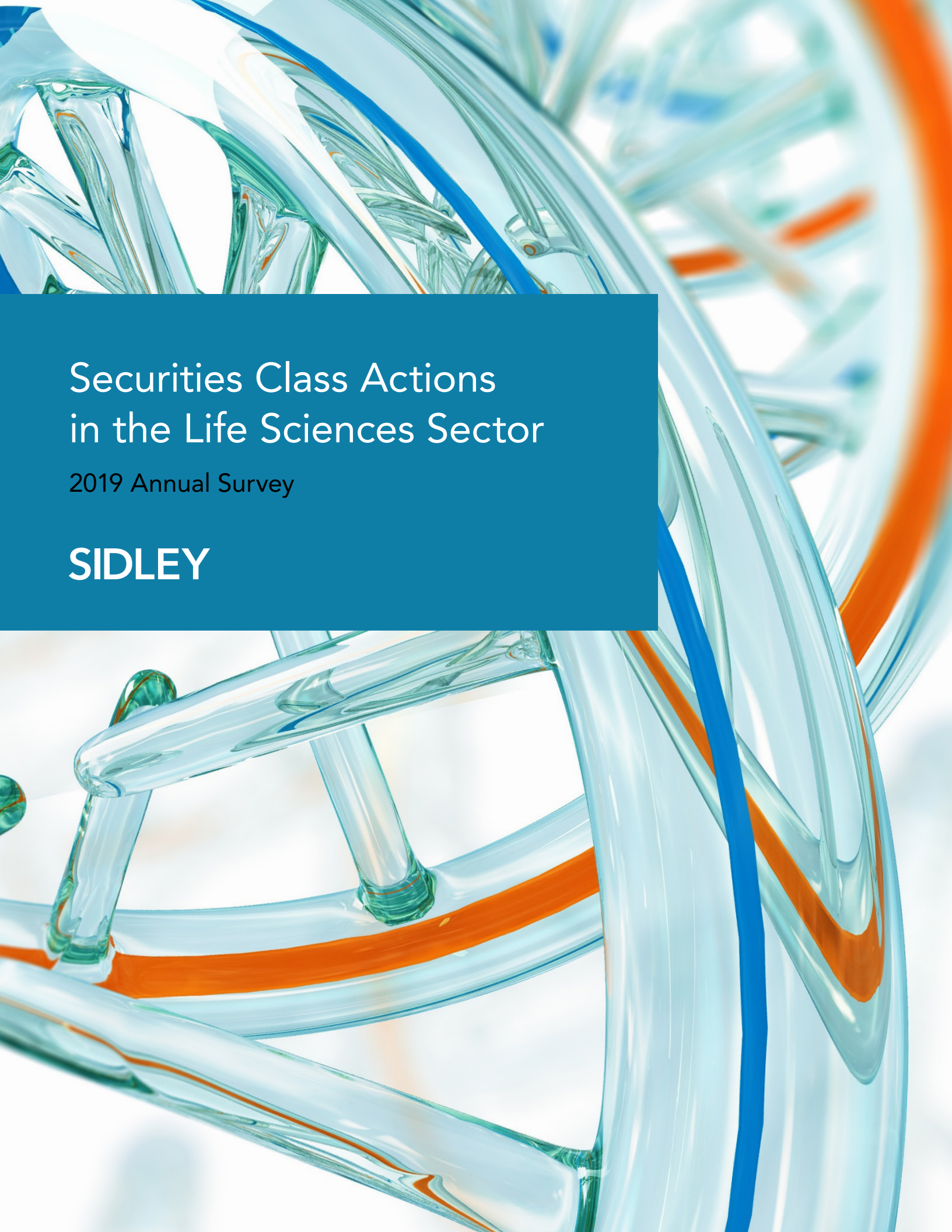

Securities Class Actions in the Life Sciences Sector

2019 Annual Survey

SIDLEY

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Introduction and Overview

Securities Class Actions in the Life Sciences Sector

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INTRODUCTION AND OVERVIEW

This year-in-review survey addresses developments in securities class actions brought against life sciences companies in 2019. 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 41 federal district court and appellate court decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2019.

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, we have structured this survey around 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 AND OTHER REGULATORS IN THE FOLLOWING AREAS:

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, anticompetitive activities or other statutory or regulatory violations.

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.

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

NON-REGULATORY ISSUES

Sales Forecasting
Financial Reporting
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]

1 *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007).

DECISIONS ISSUED IN 2019: TRENDS AND ANALYSIS

In this section (pages 3–4), 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.[2]

In the district courts, companies prevailed more often than not in 2019. Companies' success rate in 2019 was well above the recent low in 2017 but below the recent high in 2016.

2016: Companies won dismissal in 25 of the 33 decisions issued by the district courts, or 76 percent.

2017: Companies won dismissal in 13 of the 26 decisions issued by the district courts, or 50 percent.

2018: Companies won dismissal in 31 of the 48 decisions issued by the district courts, or 65 percent.

2019: Companies won dismissal in 23 of the 38 decisions issued by the district courts, or 61 percent.[3]

As in past years, companies with pre-approval products or devices fared better than those in the post-approval setting. This difference was marked in 2019. Companies prevailed in 77 percent of the pre-approval cases but only 52 percent of the post-approval cases. As we discuss, a disproportionate number of the post-approval defeats in 2019 come from a series of factually related cases stemming from state and federal investigations into price fixing in the generic drug industry.

Companies fared well in the appellate courts in 2019: They won affirmance in each of the three appeals. The appellate victories, however, are of somewhat limited impact. The Second and Ninth Circuits each affirmed dismissal in an unpublished ruling (*Arrowhead* and *Endo*). The First Circuit issued a published decision in *Biogen*, which reflects a solid victory for defendants on scienter grounds and includes favorable treatment of two recurring subjects in the scienter analysis, the core operations inference and the concept of collective scienter. But compared to the appellate activity in 2018—which included pro-plaintiff developments from the Ninth Circuit in *Orexigen* and from the Supreme Court in *Cyan*—2019 has been a quiet year on the appellate front.[4]

As we discuss more fully below, the volume of new filings has leveled off after sharp increases in 2016 and 2017:

2015: 39 new complaints

2016: 50 new complaints

2017: 54 new complaints

2018: 48 new complaints

2019: 44 new complaints

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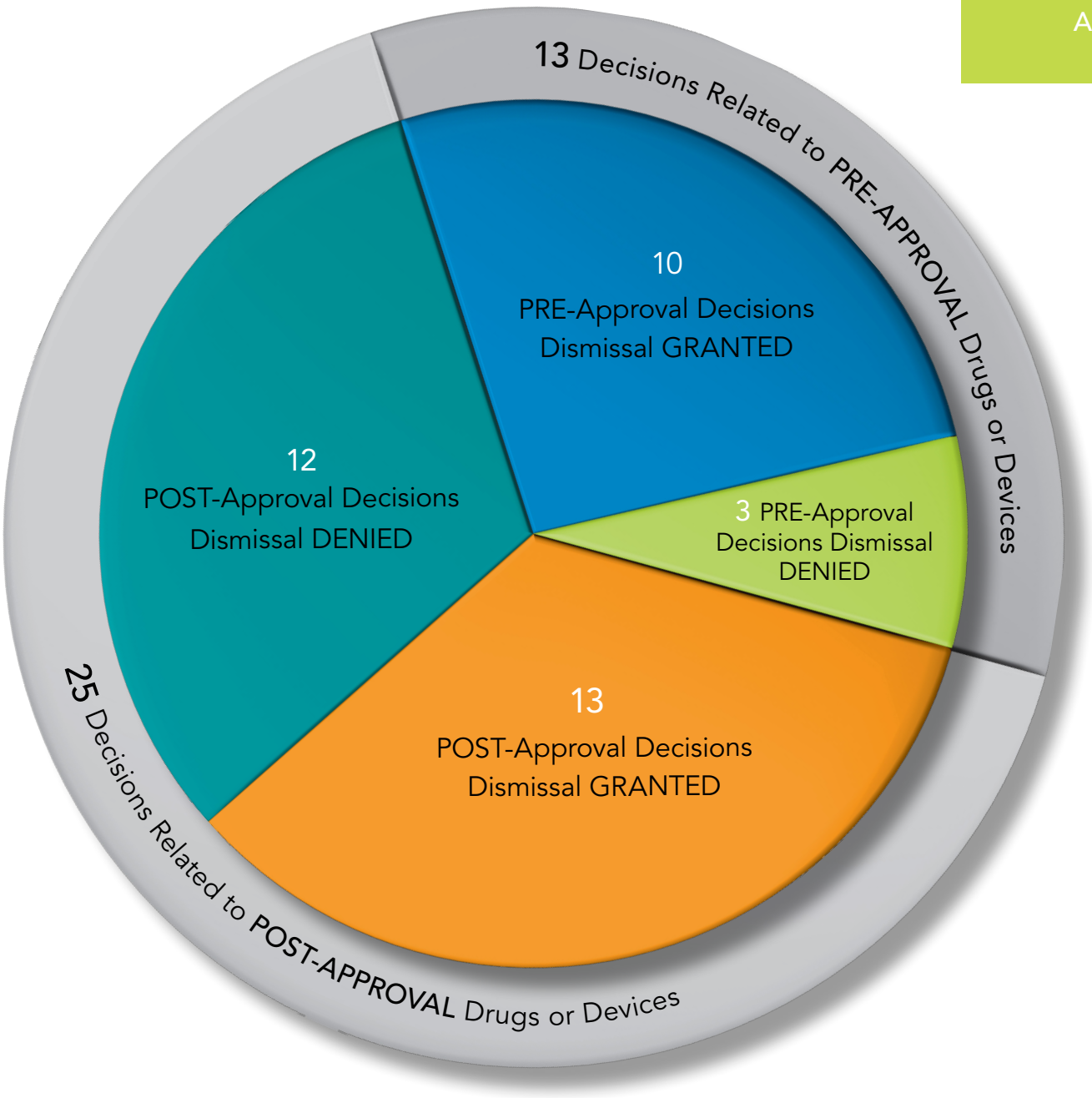
2 Under Section 10(b) (15 U.S.C. § 78j(b)), life sciences companies and their officers may be liable for consciously false or misleading statements they make in virtually any public context, including press releases, earning calls, investor conferences and SEC filings. Defendants may also be liable for participating in a "scheme" to defraud, although successful scheme claims asserted by private plaintiffs are relatively rare. Several cases discussed in this review also include claims under Sections 11 and 12 of the Securities Act of 1933 in addition to Section 10(b) claims (15 U.S.C. §§ 77k, 77l). 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.

3 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.

4 *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988 (9th Cir. 2018), *cert denied*, 139 S. Ct. 2615 (2019); *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061 (2018).



DISTRICT COURT DECISIONS

Before turning to the decisions reflected in these charts, we briefly discuss the impact of the United States Supreme Court's 2018 *Cyan* decision on securities litigation generally. As we discussed in last year's report, the result of *Cyan* is that in cases filed solely under the Securities Act—cases confined to claims arising from alleged misstatements in stock offering documents—plaintiffs are generally permitted to litigate in state court if they so choose. (Federal court remains the exclusive forum for claims under the Exchange Act.) Many plaintiffs' firms believe that state courts provide a more hospitable forum for their claims than federal courts. As expected, state court filings of Securities Act cases ballooned in 2019, with 49 new complaints filed nationwide across all industries.[5]

The number of new Securities Act cases filed in state court against life sciences companies in particular, however, was relatively modest: only five new state court complaints in 2019. In four of those five cases, the stock offering at issue was the company's IPO, and this may explain in part why the number of state court filings against life sciences companies is relatively small. Given the capital-intensive nature of drug development and clinical trial work, many life sciences companies have been public for years by the time they face the kinds of setbacks that draw securities litigation—that is, they are long past the IPO stage that provides such fertile ground for plaintiffs seeking to file in state court. But while life sciences companies appear to face relatively limited exposure to state court securities litigation, another consequence of *Cyan* appears to have affected life sciences companies no less than companies in other industries. And that is that insurers have responded to *Cyan* and the risks of state court litigation by raising the price of D&O coverage. In particular, self-insured retentions are often many times in excess of amounts available in pre-*Cyan* policies, with the consequence that life sciences companies are increasingly funding securities litigation through the motion to dismiss stage and well beyond from their own resources.

PRE-APPROVAL DECISIONS

In 2019, as in the past several years, district court decisions in cases involving development-stage companies or products broke decisively in favor of defendants. Defendants were successful in 77 percent of the district court decisions: The district courts granted defendants' motions to dismiss in 10 cases and denied motions to dismiss in whole or in part in only three.

We discuss developments in three areas below. The 2019 decisions reflect continuing analysis and application of the Supreme Court's 2015 ruling in *Omnicare*, which governs challenges to statements of opinion. The decisions illustrate the broad reach of *Omnicare* to a variety of statements incorporating interpretation or judgment. Defendants were largely successful in 2019 in showing both that particular statements should be treated as opinions and that plaintiffs had not met *Omnicare*'s standards as to those statements.

The 2019 decisions also illustrate the continued significance of the PSLRA pleading standards. Several of the 2019 decisions arose from Phase 3 trials in which patients died or health risks were otherwise sufficiently severe that the company abandoned development of a drug. But defendants won motions to dismiss in all of these cases. The decisions show that the courts require particularized, cogent explanations of falsity and scienter where plaintiffs' claims implicate matters of medicine and science no less than where plaintiffs allege fraud touching on any other area of a company's business.

We finally discuss decisions in which courts have applied the principle that challenges to a company's work in designing clinical trials lie outside the scope of the securities laws. In several cases, plaintiffs sought to account for the difference between a successful Phase 2 trial and an unsuccessful Phase 3 trial by arguing that some aspect of the Phase 2 trial was aberrant, with the result that the Phase 2 results looked better than they were. The courts rejected these claims as impermissible attacks on trial design (among other defects). Several of the 2019 decisions in this area also reflect, with varying results, the courts' recognition that in designing trials, companies may need to strike a balance between the likelihood of approval and the size of the patient population for which a drug may be marketed.

5 We are grateful to Cornerstone Research for providing us with data about state court filings in 2019.

Continuing Developments in the Application of *Omnicare*

We begin this year's trends and analysis discussion with an update on the courts' application of *Omnicare*, the 2015 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 2019 decisions applying *Omnicare* have largely been favorable for defendants.

To briefly recap the *Omnicare* decision itself: The Supreme Court there considered a challenge under Section 11 to legal compliance opinions in the defendant company's registration statement. Under prior Second and Third Circuit case law, plaintiffs could proceed with challenges to opinion statements only if they could plead with particularity that the statements were both subjectively and objectively false. The Supreme Court reshaped this law under Section 11. The Court analyzed challenges to opinion statements 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 plaintiffs can show that defendants omitted facts about the inquiry or knowledge underlying their opinions that are contrary to what a reasonable investor would expect.

The Scope of *Omnicare*. The 2019 decisions illustrate the range of statements that can be brought within the *Omnicare* framework, and make clear that obvious tags like "we believe" or "we think" are not always required. In *Ohr Pharmaceutical* (page 18), the company reported favorable Phase 2 trial results but unfavorable Phase 3 results. Plaintiffs claimed that the company had misleadingly omitted information when reporting the Phase 2 results—specifically, the fact that patients on the control arm of the Phase 2 trial had performed worse than expected, which made the results from the treatment arm look better than they were. The court analyzed the challenged statements under *Omnicare*, assuming without much discussion that any statement interpreting clinical trial results is an opinion statement.

NewLink (page 18) also illustrates *Omnicare*'s broad scope, particularly in matters related to science and medicine. There, plaintiffs challenged assumptions inherent in the company's Phase 3 trial design about patient survival rates on the control arm. In particular, plaintiffs targeted the company's statement that its assumptions were consistent with "all the major studies." The court treated this as an opinion statement, reasoning that the determination of what constitutes a "major" study requires the application of judgment.

Ohr Pharmaceutical and *NewLink* together indicate that *Omnicare* protections may apply broadly to any statement related to medical or scientific matters in which interpretation or judgment is required. A third decision, *Regulus* (page 16) illustrates a more obvious point: A statement such as "we're not worried" will also be treated as an opinion, given that it plainly characterizes the speaker's subjective state.

Differing Formulations of *Omnicare*. The 2019 decisions also show that the courts have been somewhat inconsistent in articulating *Omnicare*'s requirements. The court in *Ohr Pharmaceutical* (page 18) was asked to decide whether pre-*Omnicare* law from the Second Circuit continued to apply in analyzing opinion statements. Under that law, plaintiffs were required to plead both subjective and objective falsity. The court suggested that pre-*Omnicare* law was still relevant to show how the separate elements of subjective and objective falsity should be analyzed, but that under *Omnicare*, plaintiffs may successfully challenge opinion statements under an omission theory even without pleading subjective falsity. This differs from the conclusion reached by some district courts in the Third Circuit. In *Insmed*, which we discussed in our 2018 review, the court held that *Omnicare* governs only claims brought under Section 11 of the Securities Act, and that with respect to Section 10(b) claims, pre-*Omnicare* law remains in effect and requires plaintiffs to plead both subjective and objective falsity.[6] That is plainly a preferable approach for defendants, although it appears to be in the minority nationwide.

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6 *Hoey v. Insmed, Inc.*, 2018 WL 902266 (D.N.J. Feb. 15, 2018).

Other courts have been less careful in articulating *Omnicare*'s requirements. In *NewLink Genetics* (page 18), the court stated that a challenged opinion statement is actionable if "(1) [the speaker] did not sincerely believe it, (2) it was not reasonably supported by data, or (3) [the speaker] omitted information [that] rendered the statement misleading." Although the court concluded that plaintiffs had not satisfied any of these three alternative requirements, this formulation appears to be at odds with *Omnicare* and unfavorable to defendants. "Not reasonably supported by data" appears to be a negligence standard—but under *Omnicare*, an opinion statement is actionable under a false statement analysis only if the speaker did not subjectively believe it—which is a scienter-like standard. Because the *NewLink* court granted the company's motion to dismiss, the arguably erroneous formulation in the decision had no adverse consequences for defendants. In defending opinion statements, however, defense counsel should be wary of getting pulled into a "reasonable basis" analysis that sets a lower than optimal standard. Notably, the Ninth Circuit held in 2017 that after *Omnicare*, the "no reasonable basis" standard should no longer be used under a false statement analysis.[7]

A third decision, *Ocular Therapeutix* (page 20), is also notable for its formulation of *Omnicare*'s omission standard: The court stated there that an opinion statement is actionably misleading in cases where a defendant has "omitted material facts that would lead an investor to doubt [the opinion's] reliability." The focus here is more on investor expectations than on the speaker's state of mind and processes in formulating an opinion.

Applying *Omnicare*. In five of the 2019 pre-approval decisions, courts generally agreed with the *Omnicare* arguments advanced by defendants: The courts agreed both that the challenged statements were opinions and that the plaintiffs had failed to meet *Omnicare*'s requirements. This was the case in *Ohr Pharmaceutical, Ocular Therapeutix, NewLink* and *Regulus,* all discussed above. It was also the case in *Fergus* (page 17).

