell a successful drug called Donnatal and disclosed that it had hired 75 new sales representatives to market it. After third parties expressed interest in buying Concordia, which was heavily in debt, the company set May 31, 2016 as the deadline for final bids. On May 13, 2016, Aetna dropped Donnatal from its prescription drug formulary and the company terminated the 75 members of its Donnatal salesforce. On the same day, the company held an earnings call during which it failed to disclose either of those facts, stating only that coverage for Donnatal had changed over time due to its regulatory status. After the deadline for acquisition bids had passed, other insurers also dropped Donnatal from their formularies. In August 2016, the company issued a press release stating that it had no liquidity or debt issues. A week later, the company reported a significant decline in sales, about half of which was attributed to Donnatal. The company’s stock price fell 38%.

Investors sued, challenging statements and omissions related to Donnatal coverage, to the Donnatal sales force and to the company’s debt and liquidity. The court denied the company’s motion to dismiss with respect to the statements concerning Donnatal coverage, rejecting the company’s argument that insurers’ coverage decisions could be found in other public sources. The court also denied the motion with respect to the Donnatal sales force, finding it particularly significant that the company had voluntarily disclosed that it had hired sales representatives only two months before terminating them. The court concluded that plaintiffs had adequately pled scienter based on executives’ knowledge of the insurers’ actions, the company’s incentive to withhold negative information until it had received bids and the CEO’s pledge of shares to secure personal loans. The court granted the company’s motion, however, with respect to challenged statements about liquidity and debt, ruling that these statements constituted puffery too general to be relied upon by a reasonable investor.


Alere sold diagnostic testing devices including INRatio, a mobile device testing a patient’s blood coagulation rate to assist in prescribing blood thinners. In December 2015, Abbott Laboratories approached the company to discuss a possible acquisition, and in February 2016 Abbott announced its intention to purchase the company for $56 per share. Alere filed a Form 8-K attaching the merger agreement, in which the company warranted its compliance with various disclosure obligations. Alere later announced that it was removing INRatio from the market, that it had insufficient internal controls over its financial reporting, and that it had received subpoenas and other inquiries from the government. The company’s stock price dropped after these announcements. In April 2017, after suing one another, the company and Abbott consummated the acquisition at a reduced purchase price of $51 per share.
Investors sued, alleging that the company failed to disclose (1) the need to recall INRatio products; (2) internal control weaknesses; (3) billing improprieties in two of its divisions; and (4) purported violations of the Foreign Corrupt Practices Act. The court denied the motion to dismiss as to the INRatio recall, but granted it as to all other challenges. With respect to the recall, the court credited plaintiffs’ argument that a loss reserve for INRatio reflected the company’s awareness that the product would be recalled. The court also cited a partial recall in 2014, FDA communications related to the earlier recall, consumer complaints and injuries, and the company’s significant increase in hiring quality assurance personnel to handle INRatio complaints. The court dismissed plaintiffs’ challenge to the remaining statements on scienter grounds, holding that plaintiffs had failed to establish that senior management knew about financial reporting issues, billing improprieties, or alleged FCPA violations.

In re Akorn, Inc., Sec. Litig., 240 F.Supp.3d 802 (N.D. Ill. 2017), motion to dismiss denied. Internal control and financial statement issues

Akorn, a pharmaceutical company that made two acquisitions in 2014, struggled with internal control issues. From 2012 through 2015, three different auditors concluded that the company did not maintain effective internal controls. Akorn reported the auditors’ findings in its 10-Ks, along with management’s plans to remediate the control deficiencies. In March 2015, the company restated its financial statements for Q2 and Q3 2014 and announced that its 2014 10-K would be delayed, all as a result of financial statement issues arising from the integration of the acquired companies. In April 2015, the company announced that it would make additional restatements for 2014 based on significant overstatement of revenue. The company’s stock price dropped 22%. The company’s CFO resigned in August 2015 and the company did not file its 2014 10-K until May 2016, at which time it also restated its previously restated 10-Qs. Under the restated numbers, the company missed analysts’ quarterly and annual guidance for 2014. Under the originally reported numbers, the company had achieved or exceeded guidance. Investors sued, challenging the company’s financial reporting in its 10-Qs, earnings calls and press releases. The court denied the company’s motion to dismiss. The court rejected the company’s argument that its disclosure of material control weaknesses in its 10-Ks sufficiently warned investors that its financial statements should not be relied on, noting that the company’s officers had certified the accuracy of the financial statements notwithstanding the material weaknesses. The court also faulted the company for failing to disclose problems it encountered in integrating the acquired companies. The court found sufficient facts to support a strong inference of scienter, including the CFO’s resignation, the company’s firing of the first two auditors, the magnitude of the reporting errors, and the errors’ near-uniform effect of inflating revenue and income. The court finally concluded that the March 2015 and April 2015 announcements of impending restatements were sufficiently linked to the alleged fraud to constitute corrective disclosures for loss causation purposes.

