SIDLEY

SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

2022 ANNUAL SURVEY

TALENT. TEAMWORK. **RESULTS.**

The authors of this report are Robin Wechkin, Sarah Hemmendinger, Francesca Brody, Sara Brody and Matt Dolan. Robin is a counsel and the others are partners in the firm's Securities and Shareholder Litigation practice area. All represent life sciences companies and related individuals in securities and shareholder litigation, investigations and regulatory enforcement proceedings.
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Introduction and Overview

Securities Class Actions in the Life Sciences Sector

2022 Annual Survey

INTRODUCTION AND OVERVIEW

This year-in-review survey addresses developments in securities class actions brought against life sciences companies in 2022. We begin with an overview and analysis of trends in decisions involving life sciences companies. We then provide summaries of the year's 35 federal district court and appellate court decisions. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2022.

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 two 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 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, Establishment Inspection Reports, Warning Letters.

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

NON-REGULATORY ISSUES

Financial Forecasting and Performance

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 "strong," "cogent" and "compelling" inference that the company made deliberately false statements.[1]

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

DECISIONS ISSUED IN 2022: TRENDS AND ANALYSIS

In this section, we discuss trends in the reported federal decisions issued in securities actions at the pleading stage (or in one case, at summary judgment). 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 2022. Companies' success rate in 2022 was 52%, a decrease from the past three years.

2019: Companies won dismissal in 23 of the 37 decisions issued by the district courts, or 62%.

2020: Companies won dismissal in 20 of the 35 decisions issued by the district courts, or 57%.

2021: Companies won dismissal in 19 of the 33 decisions issued by the district courts, or 58%.

2022: Companies won dismissal in 15 of the 29 decisions issued by the district courts, or 52%.[3]

In 2021, the success rate in district courts was similar for companies with pre-approval drugs or devices and those with post-approval products: Companies prevailed in 59% of the pre-approval cases (ten out of 17) and 56% of the post-approval cases (nine out of 16).

In 2022, we saw a return to the more normal division between success rates in pre-approval and post-approval cases. In 2022, companies prevailed in close to 60% of the pre-approval cases (11 out of 19) but only 40% of the post-approval cases (four out of ten).

Companies fared well in the appellate courts in 2022, with affirmance of dismissal in all six cases. Five of the six appellate decisions addressed setbacks in the drug development process.

As we discuss more fully below, the volume of new filings in 2022 fell noticeably. In 2022, we saw 37 new securities class actions filed against life sciences companies, compared to filings in the mid to high forties in prior years.

2018–48 new complaints

2019–44 new complaints

2020–45 new complaints

2021–49 new complaints

2022–37 new complaints

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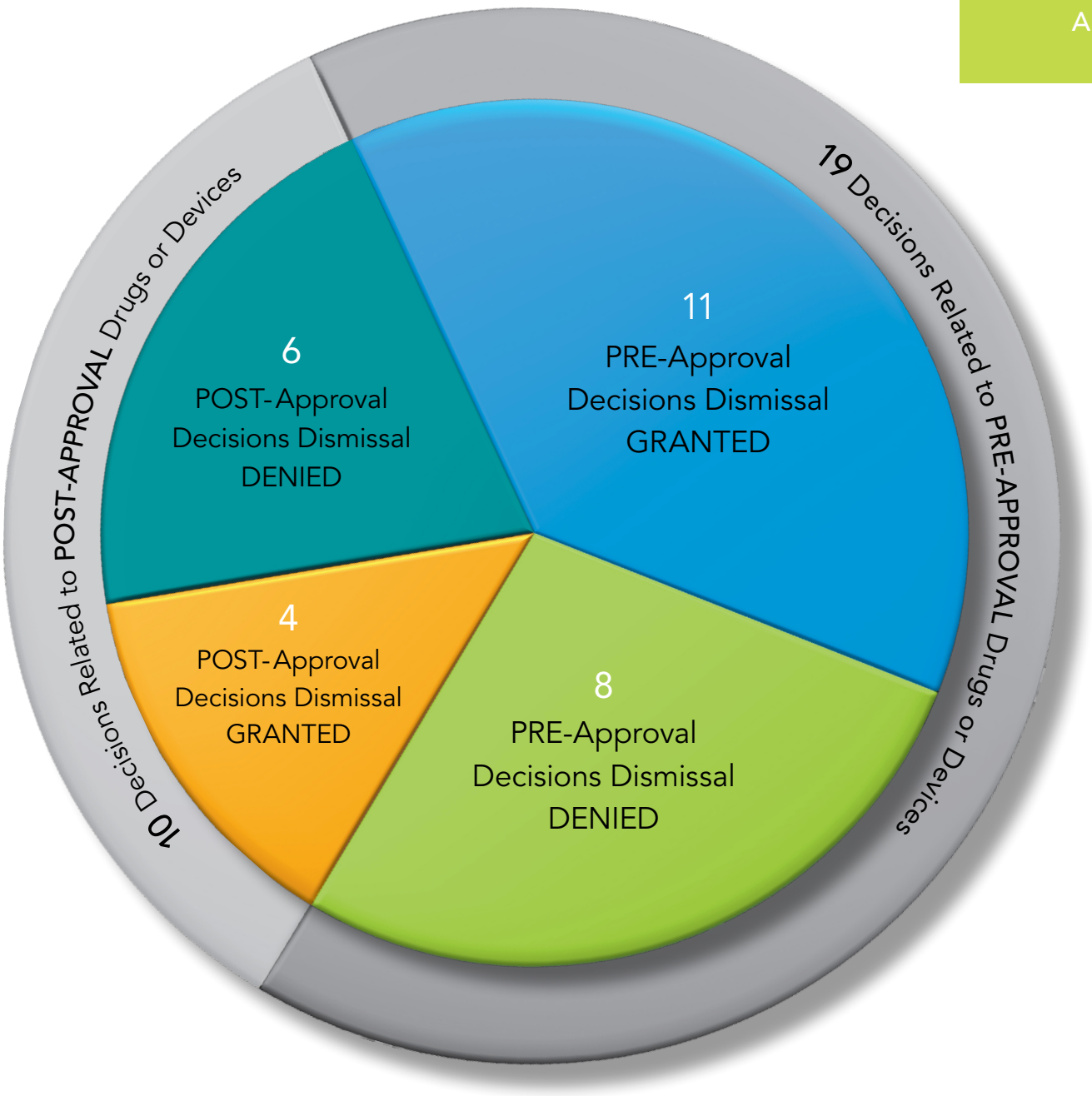
2 Under Section 10(b) (15 U.S.C. § 78j(b)), life sciences companies and their officers may be liable for consciously false or misleading statements they make in virtually any public context, including press releases, earnings calls, investor conferences, and SEC filings. Defendants may also be liable 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, 77*l*). 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.



DISTRICT COURT DECISIONS

PRE-APPROVAL DECISIONS

Companies with development-stage products had the edge in the district courts, winning motions to dismiss in 60% of the cases. Companies also prevailed in each of the five appeals. We discuss substantive developments in three areas.

First, we discuss district courts' treatment of cases filed against companies developing COVID-19 products. Companies prevailed in four of the five cases, a better success rate than we saw in the 2021 COVID-19 cases (two of four). The courts in 2022 parsed falsity allegations strictly, and were notably open to arguments that optimistic statements about the prospects for approval in the early days of the pandemic were forward-looking or non-actionable puffery. Several of the cases also bear the hallmarks we observed last year: extraordinary volatility over very short class periods as the terrain shifted rapidly in a new and confusing era.

We next turn to three appellate decisions in cases against companies with oncology or immuno-oncology products. The factual scenarios from which the cases arise exemplify some of the distinct characteristics of clinical trials for oncology drugs, and the courts' analysis shows a ready grasp of those characteristics. Decisions from the Second and Ninth Circuits should be useful precedents on issues of clinical trial uncertainty, the use of expert allegations in complaints, and causation issues that arise when plaintiffs attack the report of interim or early-phase trial results by reference to results obtained at a later stage or in a different trial.

Finally, we address divergent approaches to the analysis of economic motivation. Companies have historically succeeded in defeating scienter allegations by pointing out that if they did not believe a drug would be approved, they would not expend time and resources on development and FDA review. More recently, several courts have been receptive to an argument by plaintiffs that while a company may not know that its drug will not be approved, it can mislead investors by underselling the risk of non-approval. We discuss several difficulties presented by this approach.

Largely Favorable Results for Companies Developing COVID-19 Products

In 2022, district courts issued five decisions in cases against companies developing or hoping to develop COVID-19 products. The results were defense-friendly on the whole. Companies won motions to dismiss in three cases, *Talis*, *AstraZeneca*, and *Kodak*. In a fourth, *Chembio*, the company prevailed but its underwriters did not. In the fifth case, *Novavax*, the company largely lost its motion to dismiss.

As we saw in the decisions related to COVID-19 in 2021, courts appear to be highly sensitive to context in an area with which they are familiar through collective personal experience. One effect of the pandemic has been that narratives of drug development and FDA approval that courts otherwise encounter principally through allegations and briefing have become part of widely shared experience. In cases against companies developing COVID-19 products, courts appear to be very open to arguments that statements are not materially false or misleading in light of public knowledge about the risks of drug development and manufacturing challenges in the pandemic setting. Courts parse challenged statements in detail or dismiss them as puffery or otherwise non-actionable.

In *Talis* and *Chembio*, courts took a strict formalistic approach in dismissing allegations against developers of COVID-19 tests. In *Talis* (page 37), investors sued after manufacturing issues delayed the launch of the company's COVID-19 testing platform. The court carefully parsed plaintiffs' allegations, and rejected an attack on the company's statement that it had ordered "5,000 instruments" from manufacturing partners. The company had in fact ordered *components* for instruments, and the court concluded that this was sufficient to save the statement from falsity. In *Chembio* (page 31), the court dismissed on scienter grounds. Plaintiffs' theory of fraud was that Chembio was so dependent on the success of its COVID-19 antibody test that it was willing to "bet the company" on the product. The court concluded that the theory was too generalized to support a strong inference of fraud. As discussed below, the court also analyzed in a notably strict manner the plaintiffs' contention that the company deceived investors by concealing the risk that the FDA would revoke an Emergency Use Authorization. The court held that because plaintiffs did not allege that the company *knew* the EUA would be revoked, they fell short on scienter. The court dismissed plaintiffs' Section 11 claims against the company for largely the same reasons,

holding that the claim sounded in fraud. In an odd turn of events—and further illustrating the court's formalistic approach—the court *denied* the underwriters' motion to dismiss the Section 11 claims asserted against them. Those claims did not sound in fraud, and plaintiffs adequately pled falsity as to the company's statement that its test was 100% accurate after 11 days; plaintiffs alleged that the company had information indicating otherwise.

In two other cases, courts characterized companies' favorable statements about their COVID-19 products as non-actionable puffery, and dismissed on that and other grounds. In *AstraZeneca* (page 25), plaintiffs challenged the company's statements about the development of a COVID-19 vaccine, including statements that clinical trials were "on track" and that the company's core values were to "follow the science" and "put patients first." These statement were puffery, the court held, while statements about the likelihood of regulatory approval were forward-looking and came within the PSLRA's safe harbor. The court also rejected plaintiffs' claim that the company had wrongfully omitted information about purported dosing irregularities, holding that the company did not assume a duty to disclose granular details about dosage simply because it discussed the history of the trials. The court finally rejected the claim that the company had misleadingly omitted data about the number of participants aged 55+; this amounted to a non-actionable dispute about data interpretation.

The court in *Kodak* (page 26) also held that the challenged statements were forward-looking or amounted to puffery. Kodak anticipated receiving a government loan to convert its facilities from producing film to producing pharmaceutical products, including hydroxychloroquine. The day before the loan was announced, the company granted stock options to officers and directors, and in the days after the announcement, Kodak's stock price rose 1500%. Media outlets raised questions about the option grant, and government leaders did the same. Kodak ultimately did not get the loan. The court granted the company's motion to dismiss in full. Statements that the new manufacturing initiative "could change the course of history for Rochester and the American people" were non-actionable puffery. Statements that Kodak "will produce starter materials" and "active pharmaceutical ingredients" and "expects the loan to create around 300 jobs in Rochester, and 30 to 50 in Minnesota" were forward-looking.

In the final case, *Novavax* (page 31), the court largely denied the company's motion to dismiss. Novavax developed a COVID-19 vaccine. It joined Operation Warp Speed and entered into a contract with Fujifilm to manufacture bulk drug substance at its plants. Plaintiffs challenged Novavax's statements that it had "eliminated all of the serious hurdles" to obtaining FDA approval and had "got[ten] past (certain) supply issues." Plaintiffs adequately alleged that the statements were misleading, given the omission of information about microbial contamination at the contract manufacturing facilities, which prevented the company from achieving the levels of purity and potency the FDA required.

Appellate Victories for Companies Developing Oncology Drugs

Life sciences companies prevailed in all five of the 2022 appeals in pre-approval cases. Three cases involving oncology drugs bring into focus the appellate courts' sophisticated understanding, in this year's cases, of challenges in designing and conducting clinical trials generally. The decisions also illustrate the courts' ready grasp of issues arising from oncology and immuno-oncology trials in particular.

The companies in both *Nektar* (page 16) and *Bristol-Myers Squibb* (page 16) developed immuno-oncology drugs. Patients' responsiveness to these drugs can vary widely based on immune system differences. The facts in *BMS* show how drug sponsors address this in designing trials. BMS tested the efficacy of its checkpoint inhibitor, Opdivo, which had already been approved for other indications, in patients with non-small cell lung cancer. In designing a Phase 3 trial, BMS needed to select an enrollment eligibility requirement for what is called "PD-L1 expression." The higher a patient's rate of PD-L1 expression, the more likely the patient is to respond to the drug. Choosing a high rate of PD-L1 expression would increase the likelihood of clinical trial success. But choosing a high rate of expression could also limit the drug's commercial scope, as the drug's label would be confined to patients who expressed the protein at that rate. BMS chose a 5% rate of PD-L1 expression. BMS did not disclose that figure, but said that the trial population consisted of "strong" PD-L1 expressers. The trial failed, and

when it was over, BMS announced the 5% figure publicly. Plaintiffs attacked the word "strong" as false or misleading.