But the decisions did not all break defendants' way. In *Ophthotech* (page 21), the court agreed with defendants that a statement about "meaningful" revisions to trial design qualified as an opinion. Applying *Omnicare,* however, the court then agreed with plaintiffs that the complaint contained allegations sufficient to show that the challenged opinion was inconsistent with facts known to defendants—and hence that dismissal was inappropriate. In *Celgene* (page 21), the court again agreed with the defendants that the challenged statement—a revenue projection—was an opinion. But the court then concluded that plaintiffs had met *Omnicare*'s requirements. Somewhat unusually, the plaintiffs in *Celgene* succeeded under *Omnicare*'s false statement prong—that is, plaintiffs were able to allege facts sufficient as a pleading matter to show that the defendants did not subjectively believe in the opinions they expressed. The *Celgene* plaintiffs were able to do so through extensive confidential witness allegations. Plaintiffs used confidential witness accounts to allege not only that the individual defendants had been told that the challenged projection was out of reach, but also that management had purportedly altered internal forecasts to conceal difficulties in meeting the projection.

Taken together, the 2019 decisions illustrate *Omnicare*'s broad applicability to statements involving judgment, as well as some confusion in the courts as to how to frame an *Omnicare* analysis. The decisions also show that once a court applies that analysis, defendants are successful on motions to dismiss more often than not—although with sufficiently particularized facts, plaintiffs can meet even the demanding requirement that they demonstrate subjective falsity under a false statement analysis.

Fraud Claims Based on Deaths or Other Adverse Events in Clinical Trials

In several of the 2019 decisions, companies suffered serious clinical and business setbacks when drugs in development became linked with significant safety issues. In both *Arrowhead* (page 16) and *Regulus* (page 16), the FDA issued a clinical hold because of safety concerns; in both cases, the companies ultimately ended their development programs for the drugs at issue. In *Antares* (page 21), the FDA initially accepted the company's NDA but later told the company that it was halting review in light of unspecified deficiencies. The FDA ultimately approved the drug, but with a black box warning label. In *Esperion,* the company initially reported a favorable

7 *City of Dearborn Heights Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605 (9th Cir. 2017).

safety profile for its cholesterol-lowering drug, but, when announcing top-line results from its Phase 3 trials, disclosed deaths on the treatment arm significantly higher than deaths on the control arm.

In all four cases, the companies succeeded on their motions to dismiss. The courts were able to draw a clean line between the tragic events that may occur in the course of clinical trials—possible suicides in *Antares,* multiple primate deaths in *Arrowhead,* serious liver ailments in *Regulus*—and claims of fraud by the drug sponsor. *Esperion,* which involved patient deaths, illustrates a recurring pattern in securities litigation arising from a company's report on Phase 3 trial results. A company may learn of patient deaths or other serious adverse events on an interim basis throughout the trial, but as long as the blind is maintained—and as long the total number of deaths or adverse events is not notably different than expected—the company will not know whether the events occurred on the treatment or the control arm. For that reason, a securities claim based on the premise that the company's positive public statements were inconsistent with known adverse events will fail at the outset in the context of blinded trials.

These cases more broadly illustrate the continuing usefulness of the PSLRA's heightened pleading standards in cases arising from failed or disappointing clinical trials. Plaintiffs may claim that favorable statements about safety are false or misleading in light of patient deaths or other adverse events, but, unless plaintiffs are able to plead detailed facts showing both that the events occurred before the company made the challenged statements and that the events were linked as a factual matter with the drug, plaintiffs will not clear the pleading bar. In *Arrowhead*, plaintiffs claimed that the company's statements were misleading in light of undisclosed monkey deaths, but could not establish when the deaths occurred or when the company's executives learned of them. The claims therefore failed as a chronological matter. Plaintiffs were also unable to plead the details required to show as a pleading matter that the drug was toxic to human subjects: They pled no facts showing in what way or at what dose the toxicity manifested in humans.

The plaintiffs in *Antares* also ran into problems of chronology and specificity. They accused the company of concealing patient suicides but were unable to plead facts showing the precise number or timing of the suicides. And while plaintiffs in both *Arrowhead* and *Antares* tried to connect the dots with confidential witness allegations, those allegations failed in the absence of corroboration.

A lack of specificity as to matters of science and medicine was also fatal to plaintiffs' claims in *Regulus*. After the company discontinued its development program for a hepatitis C drug, plaintiffs claimed that "nonclinical and preclinical data" in the company's possession throughout the class period linked the drug with liver toxicity. But because plaintiffs could not explain what the data showed, the court rejected their allegations as "vague and impressionistic." In the court's words, "[b]ecause Plaintiffs have failed to provide specifics as to how and to what extent these purported preclinical and nonclinical results 'suggested a link between [the drug] and liver toxicity,' the Court is unable to determine whether the complained-of statements differed materially from the actual state of affairs that existed at the time they were made."

The outcomes in these four cases are not terribly surprising. But taken together, the decisions are a good reminder that courts can readily draw the line between a clinical trial failure or setback and fraud, and that plaintiffs must provide the same kind of cogent, particularized explanation of falsity with respect to matters of science and medicine that they are required to provide when alleging fraud as to any other area of a company's business.

Trial Design and Commercial Positioning

In previous years' reviews, we have discussed a line of decisions, anchored by the Second Circuit's 2013 ruling in *Kleinman,* holding that disappointed investors may not use the securities laws as a vehicle to dispute scientific or medical matters inherent in the drug development process.[8] In many of these decisions, the courts have characterized the plaintiffs' claims as

8 *Kleinman v. Elan Corp.*, 706 F.3d 145 (2d Cir. 2013).

attacks on trial design, and have held that such matters are appropriately resolved within the scientific community or by the FDA—not by the courts.

The Southern District of New York's decision in *NewLink Genetics* (page 18) extends this trend into 2019. In Phase 3 trials, NewLink tested its pancreas cancer drug against the standard of care, chemotherapy. Based on earlier studies, the company expected the survival rate on the chemotherapy control arm to be 18–19 months. A scheduled interim evaluation, however, revealed a survival rate of 30 months on the control arm and 27 months on the treatment arm—and the trial was discontinued. Plaintiffs attacked the company's reference to the 18–19 month survival rate, arguing that the previous trials from which that figure was drawn were flawed or irrelevant. The court rejected that theory, holding that "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how [NewLink] chose to interpret the historical data," and that "this argument is a criticism of the trial's methodology, which is insufficient to state a claim for securities fraud."

Success in Phase 2 v. Failure in Phase 3. The plaintiffs in *NewLink* also challenged the company's statements about its successful Phase 2 trial. This is a common pattern in cases where Phase 2 results are favorable but Phase 3 results are not. Plaintiffs often claim in this situation that the company concealed the fact that some aspect of the Phase 2 trial design was improper or could not be repeated in Phase 3. In each of the 2019 cases in which plaintiffs advanced such a theory, the court rejected it. The plaintiffs' theory in *NewLink* was that the favorable Phase 2 results depended on the exclusion of the sickest patients from the trial population. The court dismissed the claim. The company had disclosed its Phase 2 exclusion criteria, which meant that the plaintiffs' only quarrel was with the Phase 2 trial design itself. And such disputes, the court held, are non-justiciable under *Kleinman* and its progeny.

Ohr Pharmaceutical and *Ophthotech* are also examples of this pattern. The companies in both cases were developing treatments for Wet AMD, a degenerative eye disease. Plaintiffs claimed in *Ohr Pharmaceutical* that the company's Phase 2 trial succeeded only because patients on the control arm had underperformed, and that this rendered the company's statements about Phase 2 results misleading. The court rejected that theory, in part on policy grounds:

> On Plaintiffs' account, it is unclear whether the Company should have embarked on the phase III study after the success of the phase II study—should the Company have ignored what Plaintiffs say were aberrant results, or should it have investigated further? As an *ex post* matter, it is clear that the Plaintiffs are unhappy with the results of the [phase III] [t]rial. The shareholders, however, are not the only ones implicated here—those suffering from wet AMD are also undoubtedly disappointed with the results. Does this necessarily mean that pursuing the [phase III] [t]rial was unwise?
>
> This Court will not adopt a rule that discourages free scientific inquiry in the name of shielding investors from risks of failure. Science is risky. Science advances through those willing to take those risks and break with consensus.

This policy rationale is somewhat unusual; the court's focus has moved from the challenged *statements* about the Phase 2 trial to the company's *actions* in proceeding with a Phase 3 trial. But the court's rejection of an *ex post* attack on Phase 2 results following the failure of a Phase 3 trial follows a common pattern. The court in *Ophthotech*—the second case arising from the failure of a Phase 3 trial for a Wet AMD drug—rejected a similar attack. The *Ophthotech* plaintiffs claimed that the company had concealed the fact that patients on the Phase 2 control arm on average had a more severe condition (larger lesions) than the patients on the treatment arm, and that this made the Phase 2 results look better than they actually were. The court rejected that theory, holding both that the company had no duty to disclose the omitted information and that the company ultimately *did* reveal it.

Trial Design and Commercialization. In two of the 2019 decisions, courts examined company decisions about trial design in the context of potential commercialization. The courts recognized in these decisions that in setting eligibility criteria for inclusion in a trial, a company may need to balance the chance of success—generally higher when the patient population is narrow—with commercial potential—which will be greater when the patient population is broadened.

This was the case in *Bristol-Myers Squibb* (page 15). Bristol-Myers Squibb (BMS) oncology drug nivolumab had already been approved for certain indications and had proven to be most effective for patients who were "expressers" of a protein called PD-L1. In designing a trial testing nivolumab's efficacy for lung cancer patients, the company needed to decide what level of PD-L1 expression would make a patient eligible for inclusion in the trial. The court explained the phenomenon succinctly: "In [designing the trial] the company faces a trade-off: The higher the cut-off, the more likely that the study will yield positive results. But the lower the cut-off, the more patients are opened up for potential treatment." BMS chose a low cutoff: Patients were eligible as long as 5 percent or more of their tumor cells expressed PD-L1. In public statements, BMS did not quantify the cutoff, saying only that the patient population was limited to "strong" expressers of PD-L1. After the trial failed to show efficacy, BMS for the first time disclosed its 5 percent cutoff. Plaintiffs challenged the company's reference to "strong" expression, pointing out that BMS competitor Merck used the term "strong" to refer to *50* percent expression of PD-L1. Plaintiffs also alleged that, in post-trial statements, BMS executives admitted that a 5 percent cutoff was not "high." The court dismissed the claim on scienter grounds. The court was skeptical of plaintiffs' claim that Merck's 50 percent cutoff established fixed industry usage, and held that plaintiffs had not shown that BMS was aware of any such usage. Implicit in the court's analysis was the recognition that any disagreement plaintiffs may have had with the company's decision to draw the eligibility line at 5 percent was well beyond the scope of the securities laws.

Issues of patient inclusion and exclusion played out quite differently in *Ophthotech* (page 21). As noted, the company in *Ophthotech* reported a successful Phase 2 trial but failed to establish efficacy in Phase 3. While the court rejected plaintiffs' attack on the company's statements about its success in Phase 2, the court sided with plaintiffs on their challenge to the company's statements about the relationship between the Phase 2 and Phase 3 trial design. Between Phase 2 and Phase 3, Ophthotech altered its exclusion criteria, which related to the nature of patients' lesions. The change in criteria followed a change in available imaging technology and a new categorization system for lesions. Ophthotech publicly disclosed these changes, but at the same time characterized them as not "meaningful." The court held that plaintiffs had adequately pled fraud as to that statement. The court did so notwithstanding the company's argument that it would have had little incentive to make a knowingly meaningful change to the Phase 2 criteria, as this would have jeopardized its chances of repeating the favorable Phase 2 results. In rejecting that argument, the court made an observation about the interplay in trial design between approval and commercial potential that is almost identical to the *BMS* court's starting premise:

> Plaintiff puts forth a credible theory that Defendants determined that the allegedly increased risk of failure resulting from the change in enrollment criteria was outweighed by certain benefits that would accompany broadening the pool of patients eligible to participate in the Phase 3 trial. Specifically, Plaintiff points out that by changing the Phase 3 enrollment criteria to include patients with pure occult lesions, if the trial were successful, "[Defendants] would be more likely to secure broad approval of [the drug] for all wet AMD patients, including the 40% of patients [excluded from the Phase 2 trial]."

On one level, the difference between *BMS* and *Ophthotech* is striking. In *BMS*, the court recognized that companies need to balance likelihood of success with commercial potential in designing trials; the court then rejected the plaintiffs' attack on a subjective term the company used to characterize its exclusion criteria—"strong." In *Ophthotech*, the court appeared to recognize the same need to balance—but then viewed the incentive to design a trial with broad commercial application as a factor weighing against the company on scienter. And the court permitted plaintiffs to go forward on the basis of another subjective term related to exclusion criteria—"meaningful."

Despite this difference, however, both decisions are consistent with *Kleinman* and its progeny. In neither case did the court permit plaintiffs to proceed with a challenge to data interpretation or trial design. The pertinent question in both *BMS* and *Ophthotech* was not whether the company had committed fraud in designing its trial but instead whether plaintiffs had pled facts showing that the company's *description* of its trial design was knowingly false or misleading.

POST-APPROVAL DECISIONS

In the post-approval cases, district court decisions were nearly equally divided, with 13 victories for defendants on motions to dismiss and 12 victories for plaintiffs. When the decisions in cases arising from an alleged price-fixing conspiracy in the generic drug industry are treated separately, however, the numbers look quite different. Defendants prevailed on motions to dismiss in only one of the six antitrust-related decisions. Defendants prevailed in 12 of the 19 decisions outside the antitrust context.

DISTRICT COURT DECISIONS	MOTION TO DISMISS GRANTED	MOTION TO DISMISS DENIED
Antitrust-Related Cases	1	5
All Other Post-Approval Cases	12	7

We discuss the antitrust-related decisions first. We then consider a number of decisions outside the antitrust area in which courts have taken an approach to the interplay between securities litigation and underlying regulatory or litigation developments quite different from that reflected in the antitrust cases.

Alleged Price Fixing in the Generic Drug Industry

2019 saw further developments in an area on which we began reporting in our 2018 review—claims based on alleged price fixing in the generic drug industry. In late 2016, media outlets began reporting on state and federal investigations into alleged price fixing by generic drug manufacturers. A November 3, 2016 *Bloomberg* article predicted that criminal charges would be filed by year-end and named several companies being investigated. Stock prices fell at several of those companies. In December 2016, multiple state attorneys general filed a complaint alleging a broad conspiracy to fix prices for generic drugs, and the state attorneys general filed amended complaints in June 2018 and May 2019, naming additional manufacturers and drugs.

Securities plaintiffs filed (and subsequently amended) complaints based on the allegations in the state attorney general complaints, some supplemented with allegations based on statements plaintiffs' counsel had purportedly obtained from confidential witnesses. In 2018, five of these cases led to written decisions. Defendants prevailed in two of the 2018 cases—*Impax* and *Lannett*—and plaintiffs prevailed in three—*Mylan, Taro* and *Perrigo*. In 2019, the district courts issued six new decisions in securities cases premised on alleged generic drug price fixing. Three of these were subsequent decisions on amended complaints (*Impax, Lannett* and *Mylan*, pages 32, 36 and 38); three were decisions in new cases (*Teva, Allergan* and *McKesson*, pages 37 and 39).

In 2019, plaintiffs prevailed in whole or in part on motions to dismiss in five of the six cases; *Impax* was the single decision in which the court granted defendants' motion to dismiss in its entirety. Like the 2018 decisions, the 2019 decisions in this area can be harmonized on some issues but diverge on others.

What Categories of Statements are Actionable Where a Company Does Not Disclose That it Engaged in Alleged Price Fixing? In our 2018 review, we noted that courts drew a line between attacks on financial statements and attacks on company commentary on financial results. In the 2018 cases, plaintiffs challenged both financial statements and narrative commentary under an omission theory, claiming that both sets of statements are misleading where a company fails to disclose that its financial success is (allegedly) based on improper practices. The courts in 2018 rejected challenges to financial statements but permitted plaintiffs to move forward with challenges to commentary on financial results in MD&A or elsewhere.

Courts in 2019 have continued to allow plaintiffs to proceed with challenges to company commentary on financial performance and have continued to accept the premise that such statements may be misleading in light of a company's failure to disclose purported price-fixing activities. In *Teva,* the court held that statements attributing the company's financial results to factors other than allegedly collusive price increases were actionable. The *Teva* court explained

that these statements were "half-truths" and were actionable because, once the company began discussing the reasons for its financial success, it assumed a duty to disclose the "whole truth." In *Allergan,* the court went a step further. The court there appeared to suggest that, simply by reporting its financial results, the company may have assumed a duty to disclose that purported price fixing stood behind its success.

The approach in *Teva* and *Allergan,* which draws on the 2018 decisions in *Mylan* and *Taro,* continues to be difficult to square with principles articulated in previous case law. In past years, courts have carefully monitored the line between alleged regulatory violations and false or misleading statements under the securities laws, holding that companies are not required to accuse themselves of uncharged or unproven conduct. The approach in *Teva* and *Allergan* risks blurring that line, as it is difficult to conceive of a situation in which a company will not make some sort of substantive comment on its financial results—but obviously will stop short of attributing those results to allegedly illegal activities that have yet to be charged or proven. Likewise, the *Teva* court's reference to the "whole truth" at least arguably runs counter to a series of significant appellate decisions explicitly rejecting the concept of a "duty of completeness."[9]

Curiously, the *Teva* court also noted that the company in that case was *not* required to accuse itself of unproven wrongdoing with respect to a separate category of challenged statements: those related to the government investigation itself. In *Teva,* plaintiffs claimed that the company should have disclosed government subpoenas sooner than it did. The court rejected that claim, holding that the duty of disclosure is not a "rite of confession" and that the "federal securities laws do not require a company to accuse itself of wrongdoing." In addition, the court noted, "securities laws do not impose an obligation on a company to predict the outcome of investigations."

Of course, the rule remains that if a company does disclose a subpoena, any misleading description of it is actionable. In *Allergan,* the company disclosed a Department of Justice investigation into price fixing but also stated publicly that the investigation "really is a red herring" and "not that significant." The court denied the company's motion to dismiss as to those statements.

What is Required to Plead Loss Causation in a Securities Claim Based an Alleged Price Fixing?
As in 2018, decisions in this area continue to diverge on the issue of loss causation. The same allegedly corrective announcement—a November 3, 2016 *Bloomberg* article naming various companies involved in a government price-fixing investigation and stating that criminal charges could be expected by year-end—supported plaintiffs' allegations of loss causation in two cases but failed to support such allegations in a third.

The announcement was sufficient to establish loss causation for pleading purposes in *Lannett.* The *Lannett* court rejected defendants' argument that the stock drop following this disclosure (and others related to the revelation of investigation-related developments) reflected mere market speculation about whether fraud has occurred. The court noted that plaintiffs had pled more than the announcement of an investigation: They had also pointed to criminal charges against another company and to public reports about allegedly suspicious pricing patterns in the generic drug industry. The *Lannett* court also held more generally that the announcement of state and federal investigations could constitute a corrective disclosure. Likewise, in *Teva,* the court held that the November 3 article supported allegations of loss causation, citing to the 2018 *Taro* decision.