Rubinstein v. Gonzalez, 241 F.Supp.3d 841 (N.D. Ill. 2017), motion to dismiss denied in part. Communications about proposed merger

In April 2014, AbbVie, a U.S. pharmaceutical company, announced a proposed merger with Shire, an Irish company. In its original announcement, AbbVie did not mention tax benefits that would flow from the merger. It later acknowledged those benefits but stated that its primary motivations for merging were strategic. On September 22, 2014, the Treasury Department issued a notice eliminating certain techniques used by “inverted” companies to avoid paying U.S. taxes; the new Treasury Department policy would apply to AbbVie’s proposed merger. The company nevertheless stated in a September 29, 2014 letter to Shire employees that it was “more confident than ever about the potential of our combined organizations.” Two weeks later, however, after AbbVie’s board of directors had recommended that shareholders vote in favor of the merger, the company decided not to go through with the deal and withdrew the board recommendation. AbbVie’s stock price fell, and the company was required to pay Shire a $1.64 billion breakup fee for withdrawing from the merger.

Investors sued, challenging two of the company’s statements downplaying the tax benefits of the merger as well as the company’s statement to the Shire employees that it had increased confidence in the merger. After granting the company’s motion to dismiss an original
complaint, the court denied in part the company’s motion to dismiss plaintiffs’ amended complaint. The court held, as it had on the previous motion, that plaintiffs failed to plead falsity with respect to all statements save those in the letter to the Shire employees. But while the court had previously held that plaintiffs failed to plead scienter as to the statements in the letter, it now held that plaintiffs had sufficiently pled facts supporting an inference of recklessness as to those statements. The court held that a strong inference arose that in the seven days between the Treasury Department notice and the Shire letter, the company had concluded that a merger was less likely, not more likely in light of the loss of tax benefits.
Decisions
Post-Approval
TABLE OF NEW FILINGS IN 2017

In 2017, 54 securities fraud class actions were filed against life sciences companies, an increase over the 50 actions filed in 2016, the 39 actions filed in 2015, and the 42 actions filed in 2014.1 Of the 54 new actions filed in 2017, 34 were filed against companies with development stage drugs or devices. The remaining 20 actions involve a broad spectrum of regulatory and non-regulatory issues with mature products, ranging from alleged regulatory violations in the areas of marketing and billing, to alleged financial statement fraud, to issues concerning revenue forecasting and performance.

Several trends emerge from the new filings. The number of new cases has increased, but many of the new complaints appear weak, particularly in the pre-approval area. Several plaintiffs’ firms appear to be continuing to cast a very broad net. Seven of the new cases were filed against companies that develop or sell opioids; this activity appears to relate to an increased focus on opioids in government investigations and in the news media.

The new filings are clustered in district courts in the Second, Third, and Ninth Circuits. We show the breakdown graphically on the following page. New filings in 2017 by stage of drug or product development:

<table>
<thead>
<tr>
<th>PRODUCT LIFECYCLE</th>
<th>SECURITIES FRAUD CLASS ACTIONS FILED IN 2017</th>
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<tbody>
<tr>
<td><strong>PRE-APPROVAL</strong></td>
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<tr>
<td>Clinical Trials: Phases 1-3</td>
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<td>Submission of NDA/PMA</td>
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<td><strong>Total Pre-Approval</strong></td>
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<td><strong>POST-APPROVAL</strong></td>
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<tr>
<td>Alleged Regulatory Violations—Marketing and Billing</td>
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<td>Alleged Regulatory Violations—Adverse Event Reporting</td>
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<tr>
<td>Alleged Regulatory Violations—Facility Issues</td>
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<td>Alleged Regulatory Violations—Product Defects</td>
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<td>Antitrust Investigation Issues</td>
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<tr>
<td>Financial Statement Issues</td>
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<tr>
<td>Sales Forecast and Demand Issues</td>
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<tr>
<td>Pricing Issues</td>
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<td><strong>Other</strong></td>
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<td><strong>Total Post-Approval</strong></td>
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1 We take this figure and list of actions from the Stanford Securities Class Action Clearinghouse. This list includes those cases categorized by Cornerstone Research as within the “healthcare sector” but excludes deal litigation and cases involving hospital management issues unrelated to any drug or medical device. Those cases are outside the scope of our analysis.
NEW FILINGS IN 2017
BY CIRCUIT

<table>
<thead>
<tr>
<th>Circuit</th>
<th>New Filings</th>
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</thead>
<tbody>
<tr>
<td>First Circuit</td>
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<tr>
<td>Second Circuit</td>
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<td>Third Circuit</td>
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<td>AVINGER, INC.</td>
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<td>PIXARBIO CORPORATION (F/K/A BMP HOLDINGS, INC.)</td>
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<td>SEATTLE GENETICS, INC.</td>
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<td>NEUROTROPE, INC.</td>
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<td>AKARI THERAPEUTICS, PLC</td>
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</tr>
<tr>
<td>LION BIOTECHNOLOGIES, INC.</td>
<td>04/14/2017</td>
</tr>
</tbody>
</table>
SUMMARY OF ALLEGATIONS

**CLINICAL STAGE** Avinger develops image-guided, catheter-based systems used to treat peripheral artery disease. Plaintiffs allege that the company’s IPO Registration Statement was materially false and misleading insofar as the company failed to disclose substantial reliability issues with both device candidates and approved products.

**CLINICAL STAGE** PixarBio develops drug delivery systems for post-operative pain. Plaintiffs allege that the company failed to disclose that the market for the company’s securities reflected manipulative trading activities. Stock prices fell when the SEC suspended trading in the company’s stock.

**PHASE 1** ImmunoCellular Therapeutics produces therapies using the body’s immune system for the treatment of cancer. Its lead product, ICT-107, is designed to treat brain cancer. Plaintiffs allege that the company misrepresented Phase 1 study data and engaged in undisclosed stock promotion activities.

**PHASE 1/2** Stemline develops cancer drugs. Its leading drug is SL-401, which is used to treat blood-related cancers. During Phase 1 and 2 studies, two patients died of capillary leak syndrome, a side effect of SL-401. After the company revised the safety protocol and made positive statements about this, a third patient died. Plaintiffs allege that the company delayed reporting the third death to investors.

**PHASE 1/2** Seattle Genetics develops a drug for treatment of acute myeloid leukemia, a blood cancer. Plaintiffs allege that the company misleadingly stated that its drug candidate did not have the toxic side effects of earlier treatments. Share prices fell following patient deaths and FDA clinical holds on Phase 1 and Phase 1/2 trials.

**PHASE 2** Neurotrope’s lead product, Bryostatin, is designed to treat Alzheimer’s disease. Plaintiffs allege that Neurotrope made misleading statements about the efficacy of Bryostatin-1 during the course of a Phase 2 trial. The trial ultimately failed to meet its endpoints and the company’s stock price dropped following this the announcement.

**PHASE 2** Akari is the developer of Coversin, a cancer treatment. Plaintiffs allege that the company made misleading statements regarding its Phase 2 results, including falsely stating that a patient who withdrew from the study met the trial’s primary endpoint before withdrawing. A third-party report regarding the Phase 2 results was issued and subsequently withdrawn due to material inaccuracies. Share prices fell following that withdrawal.