In affirming dismissal, the Second Circuit was sensitive to the company's need to keep its 5% figure confidential, particularly as a major competitor, Merck, was conducting Phase 3 trials of its own checkpoint inhibitor on patients with non-small cell lung cancer (NSCLC).

> [BMS] had no obligation to disclose the precise percentage of PDL1 expression which defined "strong" expression in the Opdivo trial. The Complaint confirms that such a disclosure would have been unwise. Checkpoint inhibitors for NSCLC were expected to be highly profitable for pharmaceutical companies, and revealing the precise structure of the Opdivo trial would allow competitors to copy or undercut [BMS's] target patient population (and reap the commercial benefit that [BMS] hoped to realize from a successful trial). [BMS's] competitors likely had even more desire than the Investors to learn the exact parameters of the Opdivo trial—but neither's interest created any duty to disclose.

BMS's victory was based on the Second Circuit's understanding of both the fundamental biological facts in the immuno-oncology setting and the business context in which the company was conducting its clinical trials.

The variability in responses to immuno-oncology drugs led to a different issue in *Nektar*. The company reported that ten patients in a Phase 1 trial experienced a mean 30-fold increase in a certain kind of cancer-fighting cell, which was an important biomarker. Plaintiffs claimed that the result was driven by a single outlier patient with a 300-fold increase of cells, and that because this purportedly skewed the mean, the company's 30-fold increase figure was misleading. The Ninth Circuit affirmed dismissal on falsity grounds (among others). Plaintiffs failed to plead facts showing either what the 30-fold increase figure would have been if the purported outlier had been excluded or why that difference would matter to investors:

> [W]e do not know from the complaint whether a somewhat lower fold-change would have been material to investors. For example, without [the outlier's] data, perhaps the number of cancer-fighting cells would have increased 15-fold. Is that an excellent result from a medical perspective? Is there any material difference between a 15-fold increase and a 30-fold increase? And how would an average investor assess such a difference? Perhaps investors would not care about such a difference if it turned out that a 30-fold increase provides little marginal benefit over a 15-fold increase for most cancer patients.

The Ninth Circuit appeared to be aware of its own limitations in assessing clinical trial data, which it declined to do in a vacuum.

The *Nektar* court also nicely captured the factual realities faced by many of the development-stage companies and products on which we report in this annual review—and then framed the situation in a legally favorable way:

> Experimental drug candidates do not always live up to their potential, even if initial clinical trials yield highly promising results. But as this case illustrates, that does not mean that a pharmaceutical company has defrauded the investing public…Pharmaceutical companies often suffer setbacks in their clinical trials after earlier testing offered highly promising results. *That is the nature of the industry*…(Emphasis added.)

Both *Nektar* and *BMS* contain additional pro-defendant analysis—significant data points given the concentration of cases against life sciences companies in the Ninth and Second Circuits. In *BMS*, the Second Circuit appears to have returned to a more conventional understanding of the Supreme Court's 2015 *Omnicare* decision, which provided a framework for assessing challenges to opinion statements.[4] In 2020, the Second Circuit seemed to depart from most courts' application of *Omnicare* with its decision in *Newlink Genetics*.[5] There, the court stated that *Omnicare* had "reduced the significance" of the fact/opinion distinction, and it declined to determine whether the challenged statements addressed facts or opinions—which most courts consider a threshold issue under *Omnicare*. While the Second Circuit cited *Newlink Genetics* in *BMS*, it proceeded to

4 *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015).

5 *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165 (2d Cir. 2020).

make the more conventional determination that the challenged opinion did not contain an embedded factual statement, and that plaintiffs had failed to establish that it was actionable.

The courts in both *BMS* and *Nektar* also rejected a somewhat unusual tactic the plaintiffs used: referring in the complaint to a specified expert's opinion on industry standards or usage in an effort to buttress allegations of both falsity and scienter. The *BMS* court noted that "opinions cannot substitute for facts under the PSLRA," and held that because the expert opinion did not add particularized facts, it could not rescue plaintiffs' claim. The *Nektar* court went marginally further in addressing the merits of the expert allegations, but ultimately held that "[p]laintiffs cannot evade the PSLRA's exacting pleading standards by merely citing an expert who makes assertions about falsity based on questionable assumptions and unexplained reasoning."

The *Nektar* court finally ruled for the company on two distinct loss causation issues. First, the court held that the company's report of interim Phase 2 results "was not a corrective disclosure that exposed the alleged falsity" of earlier interim Phase 1 results. That holding may prove significant in other cases in which plaintiffs allege that disappointing results from a later trial "correct" more promising results from an earlier trial. The reasoning should apply equally to allegations that earlier interim results in a trial are "corrected" by later interim or final results in the same trial. Second, the court held that a short-seller report was not a corrective disclosure. The court drew on two 2020 decisions in which it focused on disclaimers in short-seller reports and concluded that because investors take such reports with "a healthy grain of salt," the reports will generally not provide the market with *new* information—which is necessary to establish loss causation. The Ninth Circuit's consolidation of the law on this point should also be helpful to defendants going forward.

The third decision affirming dismissal of claims against a company with an oncology product is *Karyopharm*, from the First Circuit (page 18). Karyopharm developed not an immuno-oncology drug, but a drug designed to treat patients with very advanced cancers. The court's understanding of oncology drug development and treatment options was again an important factor in affirmance. Plaintiff challenged the company's statement that a Phase 2b trial "demonstrated a predictable and manageable tolerability profile, with safety results that were consistent with those previously reported from part I of this study." Plaintiff claimed the statement was misleading because the company purportedly knew and failed to disclose that 100% of the patients in the trial experienced adverse events, 60% experienced serious adverse events, and 25% discontinued the drug because of its side effects.

In affirming dismissal, the First Circuit focused on the context of the trial. The court noted that nearly all patients with the indication addressed in the trial relapsed, that the trial population consisted of "very sick patients" who had failed to respond to "extensive and varied treatment and…were ultimately left with no other medical options"—and that the company had disclosed all of this. The court cited law holding that companies have no duty to disclose information that is already known, and concluded that "[g]iven this background information, it is difficult to imagine that any investor would read the defendants' statements that [the drug] had a 'predictable,' 'manageable,' and 'consistent' tolerability profile to indicate that [it] was benign, or that the FDA would find it so." As in *BMS* and *Nektar*, the court's solid grasp of the context in which cancer trials are conducted was critical to affirmance.

Scienter and the Risk of Non-Approval

The shifting analysis of economic motivation. In granting motions to dismiss on scienter grounds, courts at times draw on two related concepts that have special force for companies with products at the development stage. Both concepts arise from the observation that fraud claims brought against such companies often lack practical and economic plausibility.

The first concept is that economically rational actors do not spend hundreds of millions of dollars and multiple years on clinical trials for drugs or devices they know the FDA will never approve. We analyzed this line of reasoning in our 2020 and 2021 reviews. *Ampio* is an illustrative decision from 2020. The court there explained that the "crux of Plaintiffs' Complaint is that Defendants knew or were deliberately reckless[] to the fact the [trial] was poorly designed and would not be approved by the FDA." The court squarely rejected this premise.

"[T]he idea that this company, highly dependent on the success of the new drug, would knowingly or recklessly [carry] on a defective trial—so that any defects were not remedied—virtually defies reason."[6]

The second, related concept is that a company that knows its product will not receive FDA approval also knows that any fraud will ultimately be exposed when approval is not forthcoming. The leading decision here is *Endologix*, in which the Ninth Circuit observed that a theory of fraud in this setting generally "does not make a whole lot of sense."[7]

In 2022, district courts have twice rejected companies' efforts to defeat an inference of scienter through these concepts. These courts have accepted plaintiffs' arguments that while a company may not *know* that its product will not receive approval, plaintiffs can sufficiently allege both falsity and scienter by establishing that the company knew of and concealed the *risk* of non-approval.

In *BioMarin* (page 29), which arose from the FDA's rejection of a BLA for a hemophilia drug, the company pointed to the expenditures it had made on clinical trials in an effort to show that an inference of deliberate deceit was less compelling than a competing benign inference. The Northern District of California rejected the company's analysis:

> BioMarin's argument attacks a straw man, contending that it makes no sense to spend so much investment that they knew was doomed. In some circumstances that is true, as *Endologix* explained. But, here, the allegations are not that the defendants were *convinced* the FDA would deny approval, it is that they withheld important *warning signs* from the market. (Emphases in original.)

The Southern District of California reasoned along very similar lines in *Acadia* (page 29):

> Defendants further assert that it "defies common sense" for them to have misrepresented the terms of an agreement with the FDA and the likelihood of approval, knowing the whole time that approval would not be granted. However, Defendants' actions plausibly demonstrate that they misled investors into overestimating the likelihood of approval, not that Defendants knew from the start that the sNDA would not be approved.

A third decision from early 2023, also from the Northern District of California, sounds the same theme, and cites *BioMarin*:

> Plaintiffs' theory is not that Defendants knew that the FDA would withhold approval, but rather that Defendants knew of and concealed adverse facts regarding trial results from investors in order to buy time and finance the company's operations while trying to alter the potential effect of those adverse facts on the NDA process.[8]

Questions raised by the analysis in the 2022 decisions. The line of reasoning in these decisions appears to be open to question on several grounds. To begin, the courts in *BioMarin* and *Acadia* did not grapple with the companies' arguments about economic implausibility as a matter of scienter. The courts observed that statements may be misleading if a company knows but fails to disclose the risk of non-approval. But that observation does not ultimately speak to scienter. It falls short of explaining why a company would pour resources into clinical trials once it learns of serious risks of non-approval. Courts should consider drug and device developers to be economically rational actors not only at the beginning of the FDA review process but throughout it. The court in *ChemoCentryx* alone of the three framed its analysis in terms that respond to arguments about economic plausibility. The court there embraced plaintiffs' theory that other economic considerations impelled the company to continue pursuing approval in the face of serious undisclosed risk. But the circumstances that supported that theory in *ChemoCentryx* may not be present in all cases.

A second difficulty with the analysis in these cases is that the conclusion that a company has failed to adequately disclose the risk of non-approval may well be at odds with risk disclosures in the company's SEC filings. Virtually every company with a drug or device undergoing FDA review will include in its Form 10-K one or more cautionary statements about the risk of non-approval. In light of such disclosures, a holding that a company knew of but failed to disclose risks begins to

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6 *Jun Shi v. Ampio Pharm., Inc.*, 2020 WL 5092910, at *5 (C.D. Cal. June 19, 2020).

7 *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020).

8 *Homyk v. ChemoCentryx, Inc.*, No. 21-cv-03343-JST, Dkt. 61 (N.D. Cal. Feb. 23, 2023).

look like a holding that the company should have warned of risks more loudly, or even that it should have quantified risk. The first requirement would seem to lead to difficult line-drawing problems, and the latter appears unworkable.

A third problem is that the theory that a company knew of but failed to sufficiently warn of the risk of non-approval may collide with a very well-established line of decisions holding that companies have no duty to inform investors of non-final comments or criticisms they receive from the FDA in the review process.[9] When companies learn of the risk of non-approval, this almost always occurs in the context of interim communications with regulators. Courts have long recognized that the FDA review process is a dialogue in which both regulators' and sponsors' views evolve, and sponsors are often able to satisfactorily respond to the FDA's concerns. Requiring disclosure of risk in the form of non-binding agency comments may be inconsistent with both the fluidity of the regulatory process and the body of case law recognizing that fluidity.

The other side of the ledger. Not all courts confronted with the issue in 2022 have adopted the view that undisclosed risks of non-approval can establish either falsity or scienter. The starkest pro-company statement comes from *Chembio* (page 31). The company there received an EUA for its COVID-19 test, but subsequently learned that several government agencies had questioned the underlying data, which created a risk that the FDA would revoke the EUA. The court held that the company's knowledge of that risk was insufficient to establish a strong inference of scienter:

> [T]he officer and director defendants' actions would have been reckless if defendants knew, but did not disclose, that it was inevitable that Chembio would lose its EUA for the Test. But the information that the Test might not be as accurate as they claimed did not put defendants on notice that the EUA *would* be revoked…[K]nowledge of an increased risk of revocation…is not knowledge of *certain* revocation. (Emphases in original.)

The language in *Kodak* (page 26) is less pointed, but the outcome is the same. Kodak, as noted above, granted stock options to executives the day before its stock price began skyrocketing in response to the announcement that the government had entered into a letter of interest for a major loan to develop COVID-19 products. Plaintiffs challenged the company's positive statements about the loan, but because the statements were forward-looking, they were actionable only if plaintiffs could establish that the company actually knew that exposure of the option grant would cause the government to withdraw from the letter of interest. The court held that plaintiffs had not met that scienter standard. The court rejected as "entirely speculative" plaintiffs' allegation that the company "knew that the grant of the stock options 'would cause the [government] to pull the loan.'" The court did not adopt, and the plaintiffs do not appear to have advanced, the theory that the company knew but failed to disclose a *risk* that the loan would be pulled.

Plaintiffs have had some success in 2022, as in the past several years, in chipping away at pro-defense arguments that claims of fraud in the pre-approval cases are often inconsistent with economically rational behavior. This area merits attention in the coming years, particularly if companies can turn the tide by highlighting the difficulties inherent in the pro-plaintiff "conceal the risk" theory outlined above.

POST-APPROVAL DECISIONS

As in past years, companies won motions to dismiss in fewer than half of the post-approval cases. The 2022 post-approval decisions arose very largely from regulatory issues, including alleged kickbacks, pricing and billing irregularities, and unfair trade practices. We address substantive developments in two areas.

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9 *E.g.*, *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017) (companies seeking FDA approval have "no legal obligation to loop the public into each detail of every communication with the FDA"); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 541 (S.D.N.Y. 2015) ("in a series of cases, courts have rejected claims of material omissions where pharmaceutical companies did not reveal procedural or methodological commentary, or other interim status reports, received from the FDA as to drugs under review").