In marked contrast, the Northern District of California held in its 2019 *Impax* decision, just as it had held in its 2018 *Impax* decision, that the November 3 article was insufficient, and dismissed the complaint with prejudice on loss causation grounds. The *Impax* court again cited and followed Ninth Circuit law holding that the announcement of an investigation is not itself sufficient to constitute a corrective disclosure for pleading purposes.

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9 *E.g.*, *Brody v. Transitional Hosps. Corp.,* 280 F.3d 997, 1006 (9th Cir. 2002) ("Rule 10b-5…prohibits *only* misleading and untrue statements, not statements that are incomplete") (emphasis in original); *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.,* 759 F.3d 1051, 1061 (9th Cir. 2014) ("We have expressly declined to require a rule of completeness"); *In re Rigel Pharm., Inc. Sec. Litig.,* 697 F.3d 869, 880 n.8 (9th Cir. 2012); *Indiana Elec. Workers' Pension Tr. Fund IBEW v. Shaw Gr.,* 537 F.3d 527, 541 (5th Cir. 2008) (allegedly "incomplete" statements are actionable only if misleading) (citing Brody); *Winer Family Trust v. Queen,* 503 F.3d 319, 330 (3d Cir. 2007) (same). We collected and discussed the line of cases rejecting the "duty of completeness" and related disclosure concepts in our 2015 and 2016 annual reports.

Beyond the Motions to Dismiss. After the six 2019 decisions in this area, half a dozen or more of the generic price-fixing cases are now in discovery. One complicating factor as these cases move forward may be that the alleged misconduct underlying the securities claims is itself the subject of sprawling multidistrict antitrust litigation in the Eastern District of Pennsylvania. At some point, the courts presiding over the securities actions may need to confront the fact that what would appear to be a constitutive element of the securities claims is being litigated elsewhere. Whether the courts in the securities actions will permit the Section 10(b) cases to become the vehicles for adjudicating antitrust allegations directly at issue in other litigation remains to be seen—and may also highlight the downside from a judicial perspective of permitting securities plaintiffs to pursue claims based on underlying misconduct that has yet to be proven.

Securities Litigation in the Context of Regulatory or Other Litigation Activity

Securities litigation is generally a second-order problem. It follows from a regulatory or business setback that has driven a company's stock price down. In the antitrust cases, a complicating factor is that the first-order problem—the antitrust litigation—continues to develop as the securities litigation moves forward. Other decisions reflect differing judicial approaches to the interplay of securities litigation with underlying regulatory or litigation activity.

***Myriad:* Deference to Regulators.** In many of the antitrust cases, one of the events triggering a stock price decline was the announcement of a government investigation. This was also the case in *Myriad* (page 27). The company in that case sold genetic testing products for which it billed the Centers for Medicare and Medicaid Services (CMS). After the company announced that it had received a subpoena from the Department of Health and Human Services related to an investigation into improper billing practices, the company's stock price declined and investors sued. The plaintiffs' claim was that Myriad had improperly overridden rules intended to prohibit billing for two very closely tests. The court observed that the premise of all of the plaintiffs' claims was "that Myriad's billing practices were indeed illegal." After briefly reviewing the merits of that contention, the court essentially deferred to the regulators:

> Plaintiffs have pointed to no instance in which CMS denounced or criticized Myriad's billing practices generally. Likewise, Plaintiffs have failed to point to any agency action or statement establishing that Myriad's [particular] billing practices were improper. Without any such statements, Plaintiffs' suit is premature. Moreover, given the complexity of the Medicare billing framework, CMS is far better situated to evaluate Myriad's billing practices than is the court.

This approach—in which a court declines to make securities litigation the vehicle for adjudicating unresolved regulatory matters—is in marked contrast to the approach taken in many of the antitrust cases.

District courts within the Ninth Circuit have at times reached a result similar to that in *Myriad* through the different path of loss causation. As noted, the Northern District of California is the only court that granted a motion to dismiss in the antitrust cases in 2019, and the court did so on loss causation grounds. In *Impax,* the district court followed Ninth Circuit law holding that the announcement of a government investigation is not in itself sufficient to establish loss causation. The Northern District of California dismissed another case, *Huang v. Higgins* (page 27) on the same basis. The company there announced that state and federal authorities were investigating the company in connection with off-label marketing of opioids, and the court held that the announcement was insufficient to establish loss causation. The logic of these loss causation decisions is essentially that securities litigation is premature when an investigation has been announced but not concluded: At that point, the legality of the practice being investigated is an open question, which means that it is not possible to attribute a stock price decline to fraud rather than to market uncertainty. The *Myriad* court arrived at the same place through a falsity analysis: Without resolution of the underlying matter, it is not possible to determine whether the challenged statement is false or misleading.

***Avanos*: Distinguishing Securities Litigation From Consumer Litigation.** *Avanos* (page 1) also touches on the relationship between securities litigation and the resolution of claims based on alleged underlying misconduct in a different forum. In that case, manufacturers of surgical gowns were defendants not only in securities litigation but also in a consumer fraud action brought in federal court in California by purchasers of the gowns. The Southern District of New York dismissed the securities action in a 2018 decision. The plaintiffs then sought to amend by adding references in their complaint to witness testimony, judicial findings and a jury verdict from the consumer case. Plaintiffs claimed that witness testimony from the consumer case showed that company executives who were defendants in the securities action had been given documents informing them of issues with the gowns. The court rejected those allegations, holding that the proffered testimony did not show the specific content of the purported documents, did not show that the executives had read the documents, and did not show what the executives' reaction to the documents had been. The court also rejected the notion that the California court's finding that the companies had "engaged in a fraudulent business practice" established scienter.

The *Avanos* court's careful parsing of the different elements of a consumer fraud and a securities fraud claim is consistent with previous decisions in which courts have recognized that adverse regulatory or litigation developments do not automatically map onto Section 10(b) claims. Perhaps what is most notable about *Avanos* is that the court insisted on maintaining a line between adverse developments and securities claims even where the underlying litigation was also premised on alleged fraud.

Aceto (page 30), which was also a defense victory, is in one sense the flip side of *Avanos*: The company there *prevailed* in parallel litigation. Aceto was a party to numerous contracts under which it supplied pharmaceutical products to the federal government. The government terminated the contracts based on the company's purported failure to comply with contractual country-of-origin provisions. The securities plaintiffs faulted the company for not signaling earlier that this would occur by recording a charge against goodwill. The court dismissed that claim, noting that the company had disclosed the risk that it would lose the contracts, and was not required to go beyond that and assume the worst. The court also noted that the Court of Federal Claims ultimately *rejected* the government's position, which entirely undermined the securities plaintiffs' claims. That outcome appears to support the wisdom of the observation in *Myriad* and elsewhere that securities litigation may simply be premature while underlying regulatory activity or litigation is still ongoing. And this once again stands in marked contrast to the antitrust cases, in which securities litigation and antitrust litigation are proceeding in parallel.

DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 15–23), 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 well in the district courts, winning dismissal in 77 percent of the district court decisions. The district courts issued largely positive decisions where plaintiffs challenged opinion statements, which reflects both the broad reach of the Supreme Court's 2015 Omnicare decision and the generally favorable nature of the Omnicare framework.

The 2019 pre-approval decisions also reflect the continuing utility of the PSLRA pleading standards, and show that the courts require particularized, cogent explanations of falsity and scienter where plaintiffs' claims implicate matters of medicine and science no less than where plaintiffs allege fraud touching on any other area of a company's business. Finally, the 2019 decisions show that courts continue to reject challenges that defendants are able to characterize as attacks on clinical trial design.

APPELLATE DECISIONS

In re Arrowhead Pharms., Inc. Sec. Litig., 782 F. App'x 572 (9th Cir. 2019), affirming dismissal. **Phase 2(b)**

Arrowhead developed a drug called ARC-520, for the treatment of hepatitis B. After conducing animal studies and a human Phase 2(a) trial, the company sought FDA approval to proceed with Phase 2(b) studies. The FDA responded by requesting additional data from the animal and human studies and placing a partial clinical hold on ongoing trials. Arrowhead disclosed the hold, which was lifted after the company submitted the information the FDA had requested. The following year, the FDA placed another hold on trials after the company reported that monkeys in the animal trials had died. After the company disclosed this second hold, its stock fell 31 percent. Three weeks later, the company announced that it was discontinuing its ARC trials and the stock fell 67 percent.

Investors sued, alleging that the company had failed to disclose the toxicity risks to humans, FDA concerns about human safety and the monkey deaths. The district court granted the company's motion to dismiss in 2017. Plaintiffs failed to plead facts showing in what way and at what dose the drug was toxic to humans; the account of a single former employee who targeted the drug's delivery mechanism as the source of toxicity was insufficient. Plaintiffs also failed to tie the first clinical hold to FDA concerns about toxicity, and failed to show that the company's generalized statements of optimism about the drug were actionable. As to the monkey deaths, plaintiffs failed to plead facts supporting an inference that the deaths had already occurred at the time of the challenged statements. Plaintiffs also failed to plead scienter: Their allegations of motive were insufficient, and issues related to the timing of the monkey deaths again undercut plaintiffs' claim that defendants knew their statements were false.

The Ninth Circuit affirmed in a short unpublished decision. Like the district court, the Ninth Circuit held that (1) plaintiffs' single witness did not establish with sufficient particularity that the drug posed toxicity risks to humans; (2) plaintiffs failed to tie the first clinical hold to FDA concerns about safety risks; and (3) plaintiffs failed to establish when the monkey deaths occurred and who at the company knew about them. The Ninth Circuit also held that plaintiffs' motive allegations—that the company sought a collaboration deal and was planning a secondary offering—were insufficient to establish scienter, as they turned on routine corporate objectives. Plaintiffs' scienter allegations failed more generally because plaintiffs had not shown that any individual speaker knew about the alleged toxicity issues or FDA safety concerns.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

In re Regulus Therapeutics, Inc. Sec. Litig., 406 F. Supp. 3d 845 (S.D. Cal. 2019), granting motion to dismiss without prejudice. **Phase 1**

Regulus developed RG-101, a drug to treat the hepatitis C virus. Regulus reported a small number of serious adverse events during its Phase 1 trials but noted that the affected patients had comorbidities that could explain the events, and that the company was "not worried" about the drug's safety profile. After the company reported that an additional patient had suffered from jaundice, the FDA issued a clinical hold. When the company disclosed in July 2016 the steps it would need to take to have the hold removed, its stock fell 13 percent. The stock fell an additional 42 percent in January 2017, when the company reported that it would not be able to complete those steps until the end of the year. In March 2017, the company reported four additional serious adverse events involving elevated bilirubin levels; the company also disclosed that its CEO was resigning. The stock fell 30 percent. Finally, in June

2017, the company announced that its drug was likely the cause of patients' elevated bilirubin levels and that it was discontinuing the RG-101 development program. The stock fell 21 percent.

Investors sued, claiming that the company had nonclinical and preclinical data linking the drug with liver toxicity, and that the company's statements about the drug's positive safety profile were false as a result. The court dismissed plaintiffs' claims on falsity and scienter grounds. Plaintiffs' allegations about data showing liver toxicity were "vague and impressionistic" and therefore did not support an inference of falsity. This was "particularly true" with respect to the company's opinion statements: The court cited *Omnicare* for the proposition that securities defendants are not obligated to disclose every fact cutting the other way when they state their opinions. Plaintiffs' additional scienter allegations were also insufficient. Plaintiffs' motive allegations—references to debt financing and executive compensation—were generic. And while the CEO's departure was more unusual, plaintiffs had pled no facts linking that resignation to fraud.

Fergus v. Immunomedics, Inc., 2019 WL 1435917 (D.N.J. Mar. 31, 2019), granting motion to dismiss without prejudice. **Phase 2/ASCO presentation and embargo**

Immunomedics, a developer of immuno-oncology drugs, announced that the American Society of Clinical Oncology (ASCO) had accepted two of its abstracts and one poster for presentation at the June 2016 conference. (ASCO holds meetings in June of every year, and these are major industry events.) On June 3, 2016, the company reported that ASCO had canceled the presentation of one of the two abstracts, dealing with a Phase 2 breast cancer trial. ASCO presenters are prohibited from publicizing results prior to the meeting, and ASCO had determined that the company had violated this "embargo" by discussing results at a presentation in April 2016. The company also told investors that it disagreed with ASCO's decision and would seek to reverse it: In the company's view, the information presented in April 2016 pertained to a different patient population and different trial results than those at issue in the canceled abstract. ASCO did not reverse its decision. Later in June, the company announced the resignation of its CFO. The company's stock price fell 62 percent during the weeks in which these events unfolded.

Investors sued, challenging the company's announcement that ASCO had accepted its abstracts and poster. Plaintiffs alleged that the company knew at the time it made the challenged statements that it was risking cancellation by publishing results in April 2016 in violation of the ASCO embargo. The court rejected the argument and dismissed the complaint on both falsity and scienter grounds. Plaintiffs had failed to plead facts showing that the company knew that ASCO would cancel the presentation of the abstract. Indeed, plaintiffs failed to show that the information the company presented in April—allegedly in violation of the embargo—was actually the same as the information in the canceled abstract. Even if the information had been the same, moreover, the company's statements were neither false nor misleading by way of omission. The company actually *disclosed* the April presentation and its contents. The fact that the April presentation was made openly also weighed against an inference of scienter. And while two executives sold stock, they did so only after the company had announced ASCO's decision to cancel presentation of the abstract.

Tung v. Bristol-Myers Squibb Co., 412 F. Supp. 3d 453 (S.D.N.Y. 2019), granting motion to dismiss without prejudice. **Phase 3**

BMS conducted a Phase 3 trial of its approved immuno-oncology drug, Opdivo, testing whether the drug would outperform chemotherapy as a treatment for non-small cell lung carcinoma. The drug was believed to be most effective for patients who were "expressers" of PD-L1, a protein that enables the immune system to fight cancer. In designing the trial, the company needed to set a cutoff for PD-L1 expression. The company set the cutoff at 5 percent—that is, if 5 percent of a patient's tumor cells expressed PD-L1, that patient would be included in the trial. The company did not disclose the 5 percent figure to the market, stating only that the trial was limited to patients who "strongly" expressed PD-L1. The trial failed to meet its primary endpoint, and, when the company reported both that failure and the 5 percent cutoff figure, its stock fell 16 percent. Two months later, the company explained that, because of the way trial data had been collected, it could not use the existing data to determine results for any patient population that expressed PD-L1 at a rate *greater* than 5 percent. The company's stock fell an additional 10 percent.

Investors sued, claiming that the company misled the market by using the term "strongly" to characterize the degree of PD-L1 expression of patients who made the cutoff. The court dismissed the complaint on scienter grounds. Plaintiffs cited no authority suggesting that the company knew that the term "strong" as applied to PD-L1 expression was inconsistent with a 5 percent cutoff. And while the company's competitor, Merck, had used a 50 percent cutoff in the trial of a comparable drug, that did not establish that "strong" can refer only to a 50 percent cutoff in industry usage.

Lehmann v. Ohr Pharm., Inc., 2019 WL 4572765 (S.D.N.Y. Sept. 20, 2019), granting motion to dismiss with prejudice. **Phase 3**

Ohr developed eye drops to treat wet age-related macular degeneration, a degenerative eye disease. The company reported successful interim results in Phase 2 trials. In the Phase 3 trials, however, patients on the control arm outperformed patients on the treatment arm. When Ohr reported these results, its stock price fell 81 percent.

Investors sued, claiming that the only reason the Phase 2 results had appeared successful was that patients on the control arm had performed worse than anticipated, and that the company had misled investors by omitting that fact. The court granted the company's motion to dismiss. The court analyzed the company's statements reporting trial results as projections and as statements of opinion, and held that the Supreme Court's decision in *Omnicare* and related Second Circuit law do not require Section 10(b) defendants to disclose all purported facts that might undermine their projections or opinions. The court held that plaintiffs had failed to establish scienter for similar reasons, and because no allegations suggested that the company had a motive to defraud investors. Finally, the court included an unusual, high-level discussion of the role of risk in scientific inquiry and the undesirability of a judicial system that would chill "scientific advancement and human progress."

Bailey v. Esperion Therapeutics, Inc., 2019 WL 3296235 (E.D. Mich. Feb. 19, 2019), granting motion to dismiss with prejudice. **Phase 3**

Esperion developed bempedoic acid, a drug designed to lower LDL-cholesterol. The company made favorable statements about the drug's safety during Phase 3 trials but ultimately reported that deaths on the treatment arm were significantly higher than deaths on the control arm. Esperion's stock fell 32 percent.

Investors sued, alleging that the company knew about patient deaths in both Phase 2 and Phase 3 trials. The court granted plaintiffs' motion to dismiss, ruling on scienter grounds alone. The court applied an unusual nine-factor test the Sixth Circuit has adopted for analyzing scienter. Most significantly, plaintiffs were unable to plead facts showing that the company knew that patient deaths during the trial occurred disproportionately on the treatment arm, as the trial was blinded. The overall rate of patient deaths was also quite low (16 out of 4,000 patients in combined Phase 2 and 3 trials). Plaintiffs' motive allegations were also inadequate. The company's CEO and CFO increased their stock holdings over the class period, and plaintiffs' allegation that the company's future depended on approval of bempedoic acid was entirely generic.

Nguyen v. NewLink Genetics Corp., 2019 WL 591556 (S.D.N.Y. Feb. 13, 2019), granting motion to dismiss with prejudice. **Phase 3**

NewLink developed a drug called HyperAcute Pancreas, for the treatment of pancreatic cancer. In Phase 3 trials, the drug was tested against chemotherapy, on which patients were expected to have an overall survival rate of 18–19 months. A scheduled interim analysis revealed that patients on the chemotherapy arm had an overall survival rate of 30 months—far longer than expected. Meanwhile, patients on the treatment arm had an overall survival rate of 27 months. The trial was halted and the company's stock price fell 30 percent.

Investors sued, challenging a range of statements. In a 2018 decision discussed in last year's annual review, the court held that plaintiffs had failed to plead falsity and scienter, save with respect to the company's statements that it had completed enrollment in accordance with

the eligibility requirements of the Special Protocol Assessment. With respect to that statement, the court held in 2018 that plaintiffs had failed to establish loss causation. The court reached the same conclusion in its 2019 ruling granting the company's motion to dismiss plaintiffs' amended complaint. In three purported corrective disclosures, the company reported that the trial had failed to meet interim endpoints or had failed altogether; plaintiffs could not link those failures to alleged violations in enrollment. In a fourth corrective disclosure, the company reported potential violations of Good Clinical Practices, but plaintiffs were again unable to show that those violations were related to alleged enrollment issues.

Plaintiffs also challenged a new set of statements in their amended complaint—statements that previous major studies showed an overall survival rate of 18–19 months for patients on chemotherapy. According to plaintiffs, various studies undercut the 18–19 month benchmark or were themselves flawed. The court rejected these claims. One of the newly challenged statements was a statement of opinion, and the studies plaintiffs had gathered failed to show that the company lacked support for that opinion. In any event, although NewLink expected the survival rate on the control arm to be 18–19 months, the company ultimately designed its Phase 3 trial around a control arm survival in a range of months in the low 20s. As to plaintiffs' argument that the studies on which the company relied were themselves misleading or irrelevant, this was a critique of trial methodology that the court would not adjudicate. Finally, the court rejected plaintiffs' attack on the company's positive statements about Phase 2 results. Plaintiffs claimed that, by excluding the sickest patients from the Phase 2 trials, the company had artificially boosted results—but this theory of fraud too, the court concluded, depended on a non-justiciable critique of trial methodology.