**PHASE 2** Lion develops cancer immunotherapy products. Plaintiffs allege improper stock promotion activities. Share prices fell after the disclosure of an SEC subpoena and fell again following the resignation of the company’s CEO.
<table>
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<td>ROCHE HOLDING AG</td>
<td>06/06/2017</td>
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</table>
### SUMMARY OF ALLEGATIONS

**PHASE 2** Scynexis produces drugs for the treatment of invasive fungal infections. Plaintiffs allege the company failed to disclose that SCY-078, the company’s lead drug, had significant undisclosed health and safety risks. The company’s share price dropped after the FDA instructed the company to hold the initiation of any new clinical trials of the IV formulation of the drug.

**PHASE 2** Regulus produces drugs that target microRNAs to treat hepatitis C and other diseases. Plaintiffs claim that the company failed to disclose that patients treated with RG-101, a leading drug candidate, were at increased risk of contracting jaundice. The company’s stock price fell after the FDA placed RG-101 on clinical hold in connection with the occurrence of jaundice in Phase 2 trials.

**PHASE 2/3** Ocular Therapeutix develops dextenza, which treats post-surgical pain and inflammation, allergic conjunctivitis, and inflammatory dry eye disease. Plaintiffs allege that the company misleadingly failed to disclose that more than 50% of the lots of dextenza it had manufactured contain bad product, which could have imperiled FDA approval.

**PHASE 3** Acorda develops therapies for neurological disorders. Plaintiffs allege that the company failed to disclose the safety risks of tozadenant, a drug candidate for the treatment of Parkinson’s disease. The company’s stock price fell after the company announced patient deaths in Phase 3 trials.

**PHASE 3** Novan is the developer of SB204, a topical gel candidate treatment for acne. Plaintiffs allege that the company misleadingly described two Phase 3 trials as identical. The company’s stock price fell following the announcement of discordant results in the two studies, which plaintiffs allege showed that the studies were in fact not identical.

**PHASE 3** Genocea is a developer of a genital herpes immunotherapy product. Plaintiffs allege that Genocea failed to disclose that its finances were insufficient to support Phase 3 trials. Share prices fell when Genocea disclosed it was halting spending and was exploring strategic alternatives.

**PHASE 3** XBiotech is a developer of monoclonal antibodies for treating various diseases. The plaintiffs allege that the company made misleading statements regarding the success of its European Phase 3 trials. Share prices fell when final results of the European Phase 3 results were announced.

**PHASE 3** Roche is the developer of Perjeta, a breast cancer treatment. Plaintiffs allege that the company overstated the effectiveness of Perjeta in combination with another treatment. Stock prices fell after the company announced disappointing Phase 3 results.
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<td>01/06/2017</td>
<td>D. Massachusetts</td>
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</table>
**SUMMARY OF ALLEGATIONS**

**PHASE 3** Intra-Cellular Therapies develops a drug designed to treat schizophrenia and other neuropsychiatric and neurological orders. Plaintiffs allege that the company’s favorable statements about Phase 2 and 3 trials were false or misleading. The company’s stock price fell following a report that the FDA had requested additional safety information.

**PHASE 3** Puma Biotechnologies develops neratinib, a treatment for breast cancer. Plaintiffs allege that the company’s description of its drug candidate and trials generally were false or misleading. The company’s stock price fell following the resignation of the company’s head of regulatory affairs shortly before a scheduled meeting with an FDA advisory committee.

**PHASE 3** Argos developed an immunotherapy for the treatment of metastatic renal cell carcinoma. Plaintiffs allege that the company misrepresented the viability of its immunotherapy. The company’s stock price fell following a DSMB recommendation that the trial be discontinued on efficacy grounds.

**PHASE 3** Alcobra develops MDX, an extended release formulation of a drug used to treat ADHD. A Phase 3 study completed in 2014 did not show that MDX had a statistically significant effect on the treatment of ADHD. Plaintiffs allege that the company made statements discounting the results of this study. When the company revealed that a second Phase 3 study also failed to show the efficacy of MDX, its stock price declined.

**PHASE 3** Anthera develops a kidney disease treatment and a pancreatic enzyme replacement therapy for patients with cystic fibrosis. Plaintiffs allege that the company failed to disclose dosing problems in the kidney disease trial and similarly failed to disclose that patients were not improving. When the company announced that the kidney disease trial had failed, the company’s stock price fell 32%. The stock price fell again after the company announced disappointing results from the trial of the pancreatic enzyme replacement therapy.