First, we consider perennial issues in cases arising from regulatory activity or investigations. Because the underlying proceedings are generally still ongoing at the time of the securities litigation, problems with staging arise, with the prospect that the securities litigation threatens to become the forum in which the propriety of challenged activities is adjudicated in the first instance. Courts are also confronted with difficult disclosure issues, starting from the premise that a company has no duty to accuse itself of uncharged or unadjudicated wrongdoing. We discuss the problems posed by the formulation applied by many courts—that a company assumes a duty to accuse itself if it puts the alleged misconduct "at issue" by discussing the reasons for its financial performance.

We then consider an unusual decision in which a district court applied appellate authority addressing securities fraud claims in connection with public utility rate-setting proceedings. The district court approached the plaintiff's challenge to favorable predictions from the perspective of reliance, which may provide a useful tool in cases arising from regulatory activity across the pre- and post-approval spectrum.

The Enduring Challenge of Ongoing Regulatory Activity or Investigations

Timing issues. Securities fraud litigation, as noted, is generally a second-order problem. In the pre-approval cases, the first-order problem is generally a setback in the development or FDA review process—disappointing clinical trial results, or an unfavorable decision from the FDA. In post-approval cases, the first-order problem can also stem from regulatory activity: Litigation may be triggered when a company announces a government investigation or lawsuit. What is different in the post-approval setting is that the announcement may come at the beginning of the regulatory proceeding. Plaintiffs' counsel will piggy-back on regulatory developments, with the result that securities litigation may unfold long before the underlying proceedings are resolved. We have discussed in past years the awkwardness this can create. In some cases, the securities litigation will move more rapidly than the underlying proceeding, which poses the risk that underlying antitrust or kickback claims (for example) could be presented in the first instance in the context of a Section 10(b) case.

One of the 2022 decisions reflects an unusual wrinkle in the problem of staging across multiple fora or proceedings. The plaintiff in *Acadia* (page 29) alleged undisclosed kickbacks, which it claimed rendered misleading the company's statements about the successful commercialization of one of its products. The court granted two successive motions to dismiss, but in the course of its analysis resolved one materiality issue against the company. The court's conclusion on the materiality point was based on an ongoing DOJ investigation. The court explained that "[t]he strongest fact evidencing kickbacks in this case is the DOJ investigation into the matter." By the time plaintiff filed its third amended complaint, however, the DOJ had concluded its investigation and taken no action. That shifted the balance on the materiality issue:

> Based on its judicial experience and common sense, the Court finds that the reasonable inference drawn from the investigation's termination is that DOJ did not uncover evidence of kickbacks to proceed with charges against Defendants. Consequently, DOJ's termination of its investigation significantly undermines Plaintiff's kickback allegations.

While the outcome was favorable for the company, the sequence of events underscores the complexities inherent in securities litigation arising from unresolved investigations or regulatory actions. If the DOJ had moved more slowly, or if the plaintiffs had not been given a third opportunity to seek to improve their complaint, the analysis would have been different.

Uncharged or unadjudicated wrongdoing put "at issue" by statements about financial performance. Apart from timing problems, the complicated interplay between securities litigation and unresolved underlying proceedings can pose challenging disclosure questions for courts. Courts readily observe that issuers have no obligation to accuse themselves of uncharged or unadjudicated wrongdoing. This was the case in *Reckitt Benckiser* (page 39), *Teva* (page 37), and *Tactile Systems* (page 37). In *Reckitt* and *Teva*, the courts immediately qualified the observation, drawing on decisions stating that when a company puts the sources of its revenue or the reasons for its financial success "in play" or "at issue," it may assume a duty to disclose that its financial performance depends on improper conduct. Both courts applied the "in play" concept

in a fairly nuanced way. In *Teva*, the court concluded that statements attributing success to brand loyalty and patient and physician choice put the sources of revenue "in play," but that legal compliance statements did not. Similarly, in *Reckitt*, the court held that statements about patient and physician preference put the sources of revenue "at issue," but that purely quantitative financial statements did not. The line-drawing exercises in *Teva* and *Reckitt* led to more nuanced results than we have seen in past years, when courts held that even the broadest discussion of revenue performance in the Management's Discussion and Analysis portion of a Form 10-K or 10-Q put the sources of revenue "in play," and thereby saddled companies with disclosure duties.

But even the more nuanced analysis can lead to odd results. In *Teva*, the plaintiff drew on the announcement of a DOJ subpoena to allege that the company's financial performance was driven by payments to a Patient Assistance Program improperly channeled to purchases of Teva's own drug. The court concluded that plaintiff had adequately pled that Teva had put the source of its financial performance at play, and then further reasoned that

> it is largely immaterial whether Teva's actions were illegal because Plaintiff does not argue that Teva was required to disclose this scheme merely because it may have been illegal; rather, Plaintiff argues that Teva was required to disclose this scheme *because it is what made [the product] so successful*. (Emphasis in original.)

Oddly, the "at issue" approach here skirts the question of whether the alleged misconduct is improper at all. That appears to zero out the element of materiality. Imagine a company says "we had a very successful quarter for reason X," and plaintiffs challenge the statement on the ground that the quarter was instead a success for reason Y. Unless reason Y implicates improper or otherwise unsustainable business practices, the difference between reason X and reason Y does not appear to be material.

The court in *Tactile Systems* also reached an odd position through the "at issue" approach. Plaintiffs there challenged financial statements, claiming that the company's success depended on illegal kickbacks. As in *Reckitt*, the court noted that financial statements alone are not false or misleading simply because a company's financial performance allegedly depends on illegal practices. But the court in *Tactile Systems* then turned to law addressing the circumstances in which risk disclosures and forward-looking statements—not financial statements—may be actionable. Although the decision does not make the matter entirely clear, the result appears to have been that plaintiffs were permitted to proceed with a challenge to the company's financial statements based on allegations that its performance depended on kickbacks. That differs from most authorities in this area, which hold that financial statements are not themselves actionable under a theory of undisclosed misconduct.

Weighting third-party allegations and outcomes. The result in *Tactile Systems* is unusual in a second way as well. The underlying proceeding was a qui tam action, which the company told investors was brought by a competitor. The government did not intervene in the qui tam action and the qui tam plaintiff dismissed it voluntarily with prejudice. The court initially considered disregarding the allegations drawn from the qui tam complaint. But the court ultimately concluded this was not the right result. The securities plaintiffs had done more than "just parrot" the qui tam allegations; the securities plaintiffs had also reviewed unsealed documents and cited other sources. After concluding that it could appropriately consider the qui tam-based allegations, the court held that plaintiffs had adequately pled falsity as to the company's opinion statement that the qui tam action lacked merit. The court also credited some (though not all) of the allegations plaintiffs drew from a short-seller report addressing the same subject as the qui tam complaint. Other courts would presumably have treated allegations drawn from third parties with their own financial motivations—both the qui tam plaintiff and the short seller—with greater skepticism.

The third-party allegations in *Mallinckrodt* (page 38) came from a more authoritative source—the Centers for Medicare and Medicaid Services—but as in *Tactile Systems*, the court appears to have framed those allegations in an oversimplified way. Here the difficulty was timing. CMS disputed for years Mallinckrodt's calculation of rebate liability (which followed the calculation made by the company from which Mallinckrodt purchased the drug at issue).

The dispute turned on the date on which the drug was deemed to have been approved, and that determination was complicated by the fact that the drug was approved on different dates for different indications. Mallinckrodt issued financial statements and provided revenue guidance based on the premise that it was calculating its rebate liability correctly. Unable to resolve its disagreement with CMS, the company filed a declaratory relief action against CMS—and lost. Based on that outcome, the Section 10(b) plaintiffs challenged, among other things, the company's financial statements, guidance, and statement that it had low rebate expenses. In denying Mallinckrodt's motion to dismiss, the court treated CMS's victory as a foregone conclusion—stating, for example, in its historical account of the dispute, that CMS "was not so easily fooled," and that the company "failed to comply" with CMS's rebate calculation. In analyzing scienter, the court did not ask whether the company deliberately deceived investors, or whether it knew that CMS would prevail in the declaratory relief action. The court asked simply whether the company was aware of the facts underlying the dispute with CMS over rebate liability. The court tacitly equated knowledge of the facts with knowledge that the company's calculations were wrong, an approach that short-changes defendants in the scienter analysis.

Many cases arising from regulatory proceedings can become complicated because at the time of the securities litigation, the outcome of those proceedings is unknown. *Mallinckrodt* illustrates a different problem. Once the outcome *has* become known, courts may struggle to bear in mind that this was not the case when the company made the challenged statements.

Adaptation of Rate Case Analysis to Regulated Pricing

One of the four favorable post-approval decisions, *iRhythm* (page 35), reflects an approach to risk and to unknown regulatory outcomes that could prove useful for companies with products across the approval spectrum. iRhythm makes a device called the Zio XT patch, which is used to diagnose cardiac arrhythmias. Before 2021, the device was assigned a temporary CPT code with an approved Medicare reimbursement rate of $311-$316. When the American Heart Association recommended a permanent code for the device, contention arose over the reimbursement rate, which is set through notice-and-comment rulemaking. CMS issued a proposed rule with a rate of $376-$386, but noted that the company's submission did not include traditional forms of pricing information. A healthcare policy firm then filed a comment to the proposed rule, criticizing the company's pricing analysis and stating that the true cost of the device was less than $100. Over the next 15 months, regulators announced reimbursement rates between $74 and $210. The company's stock price swung widely following these announcements, and investors sued.

The district court granted the company's motion to dismiss. It concluded that the case was governed by *Epstein v. Washington Energy*, in which the Ninth Circuit affirmed dismissal of Section 10(b) claims against a public utility that had made favorable predictions about the outcome of rate-setting proceedings.[10] The Ninth Circuit reasoned that

> reliance on predictive statements in the context of regulatory proceedings is inherently unreasonable. Basing an investment decision on an anticipated and contingent outcome of a litigated regulatory proceeding, even *with* full knowledge of the prior history of the parties, is tantamount to sheer speculation; and guessing wrong hardly suggests fraud. Accordingly, an investor who relies on such information cannot be said to be misled by an "untrue statement of material fact." The context of the regulatory process does not ordinarily invoke a duty to disclose or provide a basis for a securities fraud claim. Thus, a utility that has announced it has submitted an application for a rate increase normally has no duty to inform the public of any facts or circumstances in addition to those set forth in the application. (Emphasis in original.)

The district court in *iRhythm* concluded that *Epstein* controlled the outcome there, notwithstanding certain factual differences between public utility rate-setting and CMS's price-setting procedures. As in *Epstein*, the plaintiff's theory in *iRhythm* was that the company misled investors about the likelihood that it would receive a favorable outcome by omitting information about the regulatory proceedings. The district court's rejection of that theory may be a useful precedent for companies in price-setting or other public regulatory proceedings.

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10 *Epstein v. Washington Energy Co.*, 83 F.3d 1136 (9th Cir. 1996).

The underlying proceedings in *iRhythm* differed notably from the investigations and regulatory actions discussed in the preceding section. CMS's price-setting proceedings do not concern alleged wrongdoing; they are far more akin to the FDA approval process than to a backward-looking assessment of purported improper sales, marketing or billing practices. Indeed, the *iRhythm* court drew on *Endologix* and other case law addressing the risk that the FDA will not approve a drug or device.

This raises an intriguing possibility. Is there a place in the pre-approval cases for *Epstein*'s central insight—that "reliance on predictive statements in the context of regulatory proceedings is inherently unreasonable"? Very few defendants move to dismiss on the element of reliance. In contemporary Section 10(b) cases, defendants move to dismiss on the elements of falsity, scienter and loss causation. But an emphasis on reliance could provide a way around the plaintiff-friendly analysis, discussed above, that companies may mislead investors by lowballing the risk that the FDA will not approve a product. *Supra* at 9. With a focus on reliance, the burden of handicapping risk essentially moves from the company to the investor, at least as long as the company has identified risk factors in the first instance.

One difficulty with this approach may arise from the factual differences between, on the one hand, the rate-setting and price-setting processes in *Epstein* and *iRhythm*, and on the other hand, the FDA approval process. The *Epstein* court stated that a company "that has announced it has submitted an application for a rate increase normally has no duty to inform the public of any facts or circumstances in addition to those set forth in the application." Substituting the term "NDA" for "application for a rate increase" could lead to very favorable results for life sciences companies. But at least part of the analysis in *Epstein* and *iRhythm* appears to be driven by the fact that the regulatory proceedings at issue were public. Indeed, in *iRhythm* the challenged statements themselves were made in the context of those proceedings. Extending a reliance-based analysis to the pre-approval setting would likely draw the argument from plaintiffs that shifting the burden of assessing risk to investors is appropriate only when investors have access to both the company's application and the regulator's feedback — which is rarely the case with an NDA. Nevertheless, *iRhythm*'s key insight about investment risk, drawn from *Epstein*, may provide support for arguments in motions to dismiss on the elements of falsity, scienter and loss causation at any stage of product development or commercial undertaking.

DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 15–32), 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 won dismissal in 11 of 19 cases in the district courts.

Companies fared even better in the appellate courts, which affirmed dismissal in all five of the decisions at the pre-approval stage.

APPELLATE DECISIONS

In re Nektar Therapeutics Sec. Litig., 34 F.4th 828 (9th Cir. 2022), affirming dismissal. **Phase 1**

Nektar developed NKTR-214, an immuno-oncology drug. In 2017-2018, Nektar reported favorable interim biomarker results from a Phase 1 trial: A set of ten patients had experienced an average 30-fold increase in CD8 cells, which fight cancer. Nektar also reported favorable interim results on tumor shrinkage from Phase 2 trials, in which patients were given NKTR-214 in combination with an approved drug. In June 2018, Nektar reported somewhat less favorable interim Phase 2 tumor shrinkage data, and its stock price fell 42%. In October 2018, a short seller posted a blog positing that NKTR-214 was ineffective. Among other things, the short seller said that the 30-fold increase in CD8 cells in the Phase 1 trial was driven by a single outlier patient. Nektar's stock fell 7%.