Biondolillo v. Roche Holding AG, 2019 WL 1468140 (D.N.J. Apr. 3, 2019), granting motion to dismiss without prejudice. **Phase 3**

Roche's breast cancer drug, Herceptin, entered the market in 1998. With the emergence of biosimilars and a patent expiring in 2019, Herceptin's market dominance was threatened. The company developed a combination treatment pairing Herceptin with a newer Roche drug, Perjeta, hoping to compete against new market entrants. Roche won approval of the combination therapy for pre-surgical use and moved into a Phase 3 trial testing the combination in the post-surgical setting. In March 2017, Roche issued a press release announcing that the latter study had met its primary endpoint, had shown statistically significant improvement in invasive disease-free survival and had demonstrated a safety profile consistent with that seen in earlier trials. The company reported more detailed results at ASCO in June 2017, including the facts that the improvement in disease-free survival was 19 percent, that the improvement was attributable solely to a single subgroup, and that the drug substantially increased safety risks in three areas. Some physicians and analysts found these results disappointing, and the company's stock price fell 5 percent.

Investors sued, and, in an order issued in 2018 (and discussed in our 2018 review), the court dismissed the complaint, holding that plaintiffs had failed to identify a false or misleading statement. The safety risks disclosed at ASCO, though high, were in line with data in previous studies, just as the company had stated, and while the 19 percent improvement rate was inconsistent with the market's belief that the endpoint required a 20 percent improvement, Roche had not created and was not responsible for that belief, nor did Roche have a duty in March 2017 to disclose that improvement was attributable to a single subgroup. Plaintiffs then amended their complaint, challenging (1) Roche's statement that one of its study collaborators was "independent" (plaintiffs claimed that Roche had paid a physician working for the entity $3 million in consulting and other fees), and (2) Roche's statement that the new combination treatment would "move the standard of care." The court again dismissed the complaint. Plaintiffs had failed to plead that the statement about independence was misleading because a collaborator is by definition not independent. The company's statement about standard of care was an aspirational statement of strategy, not a representation that the combination treatment had already become the standard of care.

Biondolillo v. Roche Holding AG, 2019 WL 2498928 (D.N.J. June 17, 2019), granting motion to dismiss with prejudice. **Phase 3/physician independence**

This is the third and final decision in the case discussed immediately above. In amending their complaint a second time, plaintiffs again alleged that a physician who worked with one of the study collaborators lacked independence. In their final complaint, plaintiffs claimed that the failure to disclose financial ties between the physician and Roche rendered the company's statement of trial results misleading by omission. Plaintiffs also provided significantly more detail about those ties and the exposure of the ties. In September 2018 (more than a year after Roche had reported results at ASCO), the *New York Times* published an article revealing the $3 million payment Roche had made to the physician and commenting that the physician "put a positive spin on the results of two Roche-sponsored clinical trials that many others considered disappointments, without disclosing his relationship to the company." The physician thereafter resigned his positions at Memorial Sloan Kettering Cancer Center and on a research journal. The physician's ties to Roche were also disclosed by ASCO and in the medical journal that had published the test results.

The court noted that the case "raises the interesting question of whether publishing the results of a study without disclosing conflicts of interests is a misrepresentation." The court did not, however, actually reach that question. The court instead dismissed the complaint on loss causation grounds: Plaintiffs had failed to meet their burden of showing that Roche's stock price declined when the physician's conflicts of interest were revealed to the public in 2018.

In re Ocular Therapeutix, Inc. Sec. Litig., 2019 WL 1950399 (D. Mass. Apr. 30, 2019), granting motion to dismiss. **NDA/Forms 483**

Ocular developed Dextenza, a drug designed to treat post-surgical eye pain and inflammation. In connection with its consideration of Ocular's NDA, the FDA inspected the company's manufacturing facility and issued a Form 483 containing inspectional "observations." The company disclosed those observations in its Form 10-K. The FDA subsequently issued a Complete Response Letter denying the NDA and citing manufacturing deficiencies, and the company's stock price fell 15 percent. In a subsequent earnings call, the company reported that it would resubmit its NDA and was optimistic about resolving manufacturing issues. After the company resubmitted the NDA, the FDA again inspected its facilities and again issued a Form 483. The company once again disclosed the Form 483 in its Form 10-K. In an earnings call, the company also once again expressed optimism about resolving the manufacturing issues. Several months later, media reports about the two Forms 483 drove the company's stock price down 30 percent. The FDA then issued a Complete Response Letter rejecting the resubmitted NDA based on manufacturing deficiencies, and the stock price fell an additional 12 percent.

Investors sued, challenging (1) the company's optimistic statements on the two earnings calls about resolving the manufacturing issues, and (2) statements in the company's Forms 10-K that it used "current good manufacturing practices." The court dismissed plaintiffs' claims. The court held that the company's statements about "current good manufacturing practices" were too general to support a fraud claim and were not contradicted by the Forms 483 in any event, as those forms contained "observations" rather than final agency determinations. The fact that the company disclosed the Forms 483 in its 10-Ks also undermined any inference of fraud. As to the oral statements on earnings calls, the first—post-dating the initial Complete Response Letter—was an opinion statement and was protected by *Omnicare*, as plaintiffs had identified no omitted facts that did not fairly align with the challenged opinion. The second statement—post-dating the second Form 483—was protected under the PSLRA's safe harbor. The statement was forward-looking: The company had said that it expected to be able to resolve manufacturing issues in a timely manner. And the statement was accompanied by meaningful cautionary language. The court finally concluded that plaintiffs failed to establish scienter, particularly given that the company had *disclosed* the Forms 483.

Smith v. Antares Pharma, Inc., 2019 WL 2785600 (D.N.J. July 2, 2019), granting motion to dismiss without prejudice. NDA

Antares developed a drug delivery product for use in testosterone replacement therapy and submitted an NDA after successful Phase 3 trials. The FDA initially accepted the NDA but later told Antares that it was halting review as a result of unspecified deficiencies. In a subsequent Complete Response Letter, the FDA identified safety risks related to hypertension and suicidality. The FDA ultimately approved the product with a black box warning label.

Investors challenged a range of statements, some of which were objective reports updating the market on the approval process and others of which more narrowly addressed suicides and other safety issues. The court granted the company's motion to dismiss. Plaintiffs' claims depended on a confidential witness who had purportedly said that the company had underreported suicides, but the confidential witness's account lacked both specificity and corroboration. The court also held that plaintiffs had not adequately specified which statements they were challenging, or on what basis.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED

Micholle v. Ophthotech Corp., 2019 WL 4464802 (S.D.N.Y. Sept. 17, 2019), denying in part and granting in part motion to dismiss. Phase 3

Ophthotech developed Fovista, for the treatment of wet age-related macular degeneration (a degenerative eye disease). The company conducted trials of Fovista in combination with another drug, Lucentis. The company announced favorable Phase 2(b) results, reporting that the combination therapy showed a robust benefit over the Lucentis monotherapy. In its initial press release, the company did not disclose that at the start of the trial, patients on the monotherapy arm had lesions 17 percent larger than the lesions of patients on the combination therapy arm. The company then moved to Phase 3 trials and disclosed that it had "modified the methodology used to determine a patient's eligibility" between Phase 2(b) and Phase 3. At the same time, however, the company stated that these modifications were "not meaningful." The Phase 3 trial was a failure: The combination therapy showed no benefit over the monotherapy. The company's stock price fell 86 percent.

Investors sued, challenging (1) the company's press release announcing Phase 2(b) results, on the basis that the company did not disclose the differences in lesion size between the control and treatment arms, and (2) the company's statement that the revisions to eligibility criteria in the Phase 3 trial were not meaningful. The court held that plaintiffs failed to plead falsity as to the first statement but adequately pled both falsity and scienter as to the second. With respect to the first statement, the company was not required to provide all material details in reporting trial results; in any event, the company ultimately *did* disclose the differences in lesion size—not in the initial press release but in subsequent SEC filings and scientific publications. By contrast, the court concluded that plaintiffs had pled facts sufficient to show that the company's revisions to eligibility criteria *were* meaningful: Patient populations excluded from the Phase 2(b) trials were eligible for the Phase 3 trials. The court also concluded that plaintiffs had adequately pled scienter. Plaintiffs' theory was that the company had deliberately broadened the eligibility criteria for the Phase 3 trial in an effort to broaden the commercial potential of the drug, and that the inference that the company knew that its "not meaningful" statement was false was therefore as strong as any competing inference of good faith. Finally, the court held that plaintiffs had adequately pled loss causation—a plausible link between the revisions to eligibility criteria and the failure of the Phase 3 trial and subsequent stock drop.

In re Celgene Corp. Sec. Litig., 2019 WL 6909463 (D.N.J. Dec. 19, 2019), denying in part and granting in part motion to dismiss. **Phase 3/NDA**

Celgene's principal product is Revlimid, a treatment for melanoma that will go off patent in 2022, which puts pressure on the company's other drugs and drug candidates. Three such drugs are relevant: (1) Otezla, an approved psoriasis treatment, (2) GED-301, a treatment for irritable bowel syndrome the company began developing in 2014, and (3) Ozanimid, a multiple sclerosis treatment the company began developing in 2015.[10] In 2017–18, Celgene ran into difficulties with all three drugs. In October 2017, the company announced that it was discontinuing its Phase 3 trials of GED-301, after which its stock price fell 11 percent. Also in October 2017, the company announced disappointing sales of Otezla and reduced revenue guidance for multiple years. The company's stock fell 6 percent. In December 2017, the company announced that it had filed an NDA for Ozanimid, but then reported February 2018 that the FDA had issued a Refuse to File letter. The stock dropped 9 percent. In April 2018, the company reported that it needed to test a metabolite produced by Ozanimid before refiling the NDA, and that this could delay the refiling by up to three years. The stock again dropped 9 percent.

Investors sued, challenging statements the company made about all three drugs (GED-301, Otezla and Ozanimid). The court granted the company's motion to dismiss as to all statements about the GED-301 and most statements about Otezla but denied the motion as to statements about Ozanimid. As to GED-301, plaintiffs alleged that results of a Phase 1(b) trial were unreliable because the trial had no control arm and that results of a Phase 2 trial were unreliable because they were based on patients' assessments of their conditions rather than on endoscopies. The court concluded that these were non-justiciable critiques of trial design. The court also rejected plaintiffs' contention that the company had given up on the Phase 3 trials long before announcing their discontinuation; this claim was undercut by the company's continued expenditures on the Phase 3 trials, as well as the fact that the trials were blinded, and the recommendation to discontinue came from the Data Monitoring Committee. As to Otezla, many of the challenged statements were forward-looking sales forecasts shielded by the PSLRA's safe harbors. The exceptions were non-forward looking statements in which corporate executives opined that lagging sales would bounce back. The court concluded that plaintiffs had adequately pled that the executives did not believe the stated opinions and had no reason for making them, given allegations that the executives had been warned about sales shortfalls and had told their forecasting team to alter internal forecasts in order to conceal those shortfalls. As to Ozanimid, the court concluded that plaintiffs had adequately alleged that the company's statements about the drug's favorable profile were rendered misleading by the omission of information about a metabolite that would require additional testing before an acceptable NDA could be filed. "In short, without the necessary [m]etabolite testing, the contemplated NDA was dead on arrival. The fact that Defendants told investors about the positive clinical study results but failed to disclose the [m]etabolite discovery was misleading." The court also concluded that plaintiffs had adequately alleged scienter in connection with the challenged Ozanimid statements. Plaintiffs pled facts showing that certain executives—though not all the defendants in the case—knew of the metabolite and had been told by others in the company that the FDA would issue a Refuse to File letter unless the company performed additional testing of the metabolite.

Khoja v. Orexigen Therapeutics, Inc., 2019 WL 4599882 (S.D. Cal. Sept. 23, 2019), denying in part and granting in part motion to dismiss. **Post-approval cardiovascular outcome trial**

Orexigen developed Contrave, an obesity drug. After FDA approval was granted and while EU approval was pending, the company performed a cardiovascular outcome trial to confirm safety. Results from a scheduled 25 percent interim assessment suggested that the drug might actually improve cardiovascular safety. A data access plan prohibited the company from disclosing the interim results, but, in March 2015, the company publicized those results by describing a patent it had just been granted. The company characterized the results as

10 Because two of the three drugs at issue in this case had not been approved, we have grouped the decision with other pre-approval cases.

preliminary but did not say that they were unreliable. The trial's lead investigator then directed that the trial be halted. Meanwhile, a second scheduled interim assessment, at 50 percent completion, reversed the positive trend shown in the 25 percent interim data. In May 2015, the company stated that the trial was still ongoing and suggested that it did not have access to the 50 percent data. Four days later, the chair of the trial's steering committee released the 50 percent data and accused the company of misleading both patients and investors.

Investors sued, challenging the company's March 2015 and May 2015 statements. The district court dismissed the complaint, and plaintiffs appealed. The Ninth Circuit largely reversed the dismissal in one of the leading securities decisions of 2018. The Ninth Circuit's decision both imposed duties on companies that disclose interim trial results and tightened the rules governing a court's ability to consider documents outside the complaint on a motion to dismiss. After the case was remanded, the three individual defendants moved to dismiss on scienter and loss causation grounds, as no court had previously ruled on those elements. (The company was by this time in bankruptcy.) The court largely denied the motion to dismiss. With respect to the March 2015 statements—and the claim that defendants wrongly omitted the fact that the 25 percent interim results were unreliable—the court concluded that plaintiffs had pled scienter as to two defendants who attended a meeting in which the FDA warned that the results were unreliable, but not as to a third defendant, who was not present at that meeting. With respect to the May 2015 statements, the court concluded that plaintiffs had adequately pled facts showing that all three defendants knew that the trial had been terminated, knew what the 50 percent results were, and knew that those results contradicted the 25 percent data. The court largely rejected defendants' loss causation arguments.

Decisions
Development Stage

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 25–39), 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, the district court decisions are almost evenly split, with companies prevailing on motions to dismiss in 13 cases and courts denying motions to dismiss at least in part in 12 cases.

That breakdown looks quite different when a group of six cases arising from alleged price fixing in the generic drug industry is analyzed separately. Defendants won dismissal in only one of the six cases, and in that case won solely on loss causation grounds.

Defendants won dismissal in 12 of the 19 cases outside the antitrust area, with losses in cases arising both from regulatory setbacks (FDA inspection, FDA product recall, Federal Trade Commission action) and from commercial setbacks (disappointing sales, loss of a supply contract).

APPELLATE DECISIONS

Metzler Asset Mgmt. GmbH v. Kingsley, 928 F.3d 151 (1st Cir. 2019), affirming dismissal. **Safety; revenue guidance**

Biogen developed and sold the oral multiple sclerosis medication Tecfidera. During an October 2014 earnings call, Biogen announced that a patient taking Tecfidera had died from an infection related to a weakened immune system caused by a low level of lymphocytes (lymphopenia). In November 2014, the FDA issued a public warning in which it advised physicians to monitor Tecfidera patients for side effects. In December 2014, Biogen updated Tecfidera's U.S. label—which already included a lymphopenia warning—to reflect the danger of the relevant infection. In January 2015, Biogen provided full-year revenue guidance, projecting growth of 14 to 16 percent. In July 2015, however, the company revised its guidance downward to 6 to 8 percent growth, attributing this in part to slowing Tecfidera sales. Biogen's stock price fell over 20 percent.

Investors sued, alleging that Biogen had known both that Tecfidera potentially weakened patients' immune systems and that the patient death had materially affected Tecfidera sales, and that the company had misrepresented or concealed those facts in its public statements. The district court granted defendants' motion to dismiss, concluding that, while plaintiffs had adequately pled that six challenged statements were "plausibly misleading," they had failed to plead facts creating a strong inference of scienter.

The First Circuit affirmed, assuming without deciding that plaintiffs had adequately pled falsity and ruling solely on scienter grounds. With respect to statements about Tecfidera's safety, the court noted that Biogen had already updated its safety label at the time of the challenged statements; the court concluded that plaintiffs had not pled facts showing that the company or its officers were aware that the drug was less safe than the revised label suggested. With respect to statements about the company's sales trajectory, the court again noted that, at the time the company made those statements, it had already disclosed both the patient death and an increase in Tecfidera's discontinuation rate. The court also rejected plaintiffs' claim that scienter could be shown by reference to a single doctor in Atlanta who had told the company that he had stopped prescribing Tecfidera because he had concluded from his own research that the drug was linked to low lymphocyte counts. That doctor, the court noted, represented only a very small slice of the Tecfidera market. Plaintiffs' confidential witness allegations were insufficient for largely the same reason: Those allegations that were adequately particularized again concerned only narrow segments of the market. Finally, the court considered two recurring issues in the scienter analysis: whether plaintiffs could proceed with a theory of "corporate scienter" even if they could not support a strong inference of scienter with respect to the individual defendants, and whether the court could infer scienter based on the fact that the events at issue concerned the company's "core operations." The court held that both the corporate scienter and the core operations theories were inapplicable because plaintiffs had failed to show that *anybody* in the company knew that the challenged statements were false when made.

Steamfitters' Indus. Pension Fund v. Endo Int'l PLC, 771 F. App'x 494 (2d Cir. 2019), affirming district court's denial of leave to amend following grant of motion to dismiss with prejudice. **Acquisition and integration**

Endo manufactures and distributes branded and generic drugs and devices. In May 2015, Endo acquired Par Pharmaceutical, another distributor of generic drugs. In connection with the acquisition, Endo made optimistic statements about its strong market position and ability to quickly integrate Par into its existing generics platform. Endo reported significant losses for the fourth quarter of 2015, and its stock fell approximately 21 percent. In May 2016, Endo revised its 2016 revenue expectations downward, and its stock fell 39 percent.

Investors sued, challenging Endo's optimistic statements about the Par acquisition. The district court dismissed the complaint, holding that plaintiffs had failed to establish that the

challenged statements were false when made. After the district court denied plaintiffs' motion to amend the complaint, plaintiffs appealed. The Second Circuit affirmed in a brief, unpublished decision, holding that amendment would have been futile. Like the district court, the Second Circuit concluded that a number of the challenged statements were inactionable puffery. The Second Circuit also held that the company had disclosed that it planned to make changes to its business model following the Par acquisition and that this is inconsistent with fraud. The court finally held that the company was not required to disclose those changes as "trends" under Item 303 of Regulation S-K; a change to a business model is not a trend.

DISTRICT COURT DECISIONS: MOTION TO DISMISS GRANTED

Kessman v. Myriad Genetics, Inc., 2019 WL 1330363 (D. Utah Mar. 25, 2019), granting motion to dismiss with prejudice. **Medical code billing**

Myriad Genetics sells multiple related tests designed to detect genetic mutations that increase a patient's risk for certain kinds of cancer. The tests are covered by billing codes issued by the Center for Medicare and Medicaid Services. The coding rules contain a "pair prohibition" pertinent to Myriad's products. Such prohibitions require physicians to bundle two related tests together under a single code, and provide reimbursement for only one of the two. But the billing rules also permit an override of this pair prohibition. Myriad used this override feature many thousands of times over multiple years. In March 2018, Myriad reported that it had received a Department of Health and Human Services subpoena related to an investigation into improper Medicare and Medicaid billing. The company's stock price fell 12 percent.