**PHASE 3** Kitov develops KIT-302, a drug for the treatment of hypertension. Plaintiffs allege that the Phase 3 trial for the drug did not show a statistically significant effect and further claim that to avoid conducting more trials, the company falsified Phase 3 results to create the appearance of statistical significance. When the alleged fraud was revealed, the company’s stock price fell.

**PHASE 3** Ophthotech is the developer of Fovista, a drug candidate for the treatment of age-related macular degeneration. Plaintiffs allege that the company made misleading statements regarding the efficacy of Fovista. Share prices dropped when the company announced disappointing Phase 3 results.

**PHASE 3** Inotek is the developer of a drug candidate for the treatment of glaucoma. Plaintiffs allege that the company misrepresented the efficacy of the drug. Share prices dropped when Inotek announced that the first Phase 3 trial failed to achieve its primary endpoint.
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SUMMARY OF ALLEGATIONS

PHASE 3  TG Therapeutics is the developer of two therapies —TG-1101 and TGR-1202—for the treatment of chronic lymphocytic leukemia in combination with a drug called Imbruvica. Plaintiffs allege that the company failed to disclose defects in its Phase 3 trial design. Share prices fell when the company announced its amended protocol, which excluded patients who had already taken Imbruvica.

PHASE 3  Agile is the developer of the Twirla contraceptive patch. Plaintiffs allege that the company failed to disclose that Twirla had an efficacy rating below peer group standards, and that over half of the patients in the Phase 3 study discontinued early. Share prices fell when the company announced that the efficacy measure for the patch did not meet the industry standard for approved contraceptives and that over 50% of patients failed to complete the study.

NDA  Array Biopharma is the developer of binimetinib, a cancer drug. Plaintiffs allege that Array failed to disclose that the drug did not show sufficient clinical benefit for use in patients with a particular type of melanoma, and that the company was aware that the data would not be sufficient for approval. Share prices fell when the company withdrew its NDA for use in patients with the type of melanoma at issue.

NDA  Antares is a developer of Xyosted, a testosterone injection therapy. Plaintiffs allege that the Xyosted NDA was not supported by sufficient data and that the company’s statements about the NDA were accordingly false or misleading. Share prices fell when the FDA issued a letter stating it would discontinue review of Xyosted.

NDA  Intellipharmaceutics is the developer of Rexista, an abuse-deterrent oxycodone hydrochloride extended release tablet. Plaintiffs allege that the company failed to include a human abuse liability study in its NDA for Rexista and failed to submit sufficient data to support the application; plaintiffs accordingly challenged the company’s statements about the NDA. The company’s share price fell following the FDA’s rejection of the NDA.

NDA  TherapeuticsMD produces hormone therapy pharmaceutical products. Its lead product is TX-004HR, for the treatment of vaginal pain during intercourse. Plaintiffs allege that the company’s statements about its NDA were generally false or misleading. The company’s stock price fell following the announcement that the FDA had halted review of the NDA in light of unspecified deficiencies.

NDA  Egalet produces Arymo ER, an abuse-deterrent extended-release morphine formulation. Plaintiffs claim that the company made misleading statements regarding Arymo ER’s chances of receiving abuse-deterrent labeling, and that the company knew that a direct competitor already possessed exclusivity that precluded Arymo ER from receiving intranasal abuse-deterrent labeling from the FDA. When the FDA denied the company’s request for abuse-deterrent labeling due to the competitor’s marketing exclusivity, the company’s stock price dropped.
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### New Filings