Investors sued, challenging Nektar's 30-fold increase statements. In two decisions in 2020 (discussed in our report for that year), the district court dismissed on falsity, scienter, and loss causation grounds. Plaintiffs' case was premised on the purported inclusion of outlier data, but plaintiffs failed to plead with sufficient particularity that the outlier data were included in the 30-fold mean increase figure in the first place. Plaintiffs also failed to show that including the result would have been improper; their claim was an attack on statistical methodology, and under the Ninth Circuit's *Rigel* decision, that is not actionable.[11] Plaintiffs' scienter allegations were improper for similar reasons, and plaintiffs also failed to adequately allege loss causation in connection with either the June 2018 or the October 2018 stock drops.

The Ninth Circuit affirmed dismissal. The court assumed that the purported outlier data had been incorporated into the challenged 30-fold mean increase, but held that plaintiffs failed to plead falsity because they did not allege what the increase would have been in the absence of the outlier's results. Neither the short seller, plaintiffs' confidential witness nor plaintiffs' anonymous expert had offered a reliable figure. The short seller posited a 1.8-fold increase, while the expert posited a 5.55-fold increase—but neither could satisfactorily account for the assumptions used to derive those figures. The confidential witness offered only hyperbole. As importantly, plaintiffs could not explain why any particular recalculated fold-increase figure would be significant to investors. The court analogized to a situation in which a microchip manufacturer says that a new chip is 300 times faster than its predecessor and facts emerge showing that it is only 200 times faster; without more, the significance of the difference to an investor is not clear. The Ninth Circuit also concluded that plaintiffs had failed to allege loss causation. The interim Phase 2 trial results that triggered the first stock drop did not relate to the "very fact" at issue in the Phase 1 30-fold increase figure, while the short seller report that preceded the second drop was the contribution of an anonymous and self-interested market participant who disavowed accuracy. The court commented generally that "[e]xperimental drug candidates do not always live up to their potential, even if initial clinical trials yield highly promising results," but that this "does not mean that a pharmaceutical company has defrauded the investing public."

Arkansas Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co., 28 F.4th 343 (2d Cir. 2022), affirming dismissal. **Phase 3**

BMS develops Opdivo, a checkpoint inhibitor used in immuno-oncology. In designing Phase 3 trials testing Opdivo's efficacy in treating non-small cell lung cancer, BMS needed to select an enrollment eligibility requirement for what is called "PD-L1 expression." The higher a patient's rate of PD-L1 expression, the more likely the patient is to respond to the drug. Choosing a high rate of PD-L1 expression would increase the likelihood of clinical trial success. But choosing a high rate of expression could also limit the drug's commercial scope, as the drug's label would be confined to patients who expressed the protein at that rate. BMS chose a 5% rate of PD-L1 expression. BMS did not disclose that figure, and told analysts it would not

11 *In re Rigel Pharm, Inc. Sec. Litig.*, 697 F.3d 869 (9th Cir. 2012).

do so until the trial had concluded. While the trial was ongoing, BMS stated only that the trial population consisted of "strong" PD-L1 expressers. Commentators speculated about the figure, and speculation increased when BMS's competitor, Merck, announced a trial with a 50% PD-L1 expression threshold. BMS reported in August 2016 that the trial had failed to meet its primary endpoint. BMS also disclosed the 5% expression criterion. The company's stock fell 16%.

Investors sued, alleging that BMS committed fraud by characterizing a 5% rate of PD-L1 expression as "strong." The district court granted the company's successive motions to dismiss in rulings on which we reported in 2019 and 2020.

The Second Circuit affirmed dismissal. The appellate court held that plaintiffs had failed to adequately plead that the term "strong" was false or misleading. Plaintiffs' own allegations showed a lack of consensus as to what constitutes "strong" PD-L1 expression, with values ranging from 1% to 49%. Plaintiffs cited the opinion of an industry expert that 5% expression was not "strong," but that opinion was insufficient: Unless a Section 10(b) plaintiff can plead *facts* adequately showing falsity, an expert opinion does not help. Plaintiffs' challenge to other statements characterizing the trial design favorably—for example, that the trial was designed with "great care"—were opinions as to which plaintiffs had failed to satisfy pleading requirements, or came within the PSLRA's safe harbors. Plaintiffs also failed to establish the required strong inference of scienter: BMS "did not act recklessly or with intent in disregarding the industry's consensus definition of strong PD-L1 expression because—taking the Investors' allegations as true—no such consensus definition existed."

In re Amarin Corp. PLC Sec. Litig., 2022 WL 2128560 (3d Cir. June 14, 2022), affirming dismissal.

Phase 3

Amarin develops Vascepa for the treatment of heart disease. After completing two surrogate endpoint trials aimed at showing that Vascepa lowered triglycerides, Amarin conducted a trial designed to show that the drug could reduce major adverse cardiac events. The company reported positive top-line results in September 2018 and its stock price rose over 400%. Amarin also told investors that it would release detailed results in November 2018, at the American Heart Association's annual conference. When it did so, some commentators reacted unfavorably, noting that the mineral oil placebo used in the trial may have made the conditions of some patients on the control arm worse, thereby exaggerating the positive effect of Vascepa. Amarin's stock price fell 25%.

Investors sued, claiming that Amarin's report of top-line results was rendered misleading by the omission of (1) information about the effect of the placebo, and (2) the fact that the trial data could not explain how the drug worked. In a 2021 ruling (discussed in last year's review), the district court granted the company's motion to dismiss. With respect to the placebo, Amarin had repeatedly warned investors that mineral oil might not be biologically inert and could be viewed as artificially exaggerating Vascepa's clinical effect. More generally, the court held that "dissemination of top-line results does not trigger a duty to disclose the full results of a study." The court also rejected plaintiffs' claim that the company's statements were misleading insofar as the trial failed to illuminate Vascepa's mechanism of action: Amarin never purported to know that mechanism.

The Third Circuit affirmed. The appellate court noted that the company had made no affirmative characterizations about the placebo issue when it reported top-line results, and therefore did not "put into play" the full trial data or additional information about the placebo. Amarin's report of top-line results also constituted an opinion statement, and plaintiffs' allegations about the impact of the placebo, which were drawn from medical professionals and news articles, were merely differing interpretations of the trial data. Those allegations did not show that the company lacked a reasonable basis for its stated opinions. The Third Circuit also agreed with the district court that plaintiffs had failed to show that Amarin's risk disclosures were false or misleading. The company warned of exactly the placebo-related risk that was purportedly omitted, and at the time of the challenged statements, that risk had not yet materialized.

Thant v. Karyopharm Therapeutics Inc., 43 F.4th 214 (1st Cir. 2022), affirming dismissal. NDA

Karyopharm developed selinexor for the treatment of advanced cancers. In a Phase 1 trial, only one of 56 patients responded favorably, and several patients discontinued treatment prematurely because of the drug's toxicity. In an initial Phase 2 trial, SOPRA, overall survival was significantly worse on the treatment arm than on the control arm, and all patients on the treatment arm experienced adverse events. In March 2017, the company announced that it was terminating the SOPRA trial based on poor overall survival results. The company also conducted a single-arm Phase 2(b) trial, STORM. For this trial, Karyopharm reported good news, stating in March 2018 that the trial had demonstrated efficacy, that selinexor had a manageable toxicity profile, and that the company would submit an NDA based on the STORM results. In June 2018, Karyopharm reported that it would also use real world data in the NDA—that is, data derived outside the clinical trial setting—and that it was following FDA guidance on the use of such data. In February 2019, the FDA released a briefing document in which it pointed to significant toxicity data and announced that it would delay review pending completion of an additional ongoing trial. Karyopharm's stock price fell 43%. The company thereafter amended its NDA to target a narrowed indication: patients who had already gone through four rounds of treatment and had no other treatment options left. The FDA approved selinexor for that indication in July 2019.

Investors sued, challenging the company's statements about the SOPRA trial, the STORM trial, and the use of real world data. In a 2021 ruling (discussed in last year's review), the district court concluded that plaintiffs had failed to plead falsity as to the SOPRA trial and the use of real world data, and that while they had adequately pled that the company's statements about STORM were materially misleading, they failed to plead scienter. On appeal, investors limited their challenge to the company's STORM-related statements.

The First Circuit affirmed, although on somewhat different grounds. Unlike the district court, the appellate court held that plaintiffs had failed to show that any challenged statements were misleading, including the statements about STORM. Statements that STORM's results represented an "important milestone" and a "significant step" were non-actionable puffery. Statements that selinexor had a "predictable" and "manageable" safety profile were not misleading either. Plaintiffs claimed that the statements were misleading by omission insofar as the company failed to disclose information about the serious risks of treatment, including the prevalence and severity of adverse events. But that allegation failed when the statements were viewed in context. Patients in STORM were very sick with advanced cancers. Because investors understand that treatments for this patient population are not benign, they were unlikely to be misled by references to a "predictable" and "manageable" safety profile. The court also noted that Karyopharm regularly informed investors of serious adverse events in certain patients. While plaintiffs may have wished to know more about the landscape of adverse events, that was not enough to render the company's statements materially misleading.

Lungu v. Antares Pharma Inc., 2022 WL 212309 (3d Cir. 2022), affirming dismissal. 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 it was halting review as a result of unspecified deficiencies. The company's stock price fell 38%. In a subsequent Complete Response Letter,[12] the FDA identified safety risks related to hypertension and suicidality. The FDA ultimately approved the product with a black box warning label.

Investors sued, challenging the company's statements about product safety. In a 2019 ruling (discussed in our 2019 review), the court dismissed the complaint, holding that plaintiff's confidential witness allegations lacked specificity and corroboration, and that plaintiff had failed to adequately specify which statements he was challenging. Plaintiff amended, and in a 2020 ruling (discussed in that year's review) the court again dismissed: The challenged statements consisted of non-actionable opinions and puffery, or were not materially

12 The FDA issues Complete Response Letters (or CRLs) when it has concluded that it cannot approve an NDA or BLA in its present form.

misleading. The court also held that plaintiff failed to plead particularized facts supporting his theory of scienter.

In a 2021 decision (discussed in last year's review), the district court dismissed the third amended complaint with prejudice. Plaintiff challenged the company's statements about pain data in the Phase 3 trials, but interpretations of clinical trial data are opinions, and plaintiff had failed to meet the criteria for attacking opinion statements. Plaintiff also failed to plead materiality as to these statements, which related to pain rather than to the safety issues that led to the black box label. Plaintiff's new scienter allegations were also insufficient; the confidential witness allegations in particular were generalized and ambiguous. The company's awareness that certain results were excluded from the reported data did not establish scienter either: The exclusions were made pursuant to the study design, which the FDA had approved.

The Third Circuit affirmed. Statements about "physiologically normal" testosterone levels and a "virtually painless treatment experience" were not rendered false by occurrences of hypertension, suicide, and depression in Phase 3 clinical trials. The company disclosed adverse events, and had no duty to calculate statistical risks. Adverse events unlinked to the product were not material, and other statements were either non-actionable puffery or otherwise immaterial.

DISTRICT COURT DECISIONS—MOTION TO DISMISS GRANTED

Dresner v. Silverback Therapeutics, Inc., 2022 WL 16716165 (W.D. Wash. Nov. 4, 2022), granting motion to dismiss without prejudice. **Phase 1**

Silverback Therapeutics developed SBT6050 to treat breast, gastric and non-small cell lung cancers. In July 2020, the company began a Phase 1 trial of the drug. Silverback conducted its IPO in December 2020, five months into the trial. In its offering documents, Silverback described changes in pharmacodynamic markers observed in the first dose cohort from the Phase 1 trial, and stated that it anticipated providing an update on dose-escalation groups in the second half of 2021. In September 2021, the company reported interim results both from patients given the drug as a monotherapy and from patients given the drug in combination with pembrolizumab, an approved checkpoint inhibitor made by Merck. Silverback stated that the drug's safety profile was manageable, but that among the 18 patients in the study, only one demonstrated a partial response, while three others demonstrated stable disease. Silverback's stock price fell 23%. In March 2022, the company announced that recent results showed that SBT6050 did not have sufficient anti-tumor activity when given as a monotherapy, and that an effective dose caused adverse events that were too severe for the treatment to be viable. Silverback reported that it was discontinuing SBT6050, together with another drug that had a similar clinical profile. The stock price fell 9%.

Investors sued, challenging (1) the statement that Silverback had "observed changes in pharmacodynamic markers in the first dose cohort," (2) statements about the drug's safety profile, and (3) statements about the addressable market. The first statement appeared in the IPO offering documents, and plaintiffs challenged it under Section 11. Variants of the second and third groups of statements appeared both in the offering documents and in subsequent filings, and plaintiffs challenged them under both Section 11 and Section 10(b). The court granted the company's motion to dismiss as to all statements and all claims. With respect to the pharmacodynamic markers, the company had identified changes and noted that those changes were consistent with a potential mechanism of action. But the company did not say that the changes demonstrated efficacy, which defeated plaintiffs' theory of falsity. With respect to the other challenged statements, plaintiffs' pleading style was defective. By presenting long block quotations without specifying which portions were false or why, plaintiffs had engaged in improper "puzzle pleading." Plaintiffs' scienter allegations were likewise deficient: Plaintiffs failed to plead facts showing that at the time it made the challenged statements, the company was aware of contradictory information from the Phase 1 trial.

Kim v. Allakos Inc., 2022 WL 976974 (N.D. Cal. March 31, 2022), granting motion to dismiss without prejudice. **Phase 2**

Allakos develops AK002 for the treatment of eosinophilic gastritis and gastroenteritis. (Eosinophils are white blood cells that can cause stomach problems when present in large numbers.) After the company announced favorable Phase 2 results, a short seller issued a report criticizing the company for not using a contract research organization (CRO) in the trial. The short seller also stated that the trial blind had been compromised, that inconsistent use of steroids among patients had a confounding effect on results, and that the company had underreported serious adverse events. The short seller's conclusions were based in part on social media posts by trial participants and their families. The company's stock price fell 17% following publication of the report.