Investors sued, challenging the company's legal compliance statements, Sarbanes-Oxley certifications and statements attributing revenue growth to increased sales volume. The court granted the company's motion to dismiss. All of plaintiffs' claims depended on the premise that the company's billing practices were illegal, but plaintiffs had not shown that to be the case. The coding rules provided the override feature Myriad used, and plaintiffs cited no instance in which CMS had faulted the company for using that feature (which others in the industry used as well). The court concluded that determining the validity of the company's billing practices was a task better suited to the agency that had written the rules than to the court. The court also rejected plaintiffs' claims on scienter grounds, holding that, while plaintiffs had demonstrated that corporate executives knew about the company's use of the override features, plaintiffs had not pled facts showing that the executives knew that such use was improper. The court finally held that plaintiffs had failed to establish loss causation, drawing on circuit-level precedent holding that disclosure of a single subpoena does not constitute a corrective disclosure or show that a risk concealed by the challenged statements has materialized.

Inchen Huang v. Higgins, 2019 WL 1245136 (N.D. Cal. Mar. 18, 2019), granting motion to dismiss without prejudice. **Opioid marketing**

Assertio Therapeutics acquired the rights to tapentadol, an opioid-based pain medication, in 2015. Tapentadol eventually accounted for 62 percent of the company's revenue. In November 2016, the company announced decreased revenue guidance for 2016. In March 2017, a Senate investigation into the sales and marketing practices of several opioid manufacturers, including Assertio, became public. In August 2017, Assertio announced that it had received subpoenas from federal and state authorities investigating off-label marketing. The company's stock price fell after each of these three announcements.

Investors sued, claiming that Assertio's tapentadol-driven sales growth was the result of an illegal and undisclosed off-label marketing campaign. The court dismissed the complaint, holding that plaintiffs had failed to plead facts establishing the existence of an off-label marketing scheme. Plaintiffs similarly failed to plead scienter: Their allegations lacked specificity and were insufficient to show the kind of widespread wrongdoing necessary to support an inference of scienter under the core operations doctrine. Finally, plaintiffs failed to plead loss causation. The announcement of an investigation does not establish loss causation under Ninth Circuit law; as to the reduced

revenue guidance announced in late 2016, plaintiffs failed to plead facts linking decreased sales to the curtailment of purportedly improper marketing practices.

In re Galena Biopharma, Inc. Sec. Litig., 2019 WL 5957859 (D.N.J. Nov. 12, 2019), granting motion to dismiss without prejudice. **Opioid marketing**

Galena developed hematology and oncology treatments and sold Abstral, an opioid used in managing breakthrough pain in cancer patients. The active ingredient in Abstral is fentanyl, the most powerful prescription opioid available. Most of Galena's Abstral sales were driven by a small number of clinics, and, in 2015, federal law enforcement officials shut down several of those clinics. In November 2015, Galena announced that it was divesting its commercial business and had sold Abstral to a private company for cash. Galena subsequently announced that it was facing a federal investigation based on its marketing and promotional practices for Abstral. The company's stock price fell.

Investors sued, claiming that Galena had misleadingly understated its exposure to criminal and civil liability for Abstral marketing and had failed to disclose that its sales growth was (purportedly) driven by illegal marketing and kickbacks. The court granted the company's motion to dismiss, holding that the company had adequately disclosed the existence of a federal investigation into Abstral marketing and was under no obligation to go further by outlining the possible legal ramifications of the investigation. The court also held that the plaintiffs had failed to link challenged statements about Galena's business practices and the sustainability of its revenue growth to purportedly illegal activity.

Gagnon v. Alkermes PLC, 368 F. Supp. 3d 750 (S.D.N.Y. 2019), granting motion to dismiss with prejudice. **Opioid-related marketing**

Alkermes markets and sells Vivitrol, which is used to treat opioid dependency. Vivitrol is an opioid antagonist: It occupies opioid receptors in the brain, which both reduces cravings and prevents patients from getting high if they do take opioids (save in very large amounts). Sales of Vivitrol ballooned between 2011 and 2016. The company told investors that this growth was organic and attributed it to law enforcement officials, drug courts and prison wardens who saw patients on Vivitrol achieving success in battling addiction. The company also explained that Vivitrol works differently from drugs like methadone and Suboxone. Those drugs are opioid agonists, and work by tricking the opioid receptors in the brain into thinking the patient has taken opioids. Alkermes told investors that these drugs are themselves addictive, but that Vivitrol is not. In June 2017, media pieces began to appear in which the company was accused of using deceptive and aggressive marketing practices, including attempts to suppress the use of methadone and Suboxone by lobbying for increased regulation of those drugs. The company's stock price fell 7 percent and continued to fall after the company reported that it had received a subpoena related to Vivitrol from federal prosecutors, and articles appeared in scientific journals suggesting that Vivitrol was as effective as—but not more effective than—methadone and Suboxone.

Investors sued, challenging the company's statements about its sales growth, about Vivitrol's mechanism of action and about differences between Vivitrol and methadone and Suboxone. The court granted the company's motion to dismiss. The court concluded that most of the company's statements characterizing sales growth as organic were puffery, and were additionally not misleading in light of the company's disclosure that it used standard sales and marketing channels such as advertising, selling initiatives, public relations and drug representative visits to physicians. The court concluded that one statement in this category was actionable—a statement attributing sales growth to the adoption of Vivitrol by the criminal justice system. The court held that, once the company put the sources of growth at issue, it had a duty to render a complete account of the subject, which apparently included the fact that the company had decided to attack Suboxone and had been criticized by state government officials for doing so. The court nevertheless dismissed plaintiffs' challenge to this statement on scienter grounds, holding that the maker of the statement did not know either that the company had prepared a white paper attacking Suboxone or that state regulators had told the company to stop attacking Suboxone in its interactions with legislators. The court also rejected

plaintiffs' challenge to statements about the drug's mechanism of action. The court concluded that, in explaining that an injection of Vivitrol lasts for 28 days, during which patients do not relapse, the company was not guaranteeing success but simply describing how the drug works. Finally, the court rejected plaintiffs' challenge to statements that Vivitrol patients could lead to a drug-free life—these statements were merely aspirational—and to statements differentiating Vivitrol from methadone and Suboxone—these statements were objectively true.

Paciga v. Invuity, Inc., 2019 WL 3779694 (N.D. Cal. Aug. 12, 2019), granting motion to dismiss without prejudice. **Revenue projections**

Invuity develops and sells medical devices used to provide illumination and improve visibility during surgery. In February 2016, the company issued annual revenue guidance for 2016, stating that it intended to achieve growth by adding accounts and going deeper into existing accounts. The company subsequently stated that it was performing according to plan. In November 2016, however, Invuity reported lower-than-expected revenue growth for the third quarter, reduced its 2016 revenue guidance, and projected slower revenue growth in 2017. The company's stock price fell 45 percent.

Investors sued, challenging the company's statements about revenue growth. The court granted the company's motion to dismiss on both falsity and scienter grounds. Plaintiffs argued that the company's statements about deepening its relationship with existing accounts were contradicted by data showing a "step back" pattern, in which customers made an initial large order and then subsequent smaller orders. But plaintiffs had not shown that this pattern was universal, and the existence of the pattern did not show that the company's statements about seeking to go deeper were false in any event. The court also rejected plaintiffs' attack on the company's statement that it benefited from seasonal trends showing increased sales in the second half of each year: Those statements were accurate. Finally, the court rejected plaintiffs' scienter allegations. Plaintiffs offered a confidential witness's statement that executives had access to daily reports showing that the company was not increasing its penetration into existing accounts, but did not "address what specific negative information officers knew about [the company's] sales data…that was sufficiently troubling that the officers must have known that the company was going to be unable in the long term to go deeper with existing customers."

Xiaojiao Lu v. Align Tech., Inc., 417 F. Supp. 3d 1266 (N.D. Cal. 2019), granting motion to dismiss without prejudice. **Sales promotions**

Align Technology designs, manufactures and sells clear aligners used to treat misaligned teeth. Align experienced relatively light competition until certain patents began to expire in 2017. In response to increased competition, Align began offering significant discounts and other promotions designed to boost sales. These activities led to a decrease in average sales price per unit, a metric closely watched by investors. Align's stock price fell approximately 25 percent after the company announced the decline in average sales price.

Investors sued, claiming that Align was aware of, but failed to disclose, the impact its marketing strategy would have on average sales price. Plaintiffs also alleged that Align repeatedly and inaccurately downplayed the competitive pressures it faced. The court dismissed the complaint, holding that plaintiffs had failed to plead both falsity and scienter. The accounts of former employees on which plaintiffs relied bore little connection to the challenged statements, were impermissibly vague and showed only that the company was facing increased competition—a fact the company itself had publicly disclosed.

Karth v. Keryx Biopharmaceuticals, Inc., 334 F.R.D. 7 (D. Mass. 2019), granting motion for judgment on the pleadings. **Manufacturing**

Keryx manufactures and sells Auryxia, a drug for patients with chronic kidney disease. In manufacturing Auryxia, Keryx itself produces the active ingredient and then licenses a manufacturer, Norwich Pharmaceuticals, to convert the ingredient into tablet form. Norwich was the only manufacturer approved by the FDA to manufacture Auryxia tablets during the relevant period, such that Keryx relied entirely on Norwich to maintain production. On August 1, 2016,

Keryx announced that it was halting production of Auryxia due to a production issue with Norwich. The company's stock fell 36 percent.

Investors sued, claiming that Keryx had stated repeatedly that multiple contract manufacturers were engaged in the production of Auryxia. The court granted judgment on the pleadings based on the plaintiffs' failure to establish loss causation. Months before Keryx announced the production halt, the company had disclosed its reliance on a single contract manufacturer. This previous disclosure broke the causal link between the purported misstatements and plaintiffs' alleged investment losses.

Jackson v. Avanos Med., Inc., 2019 WL 1437517 (S.D.N.Y. Mar. 31, 2019), denying plaintiffs' motion for post-judgment relief and for leave to file an amended complaint. **Manufacturing/advertising**

Halyard (which was spun off from Kimberly-Clark and which later changed its name to Avanos) manufactured medical supplies, including the MicroCool surgical gown, which is intended to protect healthcare providers from highly infectious diseases such as Ebola. The MicroCool 510(k) summary submitted to the FDA in 2010 stated that the MicroCool met the Level 4 Liquid Barrier requirements of the Association for the Advancement of Medical Instrumentation (AAMI), the highest liquid barrier protection defined by the AAMI system. On May 1, 2016, 60 Minutes reported that the MicroCool had failed numerous quality assurance tests in 2013 and that the company had knowingly provided defective surgical gowns to U.S. workers at the height of the Ebola crisis. The following day, Halyard's stock price fell 14 percent.

Investors sued, claiming that defendants had knowingly misrepresented the MicroCool as capable of providing AAMI Level 4 protection. Plaintiffs relied in part on statements from two confidential witnesses who claimed that the MicroCool had seam sealing issues. In an order issued in 2018, the court granted defendants' motion to dismiss on scienter grounds.

Plaintiffs then moved for post-judgment relief and for leave to file an amended complaint that incorporated witness testimony and judicial findings from a consumer fraud action filed in federal court in California by a purchaser of the MicroCool gowns. The securities plaintiffs claimed in their proposed amended complaint that witness testimony from the California case showed that Kimberly-Clark's CEO had been provided with documents informing him of issues that rendered purported AAMI Level 4 marketing false. Plaintiffs also alleged that the jury verdict supported the inference that executives must have been aware of these issues. But the court in the securities action rejected those allegations, holding that the proffered testimony did not show the specific content of the purported documents, did not show that Kimberly-Clark's CEO had read the documents, and did not show what the CEO's reaction to the documents had been. The court in the securities action also rejected the notion that the California court's finding that the company had "engaged in a fraudulent business practice" in the context of consumer litigation showed that any defendant had scienter for purposes of the securities litigation. Because the securities plaintiffs' new allegations did not cure their previous failure to plead scienter, the court held that amendment would be futile and denied plaintiffs' motion for relief from judgment.[11]

In re Aceto Corp. Sec. Litig., 2019 WL 3606745 (E.D.N.Y. Aug. 6, 2019), granting motion to dismiss without prejudice. **Government contracts; financial controls and projections**

Aceto produced pharmaceutical products and ingredients. Aceto held 18 five-year contracts with the federal government, and these contracts were a major revenue source. Aceto disclosed in its August 2017 Form 10-K that the government was investigating its compliance with country-of-origin provisions in the contracts, and that the government could potentially exercise remedies, including termination. In May 2018, Aceto notified investors that the government had determined that the company was not in compliance with the country-of-origin provisions, in response to which the company had recorded a large goodwill impairment. Separately, Aceto reported in November 2017 that it had discovered that in 2015 it had misapplied cash as a result of a material weakness in its internal controls governing trade receivable accounts. Both developments—the difficulty with the government contracts and the discovery of an internal

11 Plaintiffs in *Avanos* have appealed to the Second Circuit, No. 19-1300 (argued Apr. 22, 2020).

control weakness—occurred during a period of financial struggle for Aceto, as it faced increased competition in the generic drug market. In February 2018, the company issued revenue guidance of 10–15 percent growth for the remainder of its fiscal year. But in April 2018, the company withdrew that guidance and announced the departure of its Chief Financial Officer. The company's stock fell 64 percent. In May 2018, the company declared bankruptcy.

Investors sued, challenging (1) the company's August 2017 Form 10-K, on the basis that the company had failed to report the internal control weakness; (2) the company's February 2018 press release, on the basis that the company had not yet recognized the impairment of goodwill; and (3) the company's growth projection in the same February 2018 press release. The court dismissed the complaint in its entirety. Plaintiffs' attack on the company's internal controls reporting, the court held, amounted to fraud by hindsight: Plaintiffs had not shown that Aceto was aware of the internal control weakness at the time of the challenged statement. On the issue of goodwill impairment, the court noted that the company had disclosed the risk that it would lose its government contracts and was not required to assume that it would lose the contracts in valuing its goodwill. (The court also noted that the Court of Federal Claims ultimately rejected the government's position on the contracts.) As to the company's growth projections, these were forward-looking statements rendered inactionable under the PSLRA safe harbor by the company's risk disclosures. The court also concluded that plaintiffs had failed to establish scienter. The rapid withdrawal of the February 2018 guidance showed misguided optimism rather than knowing fraud; the resignation of the CFO was not probative of scienter in light of the fact that the CFO was not alleged to have been involved in the purported fraud; and the size of the goodwill impairment, in the absence of any other circumstantial indicia of fraud, was insufficient.

LSI Design & Integration Corp. v. Tesaro, Inc., 2019 WL 5967994 (D. Mass. Nov. 13, 2019), granting motion to dismiss with prejudice. **Financial position; secondary stock offering**

Tesaro develops and commercializes cancer therapies and other oncology-related products. In 2016, Tesaro was selling only one FDA-approved drug, Varubi, which treats chemotherapy-induced nausea and vomiting. In its Form 10-Q filed November 4, 2016, the company stated that its cash flows were sufficient to fund continuing operations for the next 12 months. The company made similar statements about its financial health over the next several days. On November 14–15, 2016, the company announced a public stock offering at a 9 percent discount from its trading price of $135/share. By November 16, 2016, the company's stock price had fallen to $126.65.

Investors sued, challenging the company's statements about its financial condition. The alleged class period was unusually short, running for only the 10 days between November 4, 2016 and November 14, 2016. Plaintiffs alleged that the company had missed internal sales forecasts in the second and third quarters of 2016 and hence knew that it would need to conduct an additional stock offering. The court dismissed plaintiffs' claims. In its Form 10-Q, the company had told investors that it would need additional capital for various corporate purposes; in any event, plaintiffs had conceded that the company could have financed its operations in 2017 even without the funds raised in the November 2016 offering. The company's other statements about its financial condition were forward-looking, and plaintiffs had failed to allege facts showing that defendants actually knew that the challenged statements were false or misleading. The allegation that the company had missed internal forecasts, even if credited, did not show that the company was unable to finance its operations for the next year.

Walleye Trading LLC v. AbbVie, Inc., 2019 WL 4464392 (N.D. Ill. Sept. 18, 2019), granting motion to dismiss with prejudice. **Tender offer**

AbbVie develops and manufactures a variety of drugs. In May 2018, AbbVie conducted a Dutch auction to repurchase $7.5 billion of its common stock, setting a tender range between $99 and $114 per share.[12] The auction period expired on May 29, 2018. Early in the morning of May 30, AbbVie announced that it would repurchase stock at $105 per share. Later the same day, however, after the market had closed, AbbVie announced that it had made an error in calculating the $105 price point. The company had failed to account for approximately 5.5 million shares, and when

12 A Dutch auction is a share buyback mechanism in which a company sets a range of prices at which it is willing to repurchase a fixed dollar amount of stock. Stockholders who wish to sell select a price within that range, and the company then sets a purchase price based on the lowest price it needs to pay per share in order to buy back stock of the previously specified amount (in *AbbVie*, $7.5 billion).

those shares were factored in, the repurchase price was actually $103 per share. AbbVie's stock fell by approximately 4 percent the next day, closing at $98.94 per share.

Investors sued, challenging company's announcement early on May 30 that it would repurchase shares at $105. The purported class period was extremely short, covering only 7.5 hours of trading on May 30. The court granted AbbVie's motion to dismiss, holding that plaintiffs had failed to establish that the company knew of its error when it made its early May 30 statement. Plaintiffs alleged that based on the "typical" ways in which such transactions proceed, the company either knew of its error in overlooking 5.5 million shares or was reckless in failing to learn of it. But those allegations, the court held, were insufficient to meet the particularity standards of the PSLRA. The court also held that plaintiffs had failed to establish a violation of Section 14(e) of the Exchange Act, which governs communications made in the course of tender offers. When the company made the challenged statement about the stock repurchase price, the tender offer had already closed.

New York Hotel Trades Council & Hotel Ass'n of N.Y.C., Inc. Pension Fund v. Impax Labs., Inc., 2019 WL 3779262 (N.D. Cal. Aug. 12, 2019), granting motion to dismiss with prejudice. **Antitrust**

Impax develops, manufactures and markets generic drugs. In July 2014, the Connecticut Attorney General began a broad investigation into generic drug pricing. Also that month, Impax filed a Form 8-K disclosing a subpoena it had received from the Connecticut AG requesting documents related to one of its generic drugs. In November 2014, Impax announced that one of its sales representatives had received a grand jury subpoena from the DOJ's antitrust division regarding the sale of generic drugs. In March 2015, Impax received a grand jury subpoena related to four of its generic drugs. In November 2016, *Bloomberg* reported that charges in the DOJ's antitrust investigation were expected by year-end, and it named Impax among the manufacturers who had received subpoenas from the DOJ. Impax's share price fell 20 percent.