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<td>INNOCOLL HOLDINGS PLC</td>
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<td><em>NDA</em> Innocoll’s lead product is XaraColl, a drug/device combination made up of a collagen sponge and a local anesthetic inserted into the body during surgery. Plaintiffs allege that the company improperly designed trials to test only the drug component of the product and not the device component, and that the company omitted this fact in favorably characterizing its meetings with the FDA. After the FDA responded to the company’s NDA with a Refuse to File letter, the company’s stock price fell.</td>
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<td>KEMPHARM, INC.</td>
<td>01/12/2017</td>
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<td><em>NDA</em> KemPharm is the developer of Apadaz, an opioid treatment for acute pain. Plaintiffs allege that the company failed to disclose that its study regarding Apadaz’s abuse-deterrent properties was deficient and that the drug would not be labeled abuse-deterrent by the FDA. Stock prices fell when the company announced that Apadaz would be approved for the proposed indication, but that it would not be labeled abuse-deterrent.</td>
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<tr>
<td>ENDOLOGIX, INC.</td>
<td>01/03/2017</td>
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<td><em>PRE-MARKET APPROVAL</em> Endologix manufactures a device called Nellix, used to treat abdominal aortic aneurysms. Plaintiffs challenge the company’s statements regarding anticipated FDA pre-market approval for Nellix, claiming that the company was aware of an undisclosed defect in the device. Share prices fell after the company disclosed that the FDA had required two years of additional patient follow-up data on Nellix, and fell further when the company disclosed that it intended to seek FDA approval on a second-generation Nellix device.</td>
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<td>ALKERMES PLC</td>
<td>11/22/2017</td>
<td>S.D. New York</td>
<td><em>POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS—MARKETING</em> Alkermes is the developer of Vivitrol, a treatment for alcohol and opioid dependence. Plaintiffs allege that the company failed to disclose that it engaged in deceptive marketing campaigns. Share prices fell when Congress opened an investigation into the company’s marketing of Vivitrol.</td>
</tr>
<tr>
<td>DEPOMED, INC.</td>
<td>08/18/2017</td>
<td>N.D. California</td>
<td><em>POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS—MARKETING</em> Depomed produces products for pain and other central nervous system conditions. Plaintiffs allege that the company failed to disclose that it engaged in questionable sales and marketing practices in connection with its opioid products. Share prices fell when the company disclosed that it was being investigated by Congress in connection with its promotion of opioids.</td>
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<tr>
<td>GALENA BIOPHARMA, INC.</td>
<td>02/13/2017</td>
<td>D. New Jersey</td>
<td><em>POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS—MARKETING</em> Galena sells Abstral, an opioid drug for the management of pain in cancer patients. Plaintiffs allege that the company engaged in off-label marketing and incentivized providers to prescribe Abstral to non-cancer patients. The company’s share price fell when the company announced that it was divesting this line of business and fell further on the announcement of a government investigation regarding Abstral.</td>
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<td>INTERCEPT PHARMACEUTICALS, INC.</td>
<td>09/27/2017</td>
<td>S.D. New York</td>
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<tr>
<td>DR. REDDY’S LABORATORIES LTD.</td>
<td>08/25/2017</td>
<td>D. New Jersey</td>
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<td>MERIDIAN BIOSCIENCE, INC.</td>
<td>11/15/2017</td>
<td>S.D. Ohio</td>
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<td>REWALK ROBOTICS LTD.</td>
<td>01/31/2017</td>
<td>D. Massachusetts</td>
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<td>ENDO INTERNATIONAL PLC</td>
<td>11/14/2017</td>
<td>E.D. Pennsylvania</td>
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<tr>
<td>ENDO INTERNATIONAL PLC</td>
<td>08/18/2017</td>
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<tr>
<td>ENDO INTERNATIONAL PLC</td>
<td>03/31/2017</td>
<td>E.D. Pennsylvania</td>
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Intercept is the developer of Ocaliva, a treatment for primary biliary cholangitis, a liver disease. Plaintiffs allege that the company failed to disclose safety risks, including death, associated with the drug. Share prices fell when the company issued a letter warning physicians against overdosing patients with Ocaliva and advising them that the drug had been tied to liver injuries and death. Share prices fell further when the FDA issued a safety announcement regarding Ocaliva.

Dr. Reddy’s is a generic drug manufacturer. Plaintiffs allege that the company made misleading statements regarding its corporate quality system. Share prices fell when the FDA issued a warning letter regarding the company’s manufacturing facilities.

Meridian develops and manufactures diagnostic kits. Plaintiffs allege that when the company acquired Magellan Biosciences, it made misleading statements regarding the accuracy of Magellan’s test systems for lead poisoning diagnosis. Stock prices fell upon disclosures that certain lead tests manufactured by Magellan may provide inaccurate results.