Investors sued, adopting the accusations in the short seller report. They alleged that Allakos had falsely stated that it had used a CRO, had failed to tell investors that blinding had been compromised and that steroid use was a confounding factor, and had falsely stated that only one serious adverse event had occurred. The court granted the company's motion to dismiss. The company did not state that it had used a CRO; the company said only that it used independent third parties "such as CROs." Plaintiffs' allegations about blinding and steroid use were impermissible attacks on trial design and methodology, and were not supported by particularized facts in any event. The attacks were instead based the short seller report, which was in turn based on "anecdotal postings in a private Facebook group" in which trial participants speculated about whether they had received the study drug or a placebo. The same reliance on patients' social media accounts doomed plaintiffs' charge that Allakos had underreported serious adverse events. "The court is not persuaded that it can replace the judgment of the [trial] investigators with the anecdotal reports by test subjects and their families."

Cachia v. Bellus Health Inc., 2022 WL 4367444 (S.D.N.Y. Sept. 21, 2022), granting motion to dismiss with prejudice. **Phase 2**

Bellus develops BLU-5937 for the treatment of chronic cough. Bellus conducted a successful Phase 1 trial in November 2018. In July 2019, the company announced that it had finished designing a Phase 2 trial. Bellus told investors that its drug and trial design were similar to those of three competitors, each of which had recently reported successful Phase 2 results. Like the competitors' drugs, BLU-5937 targeted P2X3 receptors. Like the competitors' trials, Bellus' Phase 2 trial was randomized, double-blind and placebo controlled. Bellus therefore projected confidence in trial results. The company also noted that it had an advantage over its competitors: Bellus' Phase 1 trial, unlike those of some of its competitors, did not show that patients lost their sense of taste. Bellus conducted its IPO in September 2019. In July 2020, the company reported that its Phase 2 trial had failed, and its stock fell 72%. Some commentators attributed the failure of the trial to its design. One of the Phase 2 eligibility criteria was a frequency of ten coughs per hour. Mean coughs per hour in the competitors' successful trials were much higher, in the 40-60 range. Bellus' own trial demonstrated statistically significant results for patients with a baseline of 32 or more coughs per hour.

Investors sued, faulting the company for failing to disclose that in designing its trial, it had disregarded the connection between high cough frequency and efficacy in its competitors' trials. The court granted the company's motion to dismiss on both falsity and scienter grounds. Plaintiffs failed to adequately allege falsity for three reasons. First, their claim was essentially an attack on trial design, and this is impermissible under Second Circuit law. Second, Bellus did not conceal its ten coughs/hour eligibility requirement; it disclosed that figure. Third, plaintiffs' challenge depended on speculation and hindsight. Plaintiffs alleged no facts showing that Bellus knew that adopting an eligibility requirement of ten coughs per hour would lead to a pre-treatment baseline below the 40-60 coughs per hour found in its competitors' trials. Those trials had no coughs per hour eligibility requirement at all. Nor did plaintiffs plead facts showing that a higher baseline frequency was necessary to establish efficacy. The company's optimistic statements about potential approval were also statements of opinion, and plaintiffs had pled at most that in not calling attention to the low coughs per

hour eligibility requirement, Bellus declined to disclose "facts cutting the other way"—which is inadequate under *Omnicare*.[13] Plaintiffs' scienter allegations were deficient for similar reasons.

Shash v. Biogen, Inc., – F. Supp. 3d –, 2022 WL 4134479 (D. Mass. Sept. 12, 2022), granting motion to dismiss with prejudice. NDA

Biogen develops aducanumab for the treatment of Alzheimer's disease. The company conducted two Phase 3 trials called Engage and Emerge. Engage began enrollment before Emerge. Approximately two-thirds of the patients in the trials had a condition that predisposed them to experience side effects of aducanumab, and these patients were initially given low doses. The trial protocol was amended twice to permit higher doses. Because Emerge started later, the higher doses were given disproportionately to patients in that study. The protocol also included an interim futility analysis, which was conducted on aggregated results from Engage and Emerge. The trials failed the interim test and were halted on futility grounds. Biogen then performed a post-hoc analysis in which it disaggregated the Engage and Emerge data; this showed that Emerge met its primary endpoints. The Engage data were also favorable when limited to patients receiving higher doses. The FDA supported Biogen's post-hoc analysis and encouraged submission of an NDA, notwithstanding the fact that the Phase 3 trials had been terminated for futility. The FDA convened an Advisory Committee, and when the FDA released its Advisory Committee briefing document, analysts reported that the document showed that the agency endorsed approval. Biogen's stock rose 40%. But the briefing document also contained a dissenting report from an FDA statistician, and the stock fell 18% the next trading day, possibly in delayed response to the dissenting report. The Advisory Committee returned a mixed vote, and the stock fell 28%. The FDA ultimately approved aducanumab under its accelerated approval program (which requires a confirmatory Phase 4 post-approval study).

Investors sued, challenging statements in four categories. The court dismissed as to all statements on falsity, scienter, and loss causation grounds. In the first group of statements, Biogen told investors that the Emerge data showed statistically significant evidence of efficacy at high doses, and that certain of the Engage data did too. Plaintiffs did not dispute that these statements were true, but argued that they were misleading because the post-hoc analysis was unreliable and alternative post-hoc analyses showed a lack of efficacy. The court rejected the claim, explaining that Biogen had carefully distinguished between the Engage and Emerge data and accurately reported what the data showed. The court also characterized the challenged statements as opinions, and held that plaintiffs' allegations amounted to a dispute over statistical methodology, which is not a basis for a fraud claim. The court rejected plaintiffs' attack on a second group of statements, in which Biogen pointed to a correlation between the reduction of amyloid plaque in patients' brains and positive clinical outcomes. Here again, data supported the company's statements, and plaintiffs' claim was an impermissible attempt to have the court adjudicate disputes over science and methodology. A third group of statements—about the "encouraging" nature of data meeting multiple endpoints under the post-hoc analysis—constituted non-actionable puffery. Plaintiffs' attack on a fourth group of statements, about the effect of regional variations, failed because plaintiffs had not shown that their alternative reading of the data was correct. On scienter, the court emphasized the fact that the FDA collaborated with Biogen in the post-hoc analysis. The court also noted that the market "knew the data [were] being drawn from a study that had been terminated early due to futility and that Biogen was mining the data to uncover evidence of aducanumab's efficacy." That critical background fact defeated the inference that Biogen intended to deceive investors or recklessly disregarded the risk of deception. The court finally held that plaintiffs had failed to allege loss causation. Plaintiffs purchased their stock during the brief interval in which the market responded favorably to the FDA's briefing document, perhaps because analysts and investors had not yet digested the dissenting report. The court concluded, somewhat oddly, that "causation is not tied to when the market reacts to information, but rather when that information became available to the public."

13 *Omnicare Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015).

Rice v. Intercept Pharms., Inc., 2022 WL 837114 (S.D.N.Y. Mar. 21 2022), granting motion to dismiss without prejudice. **NDA for new indication; adverse event reporting**

Intercept develops Ocaliva to treat liver disease. The FDA approved Ocaliva as a treatment for primary biliary cholangitis (PBC) in 2016. PBC is a rare disease. Following reports of deaths in patients taking higher than recommended doses of the drug, the company issued a Dear Healthcare Provider letter and the FDA updated the label to provide additional warnings. Throughout this period, the company reported adverse events to the FDA's database, but not all adverse event signals were included in the updated label.

In November 2019, Intercept reported that the FDA had accepted for filing an NDA for a new indication, nonalcoholic steatohepatitis (NASH), which affects as much as 3-5% of the world's population. In May 2020, the FDA informed the company of a Newly Identified Safety Signal (NISS) for Ocaliva, which related to adverse events experienced by PBC patients. Intercept did not disclose the NISS at the time. Also in May 2020, Intercept reported that an Advisory Committee meeting had been postponed to allow review of additional data. The company's stock fell 12%. In June 2020, Intercept announced that it had received a CRL, and its stock fell 50%. In August 2020, Intercept for the first time reported the NISS in the risk disclosures in its Form 10-Q. The stock price did not respond. But when a health news website published an article about the NISS in October 2020, the stock fell 8%.

Investors sued, challenging Intercept's statements about its NASH NDA. Plaintiffs also faulted Intercept for purportedly omitting PBC-related adverse events that the company had reported to the FDA's adverse event database, but that did not appear on Ocaliva's label. The court's decision leaves unclear which, if any, public statement the omission of the adverse events was alleged to have rendered misleading. The court granted the company's motion to dismiss. With respect to the adverse events in PBC patients, plaintiffs failed to establish materiality; among other things, the FDA itself had made the decision not to include the adverse events on the label. The court also strongly suggested that disclosure of the adverse events to the FDA database defeated plaintiffs' claim. With respect to the company's statements about its NASH NDA, plaintiffs' principal theory was that the statements were misleading in light of the undisclosed NISS. That theory failed because plaintiffs were unable to tie the CRL to the NISS. The NISS arose from the FDA's concern about risks to PBC patients who suffered from a condition not shared by NASH patients. The court also rejected plaintiffs' theory that the company had improperly "buried" its disclosure of the NISS in the risk factors in its Form 10-Q; the court believed the company's placement of the item was reasonable. On scienter, plaintiffs failed to show that the CEO's stock sales were suspicious in timing or amount. The CEO sold stock after publicly announcing good news—that the FDA had accepted its NDA—and not when the company learned about non-public bad news—the NISS. Plaintiffs failed to establish loss causation as to the June 2020 report of the CRL because they could not tie the CRL to the previously undisclosed NISS. And while the October 2020 health news article did relate to the NISS, it provided no new non-public information to the market.

Fisher v. Fennec Pharms., Inc., 2022 WL 7108945 (N.D. N.C. Oct. 12, 2022), granting motion to dismiss with prejudice. **NDA; manufacturing issues**

Fennec developed Pedmark to treat hearing loss in children undergoing chemotherapy. Fennec used a third party, PII, to manufacture the drug. Fennec filed an NDA in December 2018. In July 2020, the FDA issued a Form 483 identifying multiple serious manufacturing deficiencies, including product contamination. In August 2020, the FDA issued a CRL denying approval solely because of the manufacturing issues. In May 2021, the company resubmitted its NDA. For the next several months, through the end of September 2021, Fennec made generally positive statements about the likelihood of approval. On September 29, 2021, the FDA issued another Form 483 identifying numerous violations of good manufacturing practices. The company did not disclose the Form 483, although it did make indirect statements suggesting that FDA inspections had led to some negative findings. The company also began speaking with less optimism about the likelihood of approval. It stated that the FDA's findings did not foreclose approval, but that it had lined up a second manufacturer and could, if necessary, resubmit its NDA using that manufacturer (after a short delay). In

November 2021, the company reported a second CRL, again based solely on manufacturing deficiencies. The stock fell 8%.

Investors sued, challenging the company's statements about manufacturing and the likelihood of approval. The court granted the company's motion to dismiss on both falsity and scienter grounds. With respect to statements made before September 29, 2021, plaintiff pled no facts showing that PII had not addressed past manufacturing issues. The court rejected plaintiff's argument that Fennec had an obligation to perform its own inspection or manufacturing audit. As to statements after September 29, 2021, plaintiff failed to plead facts showing that the issues the FDA identified in its Form 483 made approval unlikely. As a result, the inference that the company intended to deceive investors with its optimistic—but qualified—statements did not outweigh the inference that it made those statements innocently or negligently. Finally, plaintiff pled no facts showing that Fennec had *not* lined up a second manufacturing partner. Indeed, Fennec's reference to the second partner undercut any inference that the company intended to deceive investors about the risk that issues with PII would lead to another CRL.

Leung v. bluebird bio, Inc., 599 F. Supp. 3d 49 (D. Mass. 2022), granting motion to dismiss with prejudice. **BLA; manufacturing issues**

Bluebird develops gene therapies for the treatment of cancer and severe genetic diseases. In bluebird's therapies, a patient's stem cells are extracted, lentiviral vectors are used to introduce a functional copy of a gene to the cells, and the modified cells are then reinserted into the patient's body. The company conducted a Phase 3 trial of its gene therapy, LentiGlobin, in patients with sickle cell disease; in that trial, the lentiviral vectors were manufactured using an "adherent" process. In May 2020, bluebird announced that for commercial purposes, it would shift to manufacturing lentiviral vectors through a "suspension-based" process, and that it would perform studies demonstrating the comparability of cells manufactured through the two different processes. The company also announced that it planned to submit a BLA for LentiGlobin in the second half of 2021. Bluebird cautioned that the FDA could require additional comparability studies before accepting submission of the BLA. One week after bluebird made these announcements, it conducted a public offering. In August 2020, bluebird again referred to its transition to the new manufacturing process and repeated that it intended to submit a BLA in the second half of 2021. The company also cautioned that the FDA might not accept the comparability data it intended to present and could require additional studies. On November 4, 2020, bluebird announced that it would not submit its BLA until late 2022. The company had hoped that the FDA would accept comparability data based solely on the cells of healthy donors, but the FDA had told the company that it also needed to perform a comparability analysis using the cells of patients with sickle cell disease. The company's stock price fell 17%.

Investors sued, claiming that the company misleadingly failed to disclose that it planned to perform comparability studies only on the cells of healthy donors, and that the FDA would not accept those studies. The court granted the company's motion to dismiss on falsity, scienter and loss causation grounds. Somewhat atypically, the court began by analyzing scienter. Plaintiffs' scienter allegations failed, the court held, because plaintiffs pled no facts showing that bluebird knew that the FDA would not accept comparability data limited to the cells of healthy donors. The fact that bluebird conducted a stock offering did not demonstrate scienter under a motive and opportunity framework where plaintiffs identified no other indicia of scienter (contradictory internal reports, insider trading and the like). Nor were plaintiffs' allegations sufficient under a core operations theory. Plaintiffs had identified no "plus factors"—nothing more than the product's importance to bluebird. For similar reasons, plaintiffs' allegations failed on falsity grounds: Bluebird's statements about the comparability studies it planned to perform were not false when made. Finally, plaintiffs failed to establish loss causation. Bluebird's announcement that it was delaying its BLA submission by a year did not correct any alleged untruth about the more ambitious timeline the company had previously reported.