Investors sued, challenging statements and purported omissions related to alleged generic drug price fixing. In a 2018 decision (reported in our review last year), the court held that plaintiffs had adequately pled falsity, but dismissed on scienter grounds. In dismissing plaintiffs' amended complaint in 2019, the court ruled solely on loss causation grounds, holding that, under Ninth Circuit law, announcements of investigations are insufficient in themselves to establish loss causation.

In their amended complaint, plaintiffs also challenged statements related to Impax's drugs diclofenac and budesonide, alleging that the company had concealed price erosion. The court dismissed that claim too. With respect to diclofenac, the statements at issue were puffery, were accurate representations of past performance, were non-actionable opinions, or were otherwise not adequately alleged to have been misleading. With respect to budesonide, plaintiffs had failed to adequately allege scienter.

DISTRICT COURT DECISIONS: MOTION TO DISMISS DENIED

Forman v. Meridian Bioscience, Inc., 367 F Supp. 3d 674 (S.D. Ohio 2019), granting motion to dismiss without prejudice. **Medical device reports/product recall**[13]

In March 2016, Meridian acquired Magellan Biosciences, which marketed a suite of devices for testing lead levels in blood. Before the acquisition, Magellan received complaints that the devices underreported lead levels. In response, Magellan revised product labeling to instruct users to allow the blood and testing reagent to incubate for 24 hours before performing the test. Magellan did not timely report this to the FDA. After the acquisition, Meridian commented favorably on revenue received from the Magellan devices, which it described in its November 2016 Form 10-K as "FDA cleared." But problems continued. In May 2017, the

13 We have placed this decision under the "motion denied" heading because, after granting the company's motion to dismiss, the court reconsidered its ruling and denied the motion to dismiss. We discuss the court's ruling on reconsideration immediately below. In recording wins and losses for defendants in post-approval cases, we have counted the two *Forman* decisions as one win and one loss for defendants.

FDA inspected the Magellan manufacturing facility and issued a press release warning that the devices produced inaccurate results when used on venous blood. Meridian's stock price dropped 9 percent. The FDA then issued a product recall and a Form 483 inspection report stating that the company had concealed product defects and committed regulatory violations. In October 2017, the FDA issued a Warning Letter stating that the products were adulterated and misbranded as a result of unapproved label and design changes. The company's stock fell 8 percent. In January 2018, the company reported a 20 percent year-over-year decrease in revenue from the Magellan lead testing devices.

Investors sued, challenging statements in four categories. The court concluded that plaintiffs failed to plead falsity as to three of the four: (1) representations and warranties about FDA compliance in the merger agreement were not actionable because they were made by Magellan rather than Meridian; (2) revenue guidance was protected by the PSLRA's safe harbor, as it was accompanied by meaningful cautionary language; and (3) Sarbanes-Oxley certifications of internal controls were not shown to have been false when made. By contrast, the court concluded that plaintiffs had adequately pled that a fourth statement was false or misleading—the statement in the November 2016 Form 10-K that the testing devices were "FDA cleared." The court nevertheless dismissed the complaint as to that statement on scienter grounds. Using the Sixth Circuit's unusual nine-factor test for assessing scienter, the court concluded that certain internal documents showed that the company knew that an incubation period was necessary to ensure accurate results, and thus supported an inference of scienter. On the other hand, the FDA did not initiate the product recall until six months after the company had stated that the devices were "FDA cleared." And on a holistic level, it made little sense to posit that Meridian would have acquired Magellan while knowing of problems with its products serious enough to trigger an FDA recall.

Forman v. Meridian Bioscience, Inc., 387 F. Supp. 3d 791 (S.D. Ohio 2019), granting plaintiffs' motion for reconsideration and denying in part motion to dismiss. **Medical device reports/product recall**

In reconsidering the ruling described above, the court concluded that plaintiffs in fact had adequately pled scienter as to the company's statement that the lead-testing devices were "FDA cleared." The court noted that, in November 2016, after Meridian had acquired Magellan, the company issued a new product bulletin telling customers to use an incubation period for certain of the Magellan devices. Meridian also sought to inform the FDA of this change, as required by law. But when the FDA returned Meridian's submission due to formatting errors, the company did nothing for six months. Meridian's submission showed that the company knew that it needed to take certain steps to keep the product "FDA cleared." The court also concluded that it had given undue weight to defendants' attack on the premise, inherent in plaintiffs' claim, that Meridian would acquire a company with known compliance issues. While that argument might defeat an inference of scienter for statements made at the time of the acquisition—in March 2017—it could not account for the "FDA cleared" statement the company made in November 2017, eight months later. Finally, the court concluded that it had mistakenly conflated the issue of efficacy—whether allowing samples to incubate would cure the under-reporting problem—with the issue of FDA compliance, and in particular the requirement that the company notify the FDA and obtain approval of label changes.

In re Allergan PLS Sec. Litig., 2019 WL 4686445 (S.D.N.Y. Sept. 20, 2019), denying in part and granting in part motion to dismiss. **Product recall**

Allergan manufactures various breast implant products, which are regulated by the FDA as class III medical devices. Breast implants have long been associated with a cancer of the immune system called ALCL. Reports published between 2014 and 2017 associated ALCL primarily with "textured" breast implants, of which Allergan's Biocell product is one. Allergan disclosed the possible link between breast implants and ALCL in its SEC filings, noting that negative publicity could hurt its implant business and that product liability claims or investigations could lead to restrictions on the use and sale of the implants. In December 2018, French regulatory authorities asked Allergan to recall its textured implants, which it did. The company's stock price declined. U.S. and Canadian regulators thereafter asked Allergan to recall the Biocell implant.

Investors sued, challenging Allergan's statements about (1) the quality and safety of its breast implants, (2) its compliance with applicable regulatory requirements and (3) its commitment

to advancing knowledge of ALCL. The court dismissed plaintiffs' claims as to statements in the second and third categories but denied the company's motion to dismiss as to certain statements in the first category. Plaintiffs' principal theory as to the first category was that the company had breached a duty to disclose an allegedly definitive link between its products and ALCL. The court rejected that theory, holding that plaintiffs had failed to establish that the implants had in fact been definitively linked to ALCL. But the court credited plaintiffs' alternative theory—that Allergan's risk disclosures were misleadingly incomplete. For five years in a row, Allergan made the same statement in the risk factor discussion in its Form 10-K: that "a breast implant manufacturer that is not affiliated with the Company" was subject to "negative reports from regulatory authorities in Europe." The court agreed with plaintiffs that, for pleading purposes, this statement "created the false impression that Allergan's breast implants were no more likely to be found in individuals suffering from ALCL than other companies' products." Plaintiffs had plausibly alleged that this was untrue by pointing to studies from which "one could reasonably infer…that Allergan's implants were more closely associated with the incidence of [ALCL] than other breast implants on the market." In reaching that conclusion, the court drew on a 2014 Second Circuit decision for the proposition that "once a company speaks on an issue or topic, there is a duty to tell the whole truth."

In re Dr. Reddy's Lab. Ltd. Sec. Litig., 2019 WL 1299673 (D.N.J. Mar. 21, 2019), denying in part and granting in part motion to dismiss. **Manufacturing**

Dr. Reddy's develops and manufactures generic drugs and active pharmaceutical ingredients. In November 2014, the FDA observed nine potential violations of current good manufacturing practices (cGMP) at one of the company's largest facilities and issued a Form 483. Dr. Reddy's acknowledged the Form 483 publicly but stated that it had no "implication on manufacturing," and that the company was confident that the Form 483 would not lead to further enforcement. Over the next 22 months, however, Dr. Reddy's was subject to a series of additional regulatory actions related to manufacturing; in several instances, the company told investors that these actions would not have a significant impact on its business. In early 2015, the company received two additional Forms 483 related to other facilities. In discussing the regulatory landscape in July 2015, the company stated that all outstanding compliance issues related to a single site, and that the company had addressed nearly all of the observations raised by the FDA. In November 2015, the FDA issued a Warning Letter in which it described violations at three sites and recommended that the company evaluate its global manufacturing operations to ensure compliance with cGMP. The company publicly acknowledged the Warning Letter but stated that it would have minimal impact on manufacturing. In February 2016, however, and again in July 2016, the company disclosed that production had slowed as a result of its remediation activities. In October 2016, the company said that it had completed remediation activities. In February–March 2017, the FDA re-inspected the three sites and found continuing issues at each. In the summer of the 2017, the German equivalent of the FDA rescinded the company's compliance certificate for a new facility. In September 2017, the FDA found further instances of non-compliance at a facility in the United Kingdom. The company's stock price fell over 50 percent between November 2015 and September 2017.

Investors sued, challenging the company's statements about its compliance with manufacturing quality regulations, the scope and severity of the FDA's observation of non-compliance, and the impact of the FDA's actions on ongoing production. The court dismissed the plaintiff's challenge to statements made before November 2015 on standing grounds. The FDA's November 2015 Warning Letter corrected all statements made before that date, and the plaintiff did not purchase stock until March 2016. The plaintiff also lacked standing as to alleged misstatements made after its final stock purchase on April 6, 2016. The plaintiff accordingly had standing as to only four of the 26 statements it challenged. With respect to those four, however, the court denied the company's motion as to all portions of the challenged statements that were neither forward-looking nor puffery. The court relied principally on the fact that the FDA continued to find violations after the company had stated that it had adequately addressed the issues in the Warning Letter. The court also credited the plaintiff's contention that the company failed to investigate violations. And the court invoked the core operations inference as part of the holistic analysis of scienter.

Shenk v. Mallinckrodt, Plc, 2019 WL 3491485 (D.D.C. July 30, 2019), denying in part and granting in part motion to dismiss. **Antitrust; Medicare and Medicaid exposure; sales performance**

In 2014, Mallinckrodt acquired Questcor Pharmaceuticals for $5.6 billion. Questcor had earlier bought two drugs, Acthar, which is FDA-approved and Synacthen, which is approved in the European Union. These are the only drugs in their class (naturally derived adrenocorticotropic hormones), which arguably gave Questcor (and then Mallinckrodt) a monopoly position. After the Questcor acquisition, Acthar became Mallinckrodt's principal drug. Retrophin, which had also sought to acquire Synacthen, brought antitrust claims against Questcor; the FTC also began an investigation. Mallinckrodt did not disclose the FTC investigation when it acquired Questcor, although it began doing so in SEC filings beginning in November 2014, six months after the acquisition. In early 2017, the company entered into a $100 million settlement and consent decree with the FTC, and its stock price fell 6 percent. Throughout the same period, the company also publicly estimated the amount of its sales covered by Medicare and Medicaid—as opposed to private insurance—at 25 percent. A third-party report questioned this, suggesting the true figure was as high as 60 percent. When the company disclosed a Medicare/Medicaid exposure figure in the mid-40s in late 2016, its stock price fell 18 percent. In late 2017, the company reported declining Acthar sales, and its stock fell 36 percent.

Investors sued, challenging three categories of statements about Acthar: (1) those about the drug's commercial durability, (2) those about its Medicare/Medicaid exposure and (3) those about its 2017 sales prospects generally and insurance coverage in particular. The court largely granted the company's motion to dismiss as to statements in the first category. Plaintiffs' theory as to those statements was that the company had misleadingly failed to disclose that its success in selling Acthar depended on anticompetitive conduct. Plaintiffs had not shown this to be the case, among other reasons, because they had not shown that, at the time of the challenged statements, Synacthen could have viably competed with Acthar; Synacthen was not yet approved in the US. The court denied the company's motion, however, as to plaintiffs' claim that the company had misleadingly omitted the impending FTC settlement in its 2016 Form 10-K. By the time it issued the 10-K, the company knew with substantial certainty that the settlement was coming. The court also largely denied the company's motion to dismiss as to statements in the second category—those estimating Medicare/Medicaid exposure at 25 percent. The company's later estimate of exposure in the mid-40s showed that the earlier statement was false. The court similarly denied the motion as to statements in the third category—positive statements about growth in light of expanding acceptance of the drug by insurers. Plaintiffs sufficiently pled facts showing that insurers were increasingly restricting coverage of the drug. And the safe harbor did not protect the statements, the court held, because the company's risk disclosures were not sufficiently specific to qualify as meaningful cautionary language.

In re Obalon Therapeutics, Inc., 2019 WL 4729461 (S.D. Cal. Sept. 25, 2019), denying in part and granting in part motion to dismiss. **Sales performance & revenue recognition**

Obalon markets and sells the Obalon Balloon, a medical device that is placed in a patient's stomach and inflated with gas as a weight loss therapy. Obalon conducted its IPO in October 2016. In its offering materials, the company described the benefits of the Balloon but also disclosed a 91 percent adverse device event rate. In June 2017, a third party published a report criticizing the device. In January 2018, Obalon announced a secondary public offering, and the company's stock price fell 34 percent following the announcement. One week later, Obalon reported that a whistleblower had submitted a complaint to the company's auditors, accusing the company of improper revenue recognition; Obalon also reported that it was canceling the secondary offering to investigate the whistleblower complaint. The company's stock price fell 33 percent. In February 2018, Obalon reported that it had completed its investigation and had concluded that the whistleblower's complaint was without merit. In May 2018, Obalon announced disappointing first-quarter earnings; the company also announced that $147,000 of revenue recognized in the fourth quarter of 2017 was being deferred until 2018. The stock price fell 34 percent.

Investors sued, challenging (1) positive statements about the Balloon's advantages, (2) positive statements about sales and (3) the company's 2017 financial statements. The court granted the company's motion to dismiss as to the first set of statements but denied the motion as to the second and third. Plaintiffs challenged the first set of statements—about the Balloon's

advantages—both under Section 10(b) and under the 1933 Act, as those statements appeared in the company's IPO registration statement. The court held that the statements were inactionable corporate puffery and that the purportedly concealed facts—about the Balloon's disadvantages—were in reality revealed to investors by means of the company's references to the 91 percent adverse device event rate. As to the favorable statements about sales, however, the court concluded that plaintiffs had adequately alleged both falsity and scienter. The company's statements suggested to investors that customers were broadly reordering Balloons after working through their initial orders, but plaintiffs had alleged facts showing that reorder sales were concentrated in a small number of customers. As to the financial statements, the court concluded that plaintiffs had adequately alleged that the company improperly failed to "defer an appropriate amount of revenue associated with certain patient lead lists offered to physicians as part of [its] year-end sales promotion." The court also concluded that plaintiffs had adequately pled scienter: The court pointed both to the whistleblower complaint and to the company's incentive to rush the calculation of fourth-quarter 2017 financial results in connection with the secondary offering. Finally, the court held that plaintiffs had adequately pled loss causation. Although the announcement of an investigation is not sufficient in itself to establish loss causation under Ninth Circuit law, plaintiffs had also pled post-investigation disclosures—the correction of $147,000 of revenue recognized in the fourth quarter of 2017 and poor results for the first quarter of 2018.

In re Restoration Robotics, Inc. Sec. Litig., 417 F. Supp. 3d 1242 (N.D. Cal. 2019), denying in part and granting in part motion to dismiss. **Sales; purported product defect**

Restoration Robotics developed and commercialized a robotic device, the ARTAS System, designed to assist physicians in performing a hair restoration procedure called follicular unit extraction surgery. Restoration generated revenue from the ARTAS System through sales of the device, post-warranty maintenance charges and a per-procedure charge that physicians were required to pay each time they used the device for a particular procedure. Because Restoration relied on per-procedure charges for most of its revenue, its sales model prioritized working with physicians to build brand awareness and to increase the overall number of procedures performed. Restoration conducted an IPO in October 2017 at $7 per share. The company announced disappointing earnings in the first and third quarters of 2018, and, by November 2018, its stock had fallen 84 percent, to $1.13 per share.

Investors brought claims under the Securities Act, challenging statements in the IPO registration statement. Specifically, plaintiffs claimed that the offering materials misled investors about the efficacy of the company's marketing in generating new procedures, the quality and design of the ARTAS System, and the number of devices available to generate revenue. The court ruled that a number of the challenged statements in the offering materials were inactionable expressions of opinion, and in any event were coupled with sufficient cautionary language related to the company's lack of commercial success to prevent those statements from misleading investors. The court also held that plaintiffs had failed to establish the existence of an undisclosed "trend" under Item 303 of Regulation S-K. The court denied the motion to dismiss, however, with respect to a statement about the company's needle technology: A confidential witness had provided plausible information that the needles in the ARTAS System were faulty and damaged hair grafts. The court also denied the company's motion to dismiss with respect to a challenged statement about the number of systems that had been installed; plaintiffs plausibly alleged that some of these systems had been sold but not actually installed.

Strougo v. Lannett Co., 2019 WL 1172992 (E.D. Pa. Mar. 13, 2019), denying in part and granting in part motion to dismiss. **Supply contract**

Lannett develops and distributes pharmaceuticals. Roughly 30 percent of Lannett's revenue came from sales of two drugs provided to Lannett by a supplier called JSP. Lannett and JSP had entered into several multi-year contracts in which Lannett paid JSP in part with Lannett stock. Over the years, Lannett had transferred approximately 15 percent of its stock to JSP in this way. The companies' most recent contract was due to expire in March 2019, and Lannett publicly discussed its efforts to negotiate an extension of the contract throughout 2018. Lannett's CEO

expressed optimism that the contract would be renewed but also emphasized that he could not speak for JSP or predict its actions. In discussing the JSP relationship, the CEO told investors that JSP had become a large shareholder of Lannett. In August 2018, Lannett announced that JSP would not be renewing its contract. Lannett's stock price fell 60 percent.

Investors sued, challenging Lannett's optimistic statements about contract renewal as well as its statements that JSP was a large shareholder. The court granted the company's motion to dismiss with respect to the challenged statements of optimism, noting that Lannett had emphasized that it could not predict JSP's actions. The court denied the motion, however, as to statements that JSP was a large shareholder. Lannett had never disclosed JSP's stockholdings in any SEC filing, and plaintiffs alleged that JSP had simply liquidated the Lannett stock it had acquired under previous contracts. The court also concluded that plaintiffs had adequately alleged that JSP's shareholder status was material: If JSP had indeed been a Lannett shareholder, it would have had an incentive to avoid outcomes (like the non-renewal of the parties' contract) that would drive Lannett's stock price down.

Ontario Teachers' Pension Plan Bd. v. Teva Pharm. Indus., Ltd., 2019 WL 4674839 (D. Conn. Sept. 25, 2019), denying in part and granting in part motion to dismiss. **Antitrust**

Teva manufactures and sells generic drugs. In the summer of 2014, the Connecticut Attorney General began investigating pricing for the generic drug digoxin and issued subpoenas to Teva's competitors. In October 2014, Congress requested information from Teva about recent generic drug price increases. In July 2015, Teva announced that it would acquire Actavis, which was Allergan's generic drug business. In June-July 2016, Teva received subpoenas from both the DOJ and the Connecticut AG seeking information about the company's generic drug pricing. Teva disclosed these subpoenas on August 4, 2016, along with poor financial results from the second quarter of 2016. Teva's stock price declined. On November 3, 2016, *Bloomberg* published an article about the DOJ and Connecticut AG probes, noting that Teva was being investigated. Teva's stock price dropped 9 percent. On December 15, 2016 the Connecticut AG announced that it was bringing claims against Teva for antitrust violations. In early 2017, Teva reported disappointing financial results; in August 2017, Teva took a $6.1 billion charge against its U.S. generic drug business. Teva's stock price fell further.