ReWalk develops exoskeletons designed to help individuals with spinal cord injuries to walk. The FDA mandated post-market surveillance of ReWalk devices because the device’s failure to prevent falls could cause serious injury or death to users. Plaintiffs allege that the company misleadingly omitted information about required post-market surveillance from its registration statement. The company’s stock price fell when the FDA issued a warning letter stating that the company had failed to submit a required post-market surveillance study.

Endo, a pharmaceutical product and generic drug producer, acquired Par Pharmaceutical Holdings, Inc. Plaintiffs allege that the company failed to disclose that Par Pharmaceutical had colluded to fix generic drug prices. Share prices fell when media outlets reported on potential criminal charges against Par Pharmaceutical.

Endo produces Opana ER, an opioid for the management of severe pain. Plaintiffs allege that the company made misleading statements regarding the drug’s crush-resistance and its contribution to the opioid public health crises. Share prices fell following reports that the drug was not abuse-resistant and lacked claimed safety advantages.

Endo’s subsidiary, Qualitest, sells generic pain medications and controlled substances. Plaintiffs allege that Endo’s positive statements about demand for branded medications were false or misleading in light of declining demand caused when the federal government “upscheduled” hydrocodone as a Schedule II substance. Share prices dropped when the erosion in the market for pain medications was revealed.
New Filings

SUMMARY OF ALLEGATIONS

POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS—ADVERSE EVENT REPORTING
Intercept is the developer of Ocaliva, a treatment for primary biliary cholangitis, a liver disease. Plaintiffs allege that the company failed to disclose safety risks, including death, associated with the drug. Share prices fell when the company issued a letter warning physicians against overdosing patients with Ocaliva and advising them that the drug had been tied to liver injuries and death. Share prices fell further when the FDA issued a safety announcement regarding Ocaliva.

POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS—FORM 483 AND FACILITY ISSUES
Dr. Reddy’s is a generic drug manufacturer. Plaintiffs allege that the company made misleading statements regarding its corporate quality system. Share prices fell when the FDA issued a warning letter regarding the company’s manufacturing facilities.

POST-APPROVAL; ALLEGED REGULATION VIOLATIONS—PRODUCT DEFECTS
Meridian develops and manufactures diagnostic kits. Plaintiffs allege that when the company acquired Magellan Biosciences, it made misleading statements regarding the accuracy of Magellan’s test systems for lead poisoning diagnosis. Stock prices fell upon disclosures that certain lead tests manufactured by Magellan may provide inaccurate results.

POST-APPROVAL; ALLEGED REGULATION VIOLATIONS—PRODUCT DEFECTS
ReWalk develops exoskeletons designed to help individuals with spinal cord injuries to walk. The FDA mandated post-market surveillance of ReWalk devices because the device’s failure to prevent falls could cause serious injury or death to users. Plaintiffs allege that the company misleadingly omitted information about required post-market surveillance from its registration statement. The company’s stock price fell when the FDA issued a warning letter stating that the company had failed to submit a required post-market surveillance study.

POST-APPROVAL; ANTITRUST INVESTIGATION
Endo, a pharmaceutical product and generic drug producer, acquired Par Pharmaceutical Holdings, Inc. Plaintiffs allege that the company failed to disclose that Par Pharmaceutical had colluded to fix generic drug prices. Share prices fell when media outlets reported on potential criminal charges against Par Pharmaceutical.

POST-APPROVAL; ALLEGED REGULATORY VIOLATIONS—MARKETING
Endo produces Opana ER, an opioid for the management of severe pain. Plaintiffs allege that the company made misleading statements regarding the drug’s crush-resistance and its contribution to the opioid public health crises. Share prices fell following reports that the drug was not abuse-resistant and lacked claimed safety advantages.