Paxton v. Provention Bio. Inc., 2022 WL 3098236 (D.N.J. Aug. 4, 2022), granting motion to dismiss with prejudice. **BLA; manufacturing issues**

Provention develops teplizumab to delay or prevent the onset of type 1 diabetes. Provention acquired teplizumab from another company while a Phase 2 trial was ongoing. Teplizumab subsequently received a Breakthrough Therapy designation, which allowed Provention to submit its BLA (which was based on the Phase 2 trial) on a rolling basis. Because Provention intended to launch with a manufacturer different than the manufacturer that had supplied the drug used in the trial, it was required to demonstrate as part of its BLA that the new manufacturer could make a biosimilar drug. To accomplish this, the company conducted a "bridging study" to establish comparability. Provention submitted its BLA in November 2020. In January 2021, Provention conducted a secondary stock offering. In the offering documents, the company for the first time reported results from the bridging study, noting some discrepancies in pharmacokinetic data but opining that this would not impact approval. The company also cautioned that the FDA could disagree, and its stock dropped 14% the day after the offering. In February 2021, Provention reported that the FDA had raised concerns about the discrepancy in pharmacokinetic data in the bridging study, and its stock fell 12%. Provention then reported ongoing FDA concerns on two dates in April and May 2021, and the stock fell 18% and 6%, respectively. Later in May 2021, an Advisory Committee reviewing the drug voted 10-7 in favor of approval, but noted that the Phase 2 trial did not meet its enrollment goal and that safety data were limited in that patients were no longer followed once they had developed diabetes. The stock fell 29%. In July 2021, the company announced that it had received a CRL in which the FDA stated that the bridging study had failed to establish pharmacokinetic comparability. The stock fell 26%.

Investors sued, claiming that the company misleadingly omitted information about the failure of the bridging study to establish comparability and further failed to disclose the two issues identified by the Advisory Committee—under-enrollment and the limited nature of the safety data. The court dismissed the complaint on falsity and scienter grounds. Plaintiffs' own allegations undermined their contention that the company concealed information about unfavorable data from the bridging study: Plaintiffs claimed that the data first became available in January 2021, which is when the company reported them. The company's statements interpreting the bridging study data were also protected as opinions; among other things, plaintiffs failed to show that the company did not believe the opinions it expressed. (Oddly, the court did not cite *Omnicare* in analyzing the opinion statements, and relied on a formulation superseded by *Omnicare*.) The company had no duty to disclose its interim discussions with the FDA about the bridging study data, and in any event, *had* disclosed those discussions. As to the two issues identified by the Advisory Committee, Provention disclosed the first—that the trial did not meet its enrollment goal—while the company's statements about the second—adequacy of safety data—were again protected opinions. Plaintiffs' scienter allegations were also inadequate. Plaintiffs failed to satisfy the requirements of the core operations doctrine by means of allegations that teplizumab was important to the company and that the individual defendants were knowledgeable about the trials and the workings of the pharmaceutical industry. Plaintiffs also cited Provention's January 2021 stock offering as evidence of motive, but the company *disclosed* the problematic results from the bridging study in the offering documents. That weighed against any inference of intentional deceit.

In re Talis Biomedical Corp. Sec. Litig., 2022 WL 17551984 (N.D. Cal. Dec. 9, 2022), granting motion to dismiss without prejudice. **EUA; COVID-19 test**

Talis developed the Talis One System, a diagnostic platform for infectious diseases. Before the COVID-19 pandemic, the company developed the product as a test for sexually transmitted infections. After the pandemic began, it shifted to designing Talis One as a COVID-19 test. That shift enabled the company to proceed under the FDA's Emergency Use Authorization (EUA) program, which is faster than normal approval pathways. Talis submitted an EUA application on January 29, 2021. On February 11, 2021, Talis went public. In March 2021, Talis reported that the FDA had signaled a concern that the data supporting the EUA application were not sufficiently sensitive. Talis withdrew the initial EUA application and told investors that it would prepare a new EUA for a different laboratory setting, using different data. Talis's stock

fell 12%. In July 2021, Talis submitted a new EUA, which the FDA approved in November 2021. But following approval, manufacturing challenges delayed the launch of the Talis One. On March 15, 2022, the company reported that it had not started the launch, that it was engaging external manufacturing consultants, and that it was laying off 25% of its workforce. The stock fell 23%.

Investors sued, challenging Talis's statements about its manufacturing process, the performance and testing of Talis One, and its initial EUA submission. Because statements on all three subjects appeared in the company's IPO registration statement, plaintiffs brought claims under Section 11. Plaintiffs challenged similar post-IPO statements under Section 10(b). The court granted the company's motion to dismiss in its entirety. The court rejected plaintiffs' attack on the company's statement that it had ordered "5,000 instruments" from manufacturing partners. Because Talis had ordered *components* for instruments, plaintiffs failed to allege falsity. Plaintiffs also failed to allege falsity with respect to other statements about manufacturing and performance, as plaintiffs' confidential witness accounts were conclusory and vague as to time. As to Talis's statements about its EUA application, plaintiffs failed to establish that the supporting data were inadequate or that the company knew they were inadequate at the time of the challenged statements. The FDA's request for additional information came *after* the company made the statements, and therefore did not show otherwise.

In re AstraZeneca plc Sec. Litig., 2022 WL 4133258 (S.D.N.Y. Sept. 12, 2022), granting motion to dismiss with prejudice. **COVID-19 vaccine development**

In April 2020, AstraZeneca partnered with Oxford University to develop a COVID-19 vaccine made from weakened cold virus from chimpanzees. After a Phase 1/2 trial, the company stated that the vaccine was "safe and well tolerated." During Phase 2/3 trials, AstraZeneca stated that the study "remains on track," using "2-dose studies." As clinical results came in, the company stated that it was "encouraging to see [that] immunogenicity responses were similar between older and younger adults," and that "reactogenicity was lower in older adults, where the COVID-19 disease severity is higher." Immunogenicity reflects immune responses to a vaccine and their magnitude over time. Reactogenicity is the inflammatory response to vaccination. The company made similar statements about the progress of the trials throughout 2020.

On November 23, 2020, the company released an interim analysis of trials in the UK and Brazil in which both full doses and half-doses were given to patients. The company reported that its use of half-doses in certain trials was not part of the original trial design; rather, the company used half-doses because that is what its contract manufacturer had produced. On November 24, 2020, the head of Operation Warp Speed (the public-private partnership facilitating vaccine development) stated that the half-doses had not been tested in people over 55, that certain trial participants received their second dose weeks later than planned, and that groups and subgroups had been amalgamated in the trials. The company's stock price fell 5%. Two weeks later, the company published the results of its Phase 2/3 trials, concluding that efficacy in older adults could not be assessed. The stock fell 8%. In January 2021, a German newspaper quoted German government sources stating that AstraZeneca's vaccine was less than 10% effective in older adults. The German government thereafter advised against its use in older people, and the French president remarked that the vaccine seemed "quasi-ineffective" in that population. The stock fell 7%.

Investors sued, claiming that the company failed to timely disclose the use of half-doses and the fact that some trial participants received their second dose later than scheduled. The court granted the company's motion to dismiss, holding that the undisclosed information did not render any of the company's affirmative statements misleading. The court rejected plaintiffs' contention that the company's statements created a misleading impression that the trials were proceeding as expected without setbacks: "Were that the standard, every omission would be actionable." Statements that the trials were "on track" were non-actionable puffery, and in any event were not rendered misleading by the omission of information about purported "widespread design flaws." The same was true of the company's statements about its "core values" and "commitments to public safety." Statements about the likelihood of regulatory approval, meanwhile, were protected by the PSLRA safe harbor for forward-looking statements. After concluding that plaintiffs failed to adequately allege falsity, the court swiftly rejected their scienter allegations.

In re Eastman Kodak Co. Sec. Litig., – F. Supp. 3d – , 2022 WL 4473629 (W.D.N.Y. Sept. 27, 2022), granting motion to dismiss with prejudice. **COVID-19 product development**

In response to the COVID-19 outbreak, Eastman Kodak, which is primarily known for its photography and film manufacturing business, began exploring the production of chemicals used in drugs designed to combat COVID-19, including hydroxychloroquine. Kodak and the United States International Development Finance Corporation (DFC) entered into a Letter of Interest contemplating a $765million loan to support the conversion of Kodak's facilities to produce pharmaceutical products. Kodak executives participating in the project (including the CEO and general counsel) were told that knowledge of the project could be considered material non-public information (MNPI) and were warned not to trade in Kodak stock while in possession of that information. On July 27, 2020, the day before the Letter of Interest (LOI) was to be announced, Kodak's CEO and general counsel convened the board of directors, among other things, to seek approval to grant stock options to senior management. These options gave the holders the right to purchase shares at the trading price on the date of grant, which was in the $2 range—but, according to the plaintiffs, was expected to increase significantly when the LOI was announced the next day. The board approved the request. Also on July 27, 2020, Kodak leaked information about the LOI to the press. After the LOI was announced on July 28, 2020, the stock price soared over a period of days—first to $2.62, then to $9.63, and eventually to $33.20, an increase of more than 1500%. On July 30, 2020, the DFC stated that the loan was not finalized, and on July 31, the *New York Times* and *Wall Street Journal* reported on the options grant. Kodak stock dropped to $21.85, and then to $14.91 on August 3, 2020. On August 4, 2020, the media reported that the SEC was examining the disclosure of the LOI and stock surge, and Senator Elizabeth Warren asked regulators to investigate possible insider trading. On August 10, 2020, the stock price closed at $10.01. Kodak never received the $765 million DFC loan.

Investors sued, challenging Kodak's statements about the loan to various media outlets. The court granted the company's motion to dismiss. A statement that the new manufacturing initiative "could change the course of history for Rochester and the American people" was puffery. Statements about Kodak's manufacturing and hiring plans were forward-looking and made without actual knowledge of falsity. Plaintiffs' theory of actual knowledge and fraud generally was that because the company knew about what plaintiffs characterized as spring-loaded options, it also knew that the DFC would learn about those options and revoke the loan in response. The court held that this theory was impermissibly speculative; the directors and officers did not actually know what the government's response to the option grant would be. Plaintiffs' theory was also economically counterintuitive. Because the executives had every incentive to ensure that the loan was *not* revoked, a theory that they knew it *would* be revoked made little sense. The court also rejected plaintiffs' attack on the CEO's statements about his "comfort" that the loan would be finalized: Plaintiffs had pled no facts showing that the executives who made those statements disbelieved them. Plaintiffs' omission theory failed because the omitted information—about the option grant—was disconnected from the challenged statements—about the loan. The court finally rejected plaintiffs' claim for scheme liability. Plaintiffs failed to show that the option grant was deceptive or manipulative, and alleged only in an impermissibly conclusory manner that it violated Kodak's internal policies.

DISTRICT COURT DECISIONS—MOTION TO DISMISS DENIED

Nacif v. Athira Pharma, Inc., 2022 WL 3028579 (W.D. Wash. July 29, 2022), denying in part and granting in part motion to dismiss. **Pre-clinical**

Athira develops molecules to restore neuronal health and stop neurodegeneration. The company's CEO wrote a PhD dissertation and published six articles before the company held its IPO. Between 2014 and 2016, commentators on a website called PeerPub questioned certain images in the CEO's papers. Athira held its IPO in September 2020 and a secondary offering in January 2021. In May 2021, articles again began appearing on PeerPub questioning whether images in the CEO's papers had been manipulated. In June 2021, Athira announced

that the CEO had been placed on administrative leave pending an internal review of the matter, and the company's stock fell 40%. In October 2021, Athira announced that the CEO had resigned, and reported that it had determined through an independent special committee review that the CEO had "altered" images in her dissertation and subsequent research papers. Athira also stated that its lead development candidate was not the subject of the CEO's doctoral research. The CEO stated in a resignation letter that she had "enhanced" images, but did not change or manipulate underlying data.

Investors sued, challenging Athira's statements about (1) the CEO's qualifications and contributions to the company, (2) the company's licensing agreement with the university at which the CEO did her doctoral work, and (3) the company's drug development approach. Plaintiffs did not contend that any of the statements was false; they relied solely on the theory that the statements were misleading by virtue of omitted information about the CEO's data "falsification." The court denied the company's motion to dismiss as to a single statement challenged under Section 11 of the Securities Act (which does not require scienter), and only as to the CEO and the company itself (as opposed to the CFO, outside directors, and underwriters). This was a statement about the licensing agreement with the CEO's university. The court concluded that the CEO knew that she had enhanced images in her dissertation, and that plaintiffs plausibly alleged that by omitting that fact "while touting the exclusivity of a license for patents founded on [her] doctoral work," the CEO "might have misled a reasonable investor about the nature of his or her investment." (citation and internal quotation marks omitted). The court granted the defendants' motions as to all other statements. It rejected the conclusory contention that the CEO had "falsified" data and held that plaintiffs failed to establish that the bulk of the challenged statements were material, given the disconnect between the CEO's earlier work and the company's current principal drug candidate. Plaintiffs also failed to create a strong inference of scienter as to any defendant, including the CEO: "a plausible inference from the facts is that [she] believed her work had been amply vetted . . . [and] would withstand scrutiny."

Busic v. Orphazyme A/S, 2022 WL 3299843 (N.D. Ill. Aug. 11, 2022), denying in part and granting in part motion to dismiss. NDA

Orphazyme's sole drug candidate was arimoclomol, for the treatment of Niemann Pick Disease, a rare genetic disorder. A Phase 2/3 trial failed to meet either of its primary endpoints, but produced statistically significant results as to two pre-specified subgroups. Results were also statistically significant if three patients with a mutation indicative of a particularly severe form of the disease were excluded. The FDA supported the latter post-hoc analysis, as well as the subgroup analysis. Indeed, the FDA granted Breakthrough Therapy status after the trial was completed, and notwithstanding the failure of the trial to meet its endpoints. Orphazyme submitted an NDA based on the Phase 2/3 trial, and the FDA accepted the filing for priority review on September 16, 2020. On September 24, 2020, the FDA issued a deficiency letter. Orphazyme disclosed that letter in its September 29, 2020 IPO registration statement, where it described in detail six issues the FDA had identified. In March 2021, Orphazyme reported that it was in the final stages of labeling talks with the FDA and was "launch ready." But in June 2021, the company announced that the FDA had issued a CRL, and its stock fell 50%.