Investors sued, challenging statements related to generic drug pricing trends and the competitiveness of the generic drug market. Plaintiffs also challenged the company's failure to disclose subpoenas on receipt. The court largely denied the company's motion to dismiss. The court held that plaintiffs had adequately pled falsity as to Teva's statement that the generic drug market was "very competitive": The facts plaintiffs pled were sufficient to establish as a pleading matter that Teva was colluding with its competitors. In the same vein, plaintiffs adequately pled falsity as to Teva's comments on its financial performance: Teva failed to disclose that its success was due in part to collusion. Plaintiffs also adequately pled scienter with respect to both sets of statements: Plaintiffs alleged that Teva's executives approved plans to generate profit based on collusive price increases. But the court rejected plaintiffs' claim that the company wrongly failed to disclose its receipt of government subpoenas. The securities laws do not require a company to accuse itself of wrongdoing or to predict the outcome of investigations. The court denied defendants' motion to dismiss plaintiffs' Securities Act claims with respect to the same statements that survived the motion to dismiss the Section 10(b) claims.

In re Allergan Generic Drug Pricing Sec. Litig., 2019 WL 3562134 (D.N.J. Aug. 6, 2019), denying motion to dismiss. **Antitrust**

Allergan acquires, develops and markets a variety of drugs. Until August 2016, Allergan sold generic drugs through its subsidiary, Actavis Pharma, which was then acquired by Teva. On August 5, 2015, Allergan disclosed that it had received a subpoena from the DOJ seeking information related to the marketing and pricing of its generic drugs and to communications with competitors about those drugs. Allergan's stock dropped 5 percent. On November 3, 2016, *Bloomberg* reported that criminal charges were expected in connection with the DOJ's investigation into generic drug pricing. Allergan's stock again fell 5 percent.

Investors sued, alleging that Allergan had misled the market about its generic drug business. Plaintiffs challenged statements about the company's work in the generic drug industry, statements about the company's financial performance and statements about the DOJ investigation. Plaintiffs also challenged the company's Sarbanes-Oxley certifications and codes of conduct. The court denied the company's motion to dismiss as to all categories of challenged statements. The court held that plaintiffs had adequately pled that statements about competition in the generic drug industry and statements about the company's performance and pricing strategy were misleading by omission. The omitted fact was that the company was purportedly engaged in antitrust violations, and plaintiffs had adequately established those violations for pleading purposes by means of specific references, drawn from a state attorney general complaint, to collusive communications between Allergan and its competitors (among other things). Plaintiffs had also adequately pled falsity as to the company's statements that the DOJ investigation was a "red herring" and "not that significant"; again, plaintiffs had alleged facts sufficient to show as a pleading matter that the company was engaged in anticompetitive activities. Statements of income, Sarbanes-Oxley certifications and codes of conduct were actionable for the same reasons. The court also concluded that plaintiffs had adequately pled scienter, based on the facts that Allergan is a defendant in government antitrust investigations and litigation, that Allergan downplayed the seriousness of the DOJ investigation, and that the purported wrongdoing related to Allergan's then-core business.

Utesch v. Lannett Co., 385 F. Supp. 3d 408 (E.D. Pa. 2019), denying motion to dismiss. **Antitrust**

Lannett manufactures generic drugs. In July 2014, Lannett announced that it had received an inquiry from the Connecticut Attorney General regarding the pricing of its generic drug digoxin. Lannett's stock price fell 21 percent. In December 2014, the company disclosed that it had been served with a grand jury subpoena related to the DOJ's investigation of the generic drug industry. Lannett's share price fell 12 percent. In November 2016, *Bloomberg* and other media reported that criminal charges were expected in connection with the DOJ's investigation into generic drug pricing; Lannett was mentioned in the article. Lannett's stock price fell an additional 27 percent.

Investors sued, challenging statements and purported omissions related to the competitiveness of pricing in the generic drug industry and to the possible effect on the company of government investigations and antitrust actions. In a 2018 decision (reported in our review last year), the court granted defendants' motion to dismiss, holding that plaintiffs' allegations of scienter were deficient. In a 2019 decision on an amended complaint, the court denied the defendants' motion to dismiss. The court held that plaintiffs had adequately pled that statements about competition were false or misleading by means of their allegations about price spikes, media coverage of price increases, government investigations and defendants' own communications with competitors. The court rejected defendants' argument that plaintiffs failed to adequately allege that Lannett itself participated in collusive activities. The court held that, as long as plaintiffs could allege facts showing that Lannett knew that the generic drug market was anticompetitive—and plaintiffs had done this—plaintiffs were not further required to show that Lannett itself took anticompetitive actions. The court also held that plaintiffs had adequately pled scienter. The court pointed to the ongoing investigations into generic drug price fixing and invoked the core operations inference (among other factors). The court finally rejected defendants' loss causation argument, which was based on the premise that stock price drops following the announcement of investigations reflect mere market speculation about whether fraud may have occurred.

In re Mylan N.V. Sec. Litig., 379 F. Supp. 3d 198 (S.D.N.Y. 2019), denying in part and granting in part motion to dismiss. **Antitrust; Medicaid rebates**

Mylan develops and manufactures both brand-name and generic pharmaceuticals, including the EpiPen Auto-Injector. Mylan classified the EpiPen as a non-innovator multiple source drug; this is a favorable classification for companies under the Medicaid Drug Rebate Program, which requires drug companies to give certain rebates to the Centers for Medicare and Medicaid Services. In 2009, CMS told Mylan that it had misclassified the EpiPen and that Mylan would likely need to begin paying a higher rebate rate under the appropriate classification. In 2014,

Mylan received a subpoena from the DOJ regarding an investigation into whether the EpiPen was properly classified. In October 2016, Mylan announced that it had entered into a $465 million settlement with the DOJ that required it to reclassify the EpiPen. Mylan was also subject to several DOJ, Congressional and state investigations into potentially anticompetitive practices in the generic drug market.

Investors sued, alleging that Mylan had misled shareholders as to both its misclassification of the EpiPen and its alleged anticompetitive activity. Plaintiffs claimed that Mylan was involved in price-fixing agreements for generic drugs, a "pay for delay" clause in a settlement agreement, and exclusive dealing arrangements with schools. Plaintiffs challenged statements related to Mylan's sources of income, its explanations of market conditions, rebate rates and regulatory risk, and its claimed adherence to its codes of conduct and business ethics. In a 2018 decision (reported in our review last year), the district court granted defendants' motion to dismiss as to opinion statements about the general complexity and subjectivity of the regulatory environment, and statements in the company's code of business ethics, but otherwise denied the motion.

Investors then filed an amended complaint in which they alleged that Mylan was engaged in price fixing with respect to three new generic drugs and had also engaged in anticompetitive conduct to protect the EpiPen from competition. Plaintiffs alleged that this conduct rendered statements related to Mylan's compliance with U.S. antitrust laws and the competitive nature of the generic drug market misleading. Defendants moved to dismiss these new allegations. The court denied the motion as to plaintiffs' new EpiPen allegations, holding that plaintiffs had adequately pled a monopolization under Section 2 of the Sherman Act. The court granted the motion to dismiss as to the three new generic drugs, holding that plaintiffs had failed to adequately allege the existence of a price-fixing agreement as to those drugs.

Evanston Police Pension Fund v. McKesson Corp., 411 F. Supp. 3d 580 (N.D. Cal. 2019), denying in part and granting in part motion to dismiss. **Antitrust**

McKesson is a wholesaler and distributor of generic and branded drugs. In 2013 and 2014, a number of drug manufacturers increased the list prices of certain generic drugs. McKesson updated the market on the impact of the manufacturers' drug price increases on the company's business. By 2015, generic price inflation had moderated, and the company disclosed this development to investors as well. In January 2016, McKesson announced that it expected only nominal price increases in generic drugs in the year to come. The company's stock price fell. In November 2016, Bloomberg and other media reported that the DOJ was expected to bring charges by year-end against a number generic drug manufacturers it was investigating. McKesson's stock price again fell.

Investors sued, challenging statements related to increased generic drug prices, McKesson's value to its customers, the competitiveness of the generic drug market, McKesson's financial results and explanations for those results, and a McKesson subsidiary that operates in certain respects like a drug manufacturer. Plaintiff advanced two distinct theories: that McKesson was itself a part of the manufacturers' alleged price-fixing conspiracy and that McKesson merely knew about the conspiracy. The court rejected the first theory, concluding that the more plausible inference was that McKesson was a victim of, not a participant in, the alleged conspiracy. But the court allowed plaintiff to proceed on the second theory with respect to three of the six categories of challenged statements: those related to supply disruptions, to the competitiveness of the generic drug market, and to McKesson's explanation of its financial results (to the extent that explanation put generic drug prices at issue). The court held that plaintiff had adequately pled falsity as to these statements in light of detailed allegations about the manufacturers' allegedly collusive activities drawn from attorney general complaints. The court also held that plaintiff had adequately alleged scienter based on the core operations inference and on allegations about the company's access to detailed pricing information. The court finally held that plaintiff had adequately pled loss causation based in part on the same November 3, 2016 Bloomberg article at issue in several other securities cases against generic drug manufacturers. On a motion for reconsideration, the court clarified that plaintiff had adequately pled loss causation as to only two of four alleged corrective disclosure dates.

Decisions
Post-Approval

TABLE OF NEW FILINGS IN 2019

In 2019, 44 new securities fraud class actions were filed against life sciences companies.[14] This is a slight drop-off from the numbers of new complaints in the last few years, but still above what we saw in years preceding 2016:

2014 42 new complaints
2015 39 new complaints
2016 50 new complaints
2017 54 new complaints
2018 48 new complaints

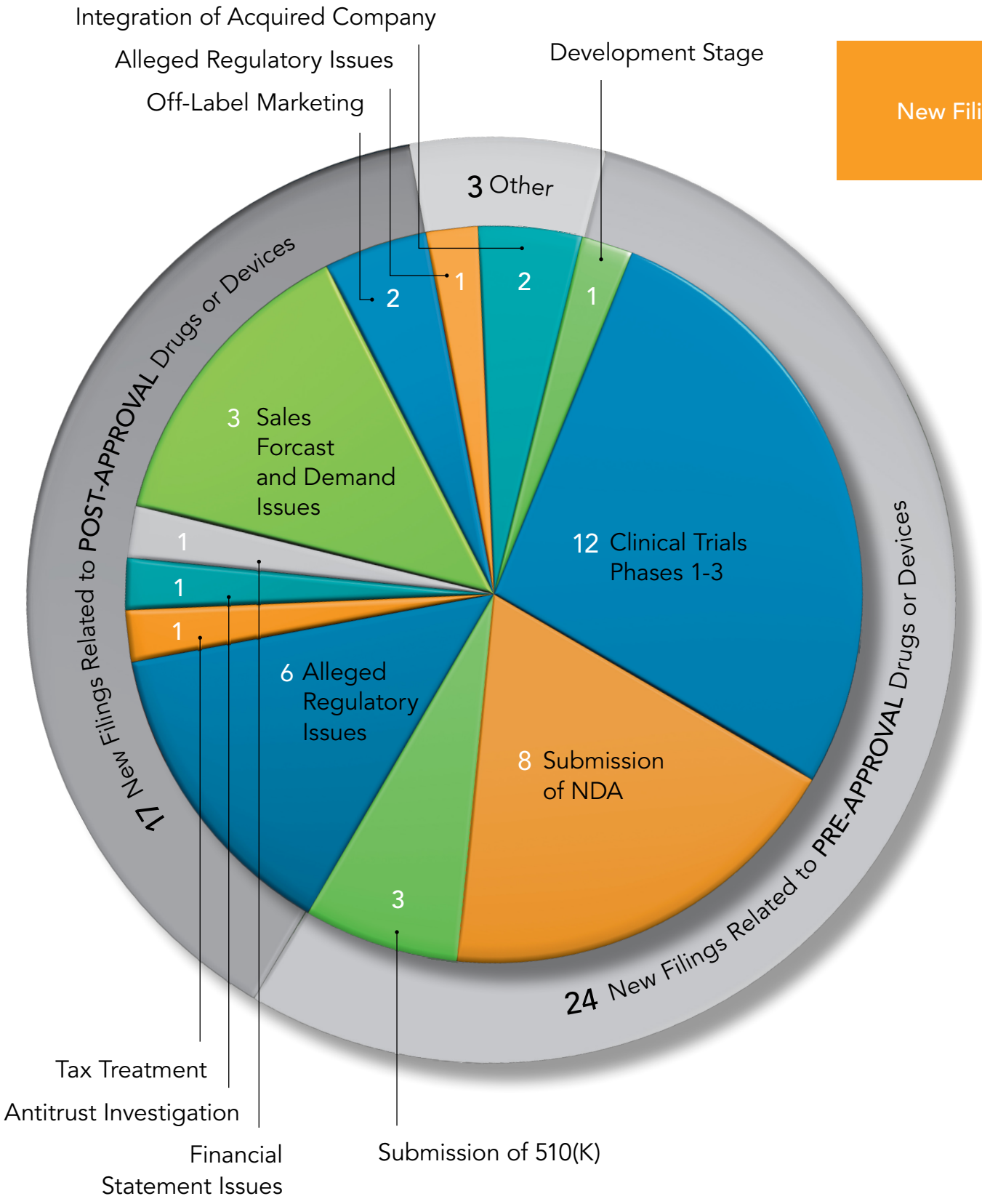
Of the new actions filed in 2019, 24 were filed against companies with development-stage drugs or devices. The remaining 20 actions involve a broad spectrum of regulatory and non-regulatory issues with mature products, ranging from alleged regulatory violations marketing to alleged financial statement fraud to issues concerning sales forecasting and performance.

Several trends emerge from the new filings. The most significant change from 2018 to 2019 came in the number of new filings in the pre-approval area, which increased from 16 to 24. Meanwhile, actions in the post-approval area have decreased—most notably, actions involving alleged financial statement irregularities.

As in previous years, the new filings are clustered in district courts in the Second, Third and Ninth Circuits. We show the breakdown graphically on page 44.

PRODUCT LIFECYCLE		SECURITIES FRAUD CLASS ACTIONS FILED IN 2019
PRE-APPROVAL	Development Stage	1
	Clinical Trials: Phases 1–3	12
	Submission of NDA	8
	Submission of 510(k)	3
	Total Pre-Approval	24
POST-APPROVAL	Alleged Regulatory Issues	6
	Antitrust Investigation	1
	Financial Statement Issues	1
	Tax Treatment	1
	Sales Forecast and Demand Issues	6
	Off-Label Marketing	2
	Total Post-Approval	17
OTHER	Alleged Regulatory Issues	1
	Integration of Acquired Company	2

14 We take this figure and list of actions from the Stanford Law School Securities Class Action Clearinghouse. The list includes those cases categorized by Cornerstone Research as within the "healthcare sector" but excludes M&A litigation and cases involving hospital management issues unrelated to any drug or medical device. The list also excludes cannabis-related litigation involving issues unrelated to FDA approval of a drug or product. Those cases are outside the scope of our analysis.


Integration of Acquired Company
Alleged Regulatory Issues
Off-Label Marketing
Development Stage
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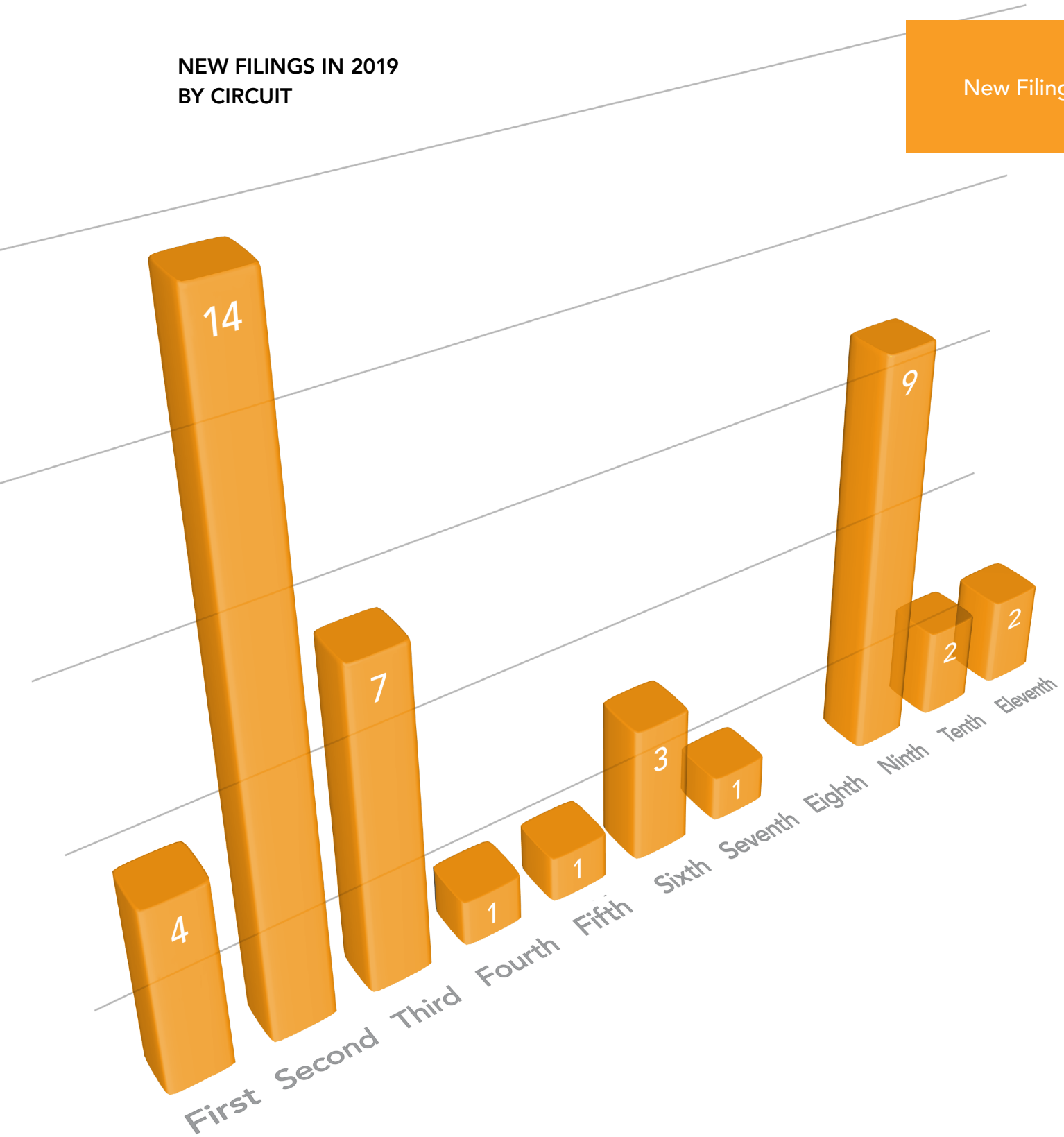

COMPANY	DATE	COURT
OASMIA PHARMACEUTICAL AB	9/29/2019	E.D.N.Y.
TYME TECHNOLOGIES, INC.	1/28/2019	S.D.N.Y.
CORBUS PHARMACEUTICAL HOLDINGS, INC.	3/12/2019	D. Mass.
KARYOPHARM THERAPEUTICS INC.	7/23/2019	D. Mass.
NEKTAR THERAPEUTICS	8/19/2019	N.D. Cal.
ZYNERBA PHARMACEUTICALS, INC.	10/23/2019	E.D. Pa.
MALLINCKRODT PUBLIC LIMITED COMPANY	7/26/2019	S.D.N.Y.
DBV TECHNOLOGIES S.A.	1/15/2019	D.N.J.