POST-APPROVAL; SALES FORECAST AND DEMAND ISSUES
Endo’s subsidiary, Qualitest, sells generic pain medications and controlled substances. Plaintiffs allege that Endo’s positive statements about demand for paid medications were false or misleading in light of declining demand caused when the federal government "upscheduled" hydrocodone as a Schedule II substance. Share prices dropped when the erosion in the market for pain medications was revealed.
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<th>COMPANY</th>
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<tbody>
<tr>
<td>TEVA PHARMACEUTICAL INDUSTRIES LTD: AMERICAN DEPOSITORY SHARES</td>
<td>08/21/2017</td>
<td>E.D. Pennsylvania</td>
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<td>INSYS THERAPEUTICS, INC.</td>
<td>03/17/2017</td>
<td>S.D. New York</td>
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<td>FOUNDATION MEDICINE, INC.</td>
<td>07/28/2017</td>
<td>D. Massachusetts</td>
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<td>INVUITY, INC.</td>
<td>02/27/2017</td>
<td>N.D. California</td>
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<td>MALLINCKRODT PLC</td>
<td>01/23/2017</td>
<td>D. District Columbia</td>
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<tr>
<td>NOVO NORDISK A/S: AMERICAN DEPOSITARY RECEIPTS</td>
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<td>OVASCIENCE, INC.</td>
<td>03/24/2017</td>
<td>D. Massachusetts</td>
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<td>SINOVAC BIOTECH LTD.</td>
<td>07/03/2017</td>
<td>D. New Jersey</td>
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<td>MAZOR ROBOTICS LTD.</td>
<td>06/09/2017</td>
<td>S.D. New York</td>
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Based on facts similar to those in the complaint described above, plaintiffs assert 1933 Act claims based on the company's January 2015 secondary offering.

Plaintiffs allege that Sinovac's CEO had bribed a member of the Chinese Food and Drug Administration in an attempt to facilitate approval of some of its clinical trials and that the company misleadingly failed to disclose this activity.

Plaintiffs allege that Mazor failed to disclose that it had engaged in conduct that subjected it to an Israeli Security Authority investigation. When Mazor disclosed that the ISA had conducted a search of its offices, the price of the company's ADS's fell.
**SUMMARY OF ALLEGATIONS**

**OTHER** Based on facts similar to those in the complaint described above, plaintiffs assert 1933 Act claims based on the company’s January 2015 secondary offering.

**OTHER** Sinovac produces vaccines against hepatitis and influenza for the Chinese market. Plaintiffs allege that Sinovac’s CEO had bribed a member of the Chinese Food and Drug Administration in an attempt to facilitate approval of some of its clinical trials and that the company misleadingly failed to disclose this activity.

**OTHER** Mazor develops surgical guidance systems. Plaintiffs allege that Mazor failed to disclose that it had engaged in conduct that subjected it to an Israeli Security Authority investigation. When Mazor disclosed that the ISA had conducted a search of its offices, the price of the company’s ADS’s fell.
Securities and Shareholder Litigation

Publicly traded companies can face securities and other shareholder suits following disappointing announcements or stock declines. Life sciences companies have industry-specific events and disclosure issues, including those relating to drug development, regulatory approval, and continued regulatory oversight of manufacturing, marketing and sales activities that can trigger litigation or investigations. Our lawyers understand the securities laws and the intersection of industry-specific issues relevant to life sciences companies.

Sidley is a leader in defending securities class action litigation and has successfully represented many life sciences clients in securities and shareholder cases. Sidley’s securities litigation practice team includes true first chair trial lawyers and experienced appellate lawyers in many offices, and some of our partners have the unusual experience of having tried securities class actions. And we are able to work collaboratively, through a coordinated team of professionals in a variety of practices, in order to provide clients with comprehensive representation.

Life Sciences

On four continents, Sidley’s Global Life Sciences team offers coordinated cross-border and national advice on Food, Drug and Medical Device Regulatory, Life Sciences Enforcement, Litigation and Compliance, Healthcare Regulatory, Products Liability, Intellectual Property, Corporate and Technology Transactions, Securities and Corporate Finance, International Trade and Arbitration, FCPA/Anti-Corruption, Antitrust/Competition, Environmental/Nanotechnology. Globally rated as one of the top life sciences practices, our team includes former senior government officials, medical doctors and leaders in various life sciences fields.
For more information on the Securities and Shareholder Litigation practice, please contact:

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