In reporting on the CRL, Orphazyme referred back to its trial results, stating that the trial had yielded a "good effect" on the "swallow domain." (A patient's ability to swallow was among the factors assessed in gauging efficacy.) The company also suggested that it might be able to resubmit the NDA without additional testing. In October 2021, Orphazyme reported on its post-CRL Type A meeting with the FDA, in which it said it had made progress in understanding how to resolve the issues identified in the CRL. In November 2021, the company issued a prospectus supplement in connection with another stock offering. The supplement included details about the CRL the company had not previously revealed. Among other things, the FDA had characterized the evidence for approval as "weak and contradictory" and had noted that Orphazyme failed to provide information the FDA had requested in connection with scores in the swallow domain. The stock fell 4%.

Investors sued, challenging statements about the prospects for approval beginning with the September 2020 registration statement. The court granted the company's motion to dismiss as to

the majority of the challenged statements. Somewhat unusually, the statements that survived came from the Orphazyme's June 2021 discussion of the CRL. These statements did not inflate the stock price—they drove it down 50%. The court dismissed statements before June 2021 on several bases. Plaintiffs' attack on the registration statement failed (and hence their Section 11 claim failed) because the company disclosed in its offering documents the issues the FDA had identified in its deficiency letter. The company also disclosed in detail the Phase 2/3 trial results. Plaintiffs faulted the company for failing to reveal negative FDA feedback from the mid-cycle review, but were unable to specify the content of that feedback. In any event, the company had no obligation to report interim FDA communications. The company's statement that it was "launch ready" was neither false nor misleading; it was a comment on the ability of the organization to enter the commercial phase, not on the likelihood of approval.

The court viewed Orphazyme's discussion of the CRL differently. This was a near-final agency determination, and the company had omitted the FDA's most negative comments (which it later disclosed in offering documents). Orphazyme also omitted a pre-CRL communication in which the FDA suggested that it needed additional clinical information to evaluate the swallow domain results. These omissions rendered misleading Orphazyme's statements that the trial had yielded strong swallow results and that resubmission might be possible without additional clinical work. Plaintiffs also adequately supported a strong inference of scienter, given the importance of the drug and its approval to Orphazyme's business, together with the company's motive to "pull off a vital capital raise."[14]

Pardi v. Tricida, Inc., 2022 WL 3018144 (N.D. Cal. July 29, 2022), denying in part and granting in part motion to dismiss without prejudice. NDA

Tricida developed veverimer for the treatment of metabolic acidosis associated with chronic kidney disease. Tricida sought approval under the FDA's accelerated approval program, in which a drug is conditionally approved based on a successful surrogate endpoint trial. The sponsor then conducts a post-approval Phase 4 trial to confirm efficacy by showing clinical benefit. Tricida conducted a Phase 3 trial in which the surrogate endpoint was an increase in patients' serum bicarbonate levels. The company reported favorable results from the trial in 2018. In November 2019, the FDA accepted Tricida's NDA for review, and in the first six months of 2020 held mid-cycle and late-cycle review meetings with the company. In July 2020, the FDA told Tricida that it had identified deficiencies that precluded further review. Tricida's stock fell 40%. In August 2020, the FDA issued a CRL identifying two deficiencies, one related to the applicability of data from foreign trial sites to U.S. patients and the other related to the magnitude and durability of the serum bicarbonate treatment effect. The company's stock fell 23%. The stock continued to fall as Tricida reported further setbacks in the approval process.

Investors sued, challenging Tricida's statements about (1) the requirements of the accelerated approval program, (2) enrollment in the Phase 4 trial, (3) the location of the Phase 3 trial sites, (4) the "multicenter" nature of the Phase 3 trial, and (5) the FDA's comments at the May 2020 late-cycle meeting. The court granted the company's motion to dismiss as to all statements save the last. Plaintiff failed to plead falsity as to the first two sets of statements. Tricida accurately described what it was required to show under the accelerated approval program; its statements were consistent with the FDA's public description of the program. Tricida also accurately described enrollment in the Phase 4 trial; the confidential witness on whom plaintiff relied conflated the concepts of enrollment and randomization. With respect to the third and fourth groups of statements, plaintiff adequately pled falsity but not scienter. Plaintiff adequately alleged that Tricida's references to trial sites in "Europe" were misleading because the company did not specify *Eastern* Europe, and the FDA may consider data from Eastern Europe to be less applicable to the U.S. population than data from Western Europe. Similarly, plaintiff adequately alleged that Tricida's reference to the "multicenter" nature of the trial was misleading because the company did not specify that one site contributed disproportionately

14 The court made one ruling that appears unfavorable as a technical securities matter. Without discussing the operative legal framework, the court permitted plaintiffs to proceed with a claim under Item 303 of Regulation S-K, which requires disclosure in periodic filings of certain trends and uncertainties. Other courts have rejected the contention that plaintiffs may assert a claim under Section 10(b) based on an omission that purportedly violates Item 303. *E.g., In re Nvidia Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014). The *Orphazyme* court not only implicitly recognized an Item 303-based Section 10(b) claim, it did so in connection with statements made in a press release—rather than in the periodic filings to which Item 303 applies.

to success as to a particular metric. But in neither case did plaintiff adequately allege scienter. Nothing about Tricida's literally true statements on these subjects made the danger of misleading investors obvious. Finally, the court concluded that plaintiff had adequately alleged both falsity and scienter as to Tricida's positive statements about its interactions with the FDA at the late-cycle meeting. The company identified the FDA's stated concern with the magnitude and durability of veverimer's treatment effect but not its concern about the applicability of data from Eastern European trial sites to U.S. patients.

City of Birmingham Relief & Ret. Sys. v. Acadia Pharms., Inc., 2022 WL 4491093 (S.D. Cal. Sept. 27, 2022), denying motion to dismiss. **sNDA**

Acadia's drug pimavanserin was approved in 2016 for the treatment of Parkinson's disease psychosis (PDP). Acadia subsequently conducted a Phase 2 trial studying pimavanserin as a treatment for Alzheimer's disease psychosis (ADP). After an end-of-Phase-2 meeting with the FDA, Acadia announced that it would conduct a single Phase 3 trial that would support approval of the drug, not for ADP specifically, but for a broader indication of dementia-related psychosis generally; this would encompass ADP, PDP, and others. The company reported that it had obtained "clear agreement" from the FDA on that approach. In September 2019, Acadia reported that the Phase 3 study, called Harmony, had yielded positive results. In February 2020, the company announced that the Harmony results would be the basis of the sNDA, "which was previously agreed upon at the end of Phase II meeting." Acadia submitted the sNDA in June 2020, and between then and February 2021, spoke favorably about the Harmony results and the prospects for approval. In March 2021, the company reported that it had received a deficiency notice from the FDA and its stock fell 45%. In April 2021, Acadia received a CRL and reported that "[d]espite prior agreements," the FDA had cited "a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with less common dementia subtypes." The stock fell 17%.

Investors sued, challenging Acadia's statements about agreement with the FDA and reports of favorable results from the Harmony trial. The court denied the company's motion to dismiss. The court concluded that plaintiffs had adequately pled falsity as to the statements about agreement with the FDA, and rejected the company's distinction between agreement on *submission* of the sNDA and agreement on *approval*. Plaintiffs also adequately pled that Acadia's reports of trial results were misleading (though not false). Plaintiffs alleged that the Harmony trial was flawed in design in that patients suffering from Parkinson's-related psychosis (for which the drug had already been approved) were grouped together with patients with psychosis related to other diseases. The court accepted plaintiffs' framing of the issue: that by reporting favorable results without criticizing its own trial design, the company had "touted" good information and failed to reveal facts cutting the other way. On scienter, the court concluded that the individual defendants' stock sales provided a motive for fraud. Although many of the sales were made under Rule 10b5-1 plans, defendants adopted those plans only after they had made several of the challenged statements. The court also rejected the defendants' argument that their disclosure of full trial results at a medical conference undermined the inference of scienter; the disclosure was made months after the challenged statements. Finally, the court rejected Acadia's argument that to posit that it would expend enormous resources on a trial that could not support approval made no sense. "Defendants' actions plausibly demonstrate that they misled investors into overestimating the likelihood of approval, not that Defendants knew from the start that the sNDA would not be approved."

In re BioMarin Pharm. Inc. Sec. Litig., 2022 WL 164299 (N.D. Cal. Jan. 6, 2022), denying motion to dismiss. **BLA**

BioMarin developed valrox for the treatment of hemophilia. Phase 1/2 trials, in which the drug was manufactured by a third party, yielded favorable efficacy results. The results for Phase 3, in which BioMarin manufactured valrox itself, were less favorable but still sufficient to support a BLA. The FDA accepted the BLA for filing in February 2020 and set a PDUFA date in August 2020 (valrox was on an accelerated pathway). During the six-month period, BioMarin expressed optimism about approval, characterized its interactions with the FDA as "collaborative" and stated that it believed the August 2020 PDUFA date would hold, notwithstanding the fact that the FDA had yet

to inspect the company's manufacturing facility. On the PDUFA date, the FDA issued a CRL rejecting the BLA. The company attributed that result to the discrepancy between the Phase 1/2 and the Phase 3 efficacy data. The stock fell 35%.

Investors sued, challenging BioMarin's statements about its interactions with the FDA and the likelihood of approval. The court denied the company's motion to dismiss. A majority of the challenged statements were forward looking, but the court rejected the company's argument that they came within the PSLRA's safe harbors. The court concluded that the company's risk disclosures were generalized and did not alert investors to the particular concerns the FDA raised in the approval process. The statements therefore did not come within the safe harbor protecting forward-looking statements accompanied by meaningful cautionary statements language. Nor did they come within the actual knowledge safe harbor. Plaintiffs had adequately pled defendants' actual knowledge as to statements about "collaborative" interactions with the FDA by means of an allegation that the FDA was uncommunicative and signaled problems when it did communicate with BioMarin. With respect to all challenged statements, the court concluded that plaintiffs had adequately alleged both falsity and scienter. Plaintiffs' theory was not that BioMarin *knew* that the FDA would deny the BLA, but that the company knew of and failed to disclose the agency's "concerns," which gave the company "reason to know that there was a heightened risk of denying approval." The court also credited plaintiffs' motive allegations in assessing scienter. One executive made class-period stock sales disproportionate to those predating the class period (albeit under a trading plan), and valrox "was going to be a significant and lucrative product," in part because exclusivity periods were expiring on two of BioMarin's other drugs. The court frequently drew on pre-PSLRA case law throughout the decision.

In a subsequent order, *In re BioMarin Pharm. Inc. Sec. Litig.*, 2022 WL 597037 (N.D. Cal. Feb. 28, 2022), the district court denied BioMarin's motion for reconsideration. The company's motion was directed at the court's rejection of its argument that a number of challenged statements fell within the PSLRA's safe harbor for forward-looking statements accompanied by meaningful cautionary language. BioMarin argued that the court had applied superseded pre-PSLRA standards. The pre-PSLRA case law required that cautionary language be sufficiently "precise" and "direct" that the risk of deception "drops to nil." The PSLRA, by contrast, requires only that the cautionary language identify "important factors that could cause actual results to differ from those in the forward-looking statements." The court rejected BioMarin's distinction between the pre-PSLRA case law and the statutory standard. According to the court, Congress intended to incorporate the existing case law—including the demanding "drops to nil" standard—when it enacted the PSLRA.

In re Fibrogen, Inc., 2022 WL 2793032 (N.D. Cal. July 15, 2022), denying in part and granting in part motion to dismiss. **NDA**

Fibrogen developed Roxadustat to treat anemia in patients with chronic kidney disease. The standard of care for such patients is Epogen, which is used only in severe cases, in which patients are on dialysis, because it increases the risk of major adverse cardiac events (MACE). In its Phase 3 trial, Fibrogen sought to show that Roxadustat was at least as effective as Epogen, without Epogen's safety issues. In November 2019, the company announced positive Phase 3 safety and efficacy results. The drug's cardiovascular safety profile was comparable to placebo for non-dialysis patients, and the risk of MACE was 30% lower than Epogen's for dialysis patients. In December 2019, the company submitted an NDA for Roxadustat. This triggered a $50 million milestone payment from AstraZeneca, which was providing development funding. In March 2021, Fibrogen announced that the FDA would hold an Advisory Committee meeting. The company's stock price fell 32%. In April 2021, the company issued a press release explaining that certain post-hoc changes it had previously made to stratification factors (groupings of clinical trial subjects by certain demographic categories) warranted clarification; the corrected data showed substantial safety concerns and indicated that the drug was less safe and effective than Epogen. The stock price fell 46%. In July 2021, the Advisory Committee held its meeting and voted against approval of Roxadustat for any population. The stock price fell 42%.

Investors sued, challenging statements about Roxadustat's safety, efficacy, and likelihood of approval. The court denied the company's motion to dismiss in large part. The court rejected the company's argument that the challenged statements were reasonable interpretations of trial data; the court credited, as a pleading matter, plaintiffs' allegations Fibrogen had "manipulated" the data through improper post-hoc analysis. The court also rejected the company's argument that disclosing its statistical analysis did not create a duty to share additional data. In the court's view, the issue was not omission of data but manipulation of data to show a reduced MACE risk. Plaintiffs also sufficiently pled scienter. Plaintiffs' confidential witness allegations, the company's press release disclosing post-hoc changes to the stratification factors, and the resignation of the Chief Medical Officer all supported an inference of scienter—as did the core operations theory, given that Roxadustat was Fibrogen's flagship product. The court granted the company's motion to as to statements about certain statistical margins and statements generally reflecting the company's confidence in its NDA and its impression of "positive" interactions with the FDA.