SUMMARY OF ALLEGATIONS

DEVELOPMENT STAGE Oasmia is a development stage biopharmaceutical company focusing on human and animal oncology. Plaintiffs allege that Oasmia's financial statements are false and misleading because certain of Oasmia's officers caused the company to engage in related party transactions. Stock prices fell after Oasmia reported that it had ended its relationship with certain officers and filed a police report against them.

PHASE 2 Tyme Technologies develops SM-88, an oncology therapy. Plaintiffs claim that the company's Phase 2 trial design was defective and did not include an appropriate control group. Stock prices fell after the company reported Phase 2 results.

PHASE 2 Corbus develops lenabasum, a drug designed to treat inflammatory and fibrotic diseases. Plaintiffs challenge the company's report of topline data from a Phase 2 trial. Stock prices fell after Seeking Alpha published an article noting that lenabasum may have failed every previous clinical trial.

PHASE 2 Karyopharm develops and markets drugs for the treatment of cancer and other major diseases. Plaintiffs challenge the company's report of Phase 2 trial results for the drug Selexinor, alleging that the company misrepresented the drug's safety profile. Stock prices fell after the FDA released a briefing document raising issues about the drug's safety and efficacy.

PHASE 2 Nektar is developing NKTR-214, an immuno-oncology drug. Nektar announced a manufacturing issue in August 2019; plaintiffs claim that the company should have disclosed the issue earlier. Nektar's stock price fell after the company disclosed the manufacturing issue.

PHASE 2 Zynerba develops cannabinoid therapies including Zygel, a transdermal gel for the treatment of epileptic encephalopathies, fragile X syndrome, and autism spectrum disorder. Plaintiffs allege that the company failed to disclose that Zygel was proving unsafe and not well tolerated in a Phase 2 trial. Stock prices fell after the company issued a press release reporting two serious adverse events possibly related to Zygel.

PHASE 2B Mallinckrodt develops, manufactures, markets, and distributes specialty pharmaceuticals, including Acthar, an injectable drug approved for the treatment of various neurological and autoimmune disorders. The company conducted a Phase 2B trial testing the drug as a treatment for ALS. Plaintiffs allege that the company failed to disclose safety concerns that rendered the drug non-viable as an ALS treatment. Stock prices fell after Mallinckrodt announced that it was discontinuing trials of Acthar as a treatment for ALS.

PHASE 3 DBV Technologies developed Viaskin Peanut, an immunotherapy product intended to treat peanut allergies. Plaintiffs allege that the company failed to disclose that its Biologics License Application did not provide the FDA with sufficient information about manufacturing and quality controls. Stock prices fell after the company issued a press release announcing that it had withdrawn its BLA for Viaskin Peanut.

COMPANY	DATE	COURT
LEXICON PHARMACEUTICALS, INC.	1/28/2019	S.D. Tex.
AMARIN CORPORATION PLC	2/22/2019	D.N.J.
AVEO INC.	2/25/2019	D. Mass.
MACROGENICS, INC.	9/13/2019	D. Md.
ABEONA THERAPEUTICS INC.	11/1/2019	S.D.N.Y.
ZOGENIX, INC.	4/12/2019	N.D. Cal.
TELIGENT, INC.	4/15/2019	S.D.N.Y.
NABRIVA THERAPEUTICS PLC	5/8/2019	S.D.N.Y.

SUMMARY OF ALLEGATIONS

PHASE 3 Lexicon develops sotagliflozin for the treatment of type 1 and type 2 diabetes. Plaintiffs allege that the company concealed increases of diabetic ketoacidosis associated with the drug in a Phase 3 trial, and failed to disclose that the FDA had warned the company not to use the endpoint it had chosen for the trial. Stock prices fell after the FDA announced that an Advisory Committee was deadlocked on approval of the drug, and fell further when the FDA issued a Complete Response Letter stating that it would not approve sotagliflozin.

PHASE 3 Amarin develops Vascepa, a drug intended to treat heart disease. Plaintiffs allege that the company failed to disclose that a placebo used in a Phase 3 trial for Vascepa may have skewed results, leading the company to overstate the drug's efficacy. Amarin's stock price fell after heart experts published articles questioning Amarin's use of the placebo.

PHASE 3 Aveo's lead drug candidate is tivozanib, an oral medication for the treatment of renal cell carcinoma. Plaintiffs allege that Aveo failed to disclose that a Phase 3 trial of tivozanib was yielding insufficient efficacy data. Stock prices fell after Aveo announced that it would not submit an NDA based on current Phase 3 results.

PHASE 3 Macrogenics develops antibody-based cancer treatments, including the drug candidate margetuximab. Plaintiffs allege that the company failed to disclose adverse facts regarding the company's Phase 3 trial for the drug. Stock prices fell after the company disclosed Phase 3 trial results.

PHASE 3 Abeona develops cell and gene therapies for rare diseases; the company's lead product is EB-101, a gene-corrected cell therapy for a genetic skin disease. Plaintiffs allege that Aboena failed to disclose inadequate chemical, manufacturing and controls during Phase 3 trials, the result of which was that the company was unable to provide the FDA with sufficient data regarding transport stability. Stock prices dropped after the FDA issued a clinical hold.

NDA Zogenix develops ZX008, a drug intended to treat epilepsy-related seizures. In its NDA for the drug, the company did not incorporate publicly available data for fenfluramine, the drug's core ingredient. Plaintiffs allege that the company omitted to disclose this defect in its NDA. Stock prices fell after the FDA issued a refuse to file letter.

NDA Teligent manufactures generic drugs. Plaintiffs allege that the company's statements about its record of compliance with FDA regulations were false and misleading in light of compliance failures at the company's facilities. Stock prices fell after Teligent disclosed a decline in its pipeline for submission of applications to the FDA for approval to market generic drugs.

NDA Nabriva develops anti-infective agents to treat serious infections; in 2018, the company submitted an NDA for Contepo, an antibiotic designed to treat urinary tract infections. Plaintiffs allege that the company's statements about its NDA were false or misleading in light of issues at the facilities where the drug was manufactured. Stock prices fell after Nabriva disclosed that the FDA did not approve the Contepo NDA.

COMPANY	DATE	COURT
HERON THERAPEUTICS, INC.	6/3/2019	S.D. Cal.
ACER THERAPEUTICS INC.	7/1/2019	S.D.N.Y.
SAREPTA THERAPEUTICS, INC.	8/30/2019	S.D.N.Y.
LIPOCINE INC.	11/14/2019	D. Utah
CORREVIO PHARMA CORP.	12/12/2019	S.D.N.Y.
APYX MEDICAL CORPORATION F/K/A/ BOVIE MEDICAL CORPORATION	4/17/2019	M.D. Fla.
HELIUS MEDICAL TECHNOLOGIES, INC.	7/9/2019	S.D.N.Y.
ELECTROCORE, INC.	9/26/2019	D.N.J.

SUMMARY OF ALLEGATIONS

NDA Heron develops HTX-011, a local anesthetic for post-operative pain management. Plaintiffs allege that the company failed to include adequate chemistry, manufacturing, and controls and non-clinical information in its NDA for HTX-011, and further failed to disclose this defect to investors. Stock prices fell after Heron reported that the FDA did not approve its NDA for HTX-011.

NDA Acer developed a drug for the treatment of a rare genetic disorder, vascular Ehlers-Danlos syndrome (EDS). Plaintiffs allege that Acer made false or misleading statements about the likelihood of FDA approval. Stock prices fell after the FDA issued a complete response letter requiring additional clinical trials to assess efficacy.

NDA Sarepta develops genetic medicine therapies for the treatment of rare diseases. Plaintiffs allege that Sarepta made materially false and misleading statements about the safety of its drug Golodirsen and the likelihood of FDA approval. Stock prices fell after the FDA issued a complete response letter raising concerns about renal toxicity.

NDA Lipocine's lead product candidate is Tlando, a testosterone replacement therapy. Plaintiffs allege that clinical trial results were insufficient to demonstrate efficacy, and challenge the company's statements about the likelihood of FDA approval. Stock prices fell after the FDA issued a complete response letter denying approval on efficacy grounds.

NDA Correvio develops Brinavess, a drug intended to treat atrial fibrillation. Plaintiffs challenge the company's statements about the data supporting a resubmitted NDA and the likelihood of FDA approval. Stock prices fell after FDA staffers said in a briefing document that they did not believe the drug's benefits outweighed its risks, and fell further after an Advisory Committee voted against approval.

SUBMISSION OF 510(K) Apyx sells a plasma surgical product called J-Plasma. Plaintiffs allege that the company failed to disclose that the drug failed to reach its endpoint in a clinical study of J-Plasma for reducing wrinkles, and that one of the trial sites failed to comply with the trial protocol. Stock prices fell when a research analyst published a report claiming that Apyx did not publicly release its study results because the study had failed, and fell further when the company announced that it had withdrawn its application for regulatory clearance.

SUBMISSION OF 510(K) Helius developed the Portable Neuromodulation Stimulator (PoNS) for the treatment of symptoms of traumatic brain injuries. Plaintiffs allege that Helius made materially false or misleading statements about the likelihood of FDA approval. Stock prices fell after Helius disclosed that the FDA had denied regulatory clearance due to the lack of clinical data supporting efficacy.

SUBMISSION OF 510(K) ElectroCore's lead product, GammaCore is used to treat migraines and episodic headaches. Plaintiffs allege that the company failed to disclose that GammaCore had no advantages over other migraine treatments and that FDA approval was unlikely. Stock prices fell after the company disclosed the FDA's request for more information and analysis of clinical data.

COMPANY	DATE	COURT
VANDA PHARMACEUTICALS INC.	2/25/2019	E.D.N.Y.
CORCEPT THERAPEUTICS INCORPORATED	3/14/2019	N.D. Cal.
INDIVIOR PLC: AMERICAN DEPOSITARY SHARES	4/23/2019	D.N.J.
BOSTON SCIENTIFIC CORPORATION	4/24/2019	D. Mass.
RA MEDICAL SYSTEMS, INC.	6/7/2019	S.D. Cal.
ACLARIS THERAPEUTICS, INC.	7/30/2019	S.D.N.Y.

SUMMARY OF ALLEGATIONS

POST APPROVAL: OFF-LABEL MARKETING Vanda sells approved drugs to treat both schizophrenia and circadian rhythm disorder. Plaintiffs allege that the company made false or misleading statements about off-label promotion of both drugs. Plaintiffs also allege that the company failed to disclose that the FDA had required a non-rodent safety study Vanda's drug candidate tradipitant, and that the company was unwilling to conduct that study. Vanda's stock price fell after a short seller accused the company of off-label marketing and after the company disclosed the absence of the tradipitant safety trial.

POST-APPROVAL: OFF-LABEL MARKETING Corcept markets Korlym, a drug approved to treat a subset of patients with endogenous Cushing's Syndrome. Plaintiffs allege that the company failed to disclose a purported off-label marketing scheme for Korlym. Stock prices fell after an investment firm issued a report criticizing off-label use of Korlym.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Indivior develops, manufactures, and sells drugs to treat opioid dependence. Plaintiffs allege that the company made false or misleading statements about suboxone film, claiming that it was safer for children, less divertible, and less likely to be abused than other drugs used to treat opioid dependence. Stock prices fell after the company increased its budget for litigation, and fell further after the DOJ filed a grand jury indictment charging the company with conspiracy to commit multiple counts of fraud related to its statements about suboxone film.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Boston Scientific develops, manufactures, and sells transvaginal surgical mesh products. Plaintiffs allege that the company made false and misleading statements about the safety and quality of these products. Stock prices fell when the FDA announced that it had ordered manufacturers to stop selling and distributing the products.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Ra Medical Systems sells a laser-based platform to treat vascular and dermatological inflammatory diseases. Plaintiffs challenge statements in the company's registration statement, claiming that the company failed to disclose purported inadequacies in its evaluation of and training program for sales force candidates, and that the company's manufacturing process could not support increased production. Stock prices fell when the company revealed that hiring and training issues and production limitations had had a negative impact on financial results.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Aclaris develops and markets products in aesthetic dermatology, including a topical treatment for a type of benign skin lesion. Plaintiffs allege that the company made false or misleading statements about the efficacy and side effects of the treatment, including statements made during a staged television interview. Stock prices fell following public disclosure of a letter from the FDA stating that the interview segment omitted information about risks associated with the treatment.

COMPANY	DATE	COURT
MYRIAD GENETICS	9/27/2019	D. Utah
MYLAN N.V.	12/16/2019	W.D. Pa.
BAXTER INTERNATIONAL INC.	11/25/2019	N.D. Ill.
AXOGEN, INC.	1/9/2019	M.D. Fla.
INOGEN, INC.	3/6/2019	C.D. Cal.
INTERSECT ENT, INC.	5/15/2019	N.D. Cal.
ABIOMED, INC.	8/6/2019	S.D.N.Y.

SUMMARY OF ALLEGATIONS

POST-APPROVAL: ALLEGED REGULATORY ISSUES Myriad develops and markets genetic lab tests. Plaintiffs allege that Myriad made false statements regarding the validity of one of its tests and failed to disclose FDA communications on the subject. Stock prices fell after the company disclosed the FDA communications in its Form 10-K, and fell after the company disclosed that revenue for another of its tests was overstated.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Mylan manufactures generic drugs. Plaintiffs allege the company failed to disclose that one of its facilities was in violation of the FDA's Current Good Manufacturing Practice regulations, that the company would need to restructure, that the company's primary segment would be substantially impacted by the restructuring, and that the company lacked effective internal controls over its financial reporting. Stock prices fell after the company disclosed a restructuring and remediation program at the facility.

POST-APPROVAL: FINANCIAL STATEMENT ISSUES Baxter provides healthcare products for use in hospitals as well as for nutritional and renal care. Plaintiffs allege that Baxter lacked effective internal controls and that its financial statements were false or misleading insofar as the company had engaged in intra-company transactions using an improper foreign exchange rate calculation. Stock prices fell after the company disclosed that its Audit Committee was investigating these issues.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Axogen sells the Avance Nerve Graft, a segment of nerve tissue that can support nerve regeneration. Plaintiffs allege that the company made false or misleading statements about the size of the market for its products. Stock prices fell after an investment firm published a report claiming that the market was a fraction of what Axogen had claimed.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Inogen manufactures portable oxygen concentrators. Plaintiffs allege that the company convinced customers to rent its products at a premium retail price rather than using their Medicare or private insurance benefits, and that the company overstated the size and potential growth of the market for its products. Stock prices fell after Inogen announced slower sales growth, and fell again after analysts reported on the company's sales practices and the company disclosed additional information about its expected growth rate.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Intersect develops products for ear, nose and throat conditions, including implants used in sinus surgery. Plaintiffs claim that the company failed to disclose that it was deeply discounting prices at the ends of quarters, and that this sales practice was unsustainable. Stock prices fell after Intersect lowered its revenue guidance, and fell again after the company announced disappointing financial results.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Abiomed designs, manufactures, and sells medical devices that assist or replace the pumping function of the human heart. Plaintiff alleges that Abiomed failed to disclose a trend of declining revenue growth, and failed to disclose that it had no plan to reverse that trend. Stock prices fell after the company revised its revenue guidance downward for fiscal year 2020.

COMPANY	DATE	COURT
VIEWRAY, INC.	9/13/2019	N.D. Ohio
ADAMAS PHARMACEUTICALS, INC.	12/10/2019	N.D. Cal.
PERRIGO COMPANY PLC SECURITIES LITIGATION	1/3/2019	S.D.N.Y.
TEVA PHARMACEUTICAL INDUSTRIES LTD.	6/21/2019	E.D. Pa.
SMILEDIRECTCLUB, INC.	10/2/2019	E.D. Mich.
CARDINAL HEALTH, INC.	8/1/2019	S.D. Ohio
MERIT MEDICAL SYSTEMS, INC.	12/3/2019	C.D. Cal.

SUMMARY OF ALLEGATIONS

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES ViewRay manufactures a medical device for MRI-guided radiation therapy in cancer treatment. Plaintiff alleges that ViewRay overstated its installation backlog and failed to disclose declining demand for its products due in part to changes in Medicare reimbursement practices. Stock prices fell after ViewRay announced that it would miss guidance due in part to distributors not fulfilling their orders, and fell further after the company disclosed low number of new orders added to its backlog.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Adamas' primary product is Gocovri, which is used to treat a form of dyskinesia. Plaintiffs allege that Adamas made false or misleading statements about insurance coverage for the product and acceptance of the product by managed care entities. Stock prices fell after the company revised its prescription growth estimates downwards.

POST-APPROVAL: TAX TREATMENT Perrigo is a pharmaceutical company domiciled in Ireland for tax purposes. Plaintiffs allege that Perrigo failed to timely disclose its exposure to a $2 billion tax liability related to royalties for a multiple sclerosis drug. Stock prices fell after the company disclosed a tax assessment.

POST-APPROVAL: ANTITRUST INVESTIGATION Teva manufactures generic drugs. Plaintiffs allege that the company colluded to fix drug prices and failed to disclose the extent of its antitrust exposure. Stock prices fell after State Attorneys General filed an amended complaint accusing the company of antitrust violations.

OTHER: ALLEGED REGULATORY ISSUES SmileDirectClub sells clear aligner dental treatments directly to consumers. Plaintiffs allege that the company overstated the efficacy of the product in its registration statement and failed to disclose that administrative personnel rather than dentists provide treatment—which exposes the company to scrutiny for the unauthorized practice of dentistry. Stock prices fell after dentists, orthodontists and consumers filed a consumer fraud class action against the company.

OTHER: INTEGRATION OF ACQUIRED COMPANY Cardinal, which sells drugs and healthcare services, purchased Cordis, a medical device manufacturer. Plaintiffs allege that Cardinal told investors that the acquisition was a success but failed to disclose inventory and supply chain issues at Cordis. Stock prices fell after Cardinal reported weak earnings and lowered earnings guidance, due in part to write-offs for excess inventory at Cordis.

OTHER: INTEGRATION OF ACQUIRED COMPANY Merit, which manufactures of disposable medical devices, acquired three companies in 2018. Plaintiffs challenge the company's positive statements about the integration of these new subsidiaries. Stock prices fell after Merit announced disappointing financial results and fell further after the company issued lowered revenue and EPS guidance and disclosed issues in integrating the acquired companies.

ABOUT THE PRACTICE

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. 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 and 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.

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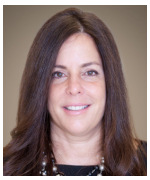

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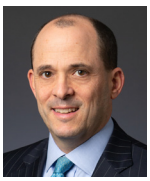

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