Sinnathurai v. Novavax, Inc., 2022 WL 17585715 (D. Md. Dec. 12, 2022), denying in part and granting in part motion to dismiss. **COVID-19 vaccine development; manufacturing issues; delayed EUA**

Novavax developed a COVID-19 vaccine. In June 2020, the company entered into a contract with the Department of Defense to deliver ten million vaccine doses by December 2020. The next month, Novavax joined Operation Warp Speed, through which it received $1.6 billion in federal funding to support late-stage clinical development. Also in July 2021, Novavax entered into a contract with Fujifilm to manufacture bulk drug substance at plants in Texas and North Carolina. Both plants experienced issues with contamination. In March 2021, the Texas plant was shut down for several months as a result of contamination incidents. In April 2021, the North Carolina plant received a Form 483. Multiple other manufacturing problems arose, concerning purity and potency criteria, scaling up production, and supply chain disruptions. On May 10, 2021, Novavax announced that its EUA application would be delayed as a result of manufacturing issues. The company's stock price fell 9% that day and 14% the next day. On August 5, 2021, Novavax reported that its EUA filing would be further delayed, and that it did not expect to submit until the fourth quarter of 2021. The stock price fell 20%. On October 19, 2021, *Politico* published an article stating that Novavax would not be able to resolve its manufacturing issues or obtain approval until the end of 2022. The stock price fell 15%.

Investors sued, challenging Novavax's statements about manufacturing and its progress toward approval. The court denied the company's motion to dismiss in part, holding that plaintiffs had adequately alleged falsity as to the company's description of manufacturing site production scale. Plaintiffs also adequately alleged that other statements about the manufacturing process were misleading by omission: Novavax failed to disclose facts about contamination and purity problems. Plaintiffs adequately alleged scienter as to these statements based on confidential witness allegations, the FDA's findings about issues at Fujifilm's plants, executive stock sales, and the fact that the vaccine was the company's "singular goal." The court granted the company's motion as to other challenged statements. Some were non-actionable puffery. For others, the purportedly omitted information about manufacturing issues did not render the challenged statements misleading because those statements addressed different subjects—the safety and efficacy of the vaccine.

In re Chembio Diagnostics, Inc. Sec. Litig., 586 F. Supp. 3d 199 (E.D.N.Y. 2022), denying in part underwriters' motion to dismiss and granting in part, without prejudice, company's motion to dismiss. **COVID-19 test; revoked EUA**

Chembio submitted an EUA application for its COVID-19 antibody test. In the EUA application, Chembio stated that the test had a 93.5% combined rate for correctly identifying the presence of Immunoglobulin M and Immunoglobulin G, and a 94.4% rate for correctly identifying the absence of COVID-19 antibodies. On April 14, 2020, the FDA issued an EUA for use of the Chembio test in laboratory settings. The FDA subsequently ordered further evaluation of the test. Meanwhile, Chembio submitted a request to amend its EUA to allow use in point-of-care settings. The test was independently evaluated by the Department of Health and Human Services, the National Institutes of Health, and the National Cancer Institute (NCI). On April 29, 2020, the FDA told the company that the NCI evaluation demonstrated higher false positive and false negative rates than

the company's data, and that the FDA would not move forward with the company's request to amend the EUA. In May 2020, Chembio conducted a secondary offering, which closed on May 11. On May 22, the FDA told the company it was concerned about additional data the company had submitted in response to the NCI evaluation results. On May 24, the company proposed modifications in an effort to address the FDA's concerns. On June 16, 2020, the FDA revoked the EUA. Both the FDA and Chembio announced the revocation the following day, and the company's stock fell over 60%.

Investors sued, challenging the company's statements about the EUA status and the accuracy of the test, including the statement that the test was 100% accurate after 11 days. Plaintiffs brought a Section 10(b) claim against the company and Section 11 claims against both the company and the secondary offering underwriters. Oddly, the court granted the company's motion to dismiss as to all claims but denied the underwriters' motion. The court dismissed the Section 10(b) claim on scienter grounds: Plaintiffs did not allege any concrete benefit to the company from the alleged fraud. The court rejected plaintiffs' "bet the company" theory—that the company's fate was dependent on the success of the test—holding that this was too generalized to support a strong inference of scienter. The court also rejected the premise that the company had information that the test might not be as accurate as it had claimed: Knowing that fact did not equate to knowing that the FDA would revoke the EUA. The court then concluded that the Section 11 claims against the company were "substantially intertwined" with the Section 10(b) claims and hence were subject to Rule 9(b)'s heightened pleading standard for fraud claims—and failed under that standard. Plaintiffs' claims against the underwriter defendants, by contrast, did not sound in fraud and survived in part under the normal Rule 8(a) pleading standard. While some of the challenged statements were non-actionable opinions or puffery, plaintiffs had adequately pled falsity as to the statement that the test was 100% accurate after 11 days, given allegations about contradictory information in the company's possession.

Plaintiffs subsequently moved the court to reconsider its rulings on scienter and the Section 11 pleading standard. The court denied the motion. 2022 WL 2872671 (E.D.N.Y. July 21, 2022).

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 33–42), 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, plaintiffs had an edge in the district court decisions. Defendants won motions to dismiss in four cases and lost their motions (at least in part) in six.

At the appellate level, defendants won the one post-approval case in 2022.

APPELLATE DECISIONS

Macomb Cty. Emps. Ret. Sys. v. Align Tech., Inc., 39 F.4th 1092 (9th Cir. 2022), affirming dismissal. **Sales performance**

Align is a medical device company that sells Invisalign, plastic braces for the treatment of misaligned teeth. The company operates globally, with a focus in recent years on sales in China. In July 2019, the company announced its second-quarter financial results, reporting that the rate of sales growth in China had fallen from 70-100% to 20-30%. Align's stock price dropped 27%.

Investors sued, challenging the company's statements about sales growth earlier in 2019. The district court granted the company's motion to dismiss (in a decision discussed in last year's review). Many of the statements were non-actionable puffery. The company also made more concrete statements—about competition, list pricing and demographic and economic features of the Chinese market—but plaintiffs failed to allege facts showing that any of these statements was false when made. The court also dismissed plaintiff's claim that certain optimistic statements about sales were rendered misleading by the company's omission of the purported fact that sales growth declined in April-May 2019: Plaintiff failed to allege facts showing that this was in fact the case. The district court granted plaintiff leave to amend, but plaintiff chose instead to appeal.

The Ninth Circuit affirmed, opening with this observation: "Securities actions often ask courts to distinguish between corporate braggadocio and genuinely false or misleading statements." The court then proceeded to reject the company's threshold argument, which was that the complaint rested on the "unsupported premise" that sales growth declined in April-May 2019. Parting ways with the district court on this point, the appellate court concluded that plaintiff had adequately alleged that this was the case. But that did not result in a victory for plaintiff. Like the district court, the Ninth Circuit came down on the side of "braggadocio" rather than fraud, holding that several of the challenged statements—*e.g.*, that "China is a great growth market for us," with "tremendous growth"—were non-actionable puffery, particularly because sales were still growing at the time of those statements. Plaintiff's attack on statements about the economics and demographics of the Chinese market failed because plaintiff pled no contradictory facts. A statement about past growth was accurate in context, while a prediction about the effect of a competitor was not misleading. The court also rejected plaintiff's argument that because the company had touted "positive facts" about its growth in China, it had an obligation to disclose negative facts, stating that "our securities laws 'do not create an affirmative duty to disclose any and all material information.'" (citation omitted).

DISTRICT COURT DECISIONS—MOTION TO DISMISS GRANTED

Sneed v. AcelRx Pharms., Inc., 2022 WL 4544721 (N.D. Cal. Sept. 28, 2022), granting motion to dismiss without prejudice. **Product launch/misbranding**

AcelRx develops DSUVIA, an opioid painkiller administered sublingually. The FDA approved the drug in November 2018, as well as AcelRx's Risk Evaluation and Mitigation Strategy (REMS) for the drug. In 2021, the FDA sent the company a warning letter asserting that two of its promotional materials—a banner advertisement and a tabletop display—contained false or misleading statements about risk and efficacy. After the company disclosed the warning letter, its stock price fell 8%.

Investors sued, challenging the company's statements about its launch efforts and plans, the use and administration of the drug, the REMS, and the risks the company faced. The court granted the company's motion to dismiss. The court concluded that while the "misbranding allegations are serious," plaintiffs failed to connect the issues the FDA identified with the public statements plaintiffs challenged. The fact that the FDA believed that statements in promotional

materials were false or misleading did not mean the company's public statements about the drug or its business plans were false or misleading too. Plaintiffs also fell short on scienter. They failed to show that insider stock sales were unusual in timing or amount, and their confidential witness allegations—concerning the individual defendants' role in approving marketing materials—did not show that the company knew that any challenged statement was false when made. Plaintiffs' core operations theory failed in the absence of facts establishing access, and their reliance on defendants' role in signing SOX certifications also failed in the absence of particularized facts.

In re Acadia Pharm., Inc. Sec. Litig., 2022 WL 36493 (S.D. Cal. Jan. 3, 2022), granting motion to dismiss with prejudice. **Product launch; kickbacks**

Acadia manufactures Nuplazid for the treatment of psychosis associated with Parkinson's disease. The drug was approved in 2016, albeit with a black box label warning of the risk of death in certain patient populations. The company made positive comments about its commercialization efforts over the next 18 months. In April 2018, CNN reported concerns about patient deaths, and Acadia's stock price fell 23%. Later that month, CNN reported that the FDA was reexamining Nuplazid, and the stock dropped 22%. The company responded to the CNN reports with a statement that as the manufacturer of a newly-launched drug, it was routinely in contact with the FDA, and that it provided post-marketing safety information, which the FDA incorporates into a publicly available adverse event database. In July 2019, another media outlet alleged that Acadia had provided cash incentives to doctors to prescribe Nuplazid. The company's stock fell 7%. In November 2018, Acadia reported that the DOJ had issued a civil investigative demand related to sales and marketing. Two years later, the DOJ had informed the company that it would take no further action related to the civil investigative demand.

Investors sued. They claimed that Acadia's statements that Nuplazid had a favorable safety profile were misleading in light of undisclosed adverse events, and that statements about successful commercialization efforts were misleading in light of undisclosed kickbacks. The court granted the company's motion to dismiss. With respect to adverse events, the relevant information was available on the public adverse event database, and plaintiffs had cited no authority supporting their argument that such disclosure is inadequate because an average investor cannot decipher it. Acadia also warned investors of the risk of regulatory scrutiny related to adverse events in its SEC filings. In any event, plaintiffs had failed to show that the number and nature of adverse events in Nuplazid's launch showed that the drug did *not* have a favorable safety profile. As to purported kickbacks, the court noted that it had held in an earlier order that plaintiffs' allegations on this subject were sufficient, but that the DOJ's investigation was at that time ongoing, and that this was no longer the case. With the investigation closed, plaintiffs had no longer pled facts showing that Acadia's sales and marketing efforts were improper. The company had also disclosed its payments to physicians, as well as the risk that regulatory authorities could scrutinize those payments and conclude that they were improper. Those disclosures undercut plaintiffs' claim that the company hid ostensible kickbacks from investors.

Habelt v. iRhythm Techs., Inc., 2022 WL 971580 (N.D. Cal. Mar. 31, 2022), granting motion to dismiss. **Regulated pricing**

iRhythm, a digital healthcare company, provides long-term ambulatory electrocardiogram devices designed to diagnose cardiac arrhythmias. The Zio XT patch generates a substantial part of the company's revenues, a portion of which comes from Medicare reimbursement. Before 2020, iRhythm billed Medicare $311-$316 using Category III Current Procedural Technology (CPT) codes for the Zio XT patch. CPT codes provide uniform descriptions of medical services and procedures. Category III codes are used for temporary and developing procedures; Category I codes are the "usual" codes. For 2021 rates, the American Medical Association recommended that CMS adopt Category I codes for Zio XT, indicating that the service had become the standard of care. CMS then proposed a rule with reimbursement rates of $376-$386 for devices including the Zio XT. A healthcare policy firm filed a comment urging a lower rate for patches—including Zio XT—and arguing that iRhythm's expenses were inflated. As a result, CMS declined to set a national rate for 2021, leaving determination to Novitas, which is the Regional Medicare Administrative Contractor responsible for setting reimbursement rates. iRhythm's stock price fell 24%. Novitas then reduced the average rate for Zio XT to $74-$89, a decrease of roughly

75%. iRhythm's stock fell 33%. Novitas subsequently revised the reimbursement rate *up* to $115—but iRhythm's stock price again fell, this time by 40%. When CMS released a proposed rule for 2022, it noted concerns with supply costs and ECG monitoring. iRhythm's stock fell 9%. CMS's final rule for 2022 did not set a rate but endorsed a rate of $200. Novitas adopted a rate of $210 for 2022.

Investors sued, alleging that the company made false or misleading statements about the regulatory price-setting process and the risks it faced. The court granted the company's motion to dismiss, based in large part on a 1996 decision, *Epstein v. Washington Energy*, in which the Ninth Circuit held that once a defendant has alerted the market to pending regulatory rate-making proceedings, it has no further obligation to disclose information about those proceedings.[15] Adapting that principle from the context of public utilities to the context of life sciences companies whose "rates" are determined by CMS, the court emphasized the inherently unpredictable nature of rate-making proceedings—and the illogic of alleging fraud when those proceedings produce results unfavorable to an issuer. The very existence of public proceedings tells the market that a company's revenue is determined in part by regulators, and that the regulators may make decisions that do not favor the company. "[R]eliance on predictive statements in the context of regulatory proceedings is inherently unreasonable" because it is "tantamount to sheer speculation," while "guessing wrong hardly suggests fraud." The court rejected plaintiff's attack on the company's predictions about the final rate decision, as well as its contention that other statements were rendered misleading by the purported omission of information that was part of the regulatory process. Statements that were not "categorically swept away" by application of the *Epstein* rule were immaterial or were protected by the PSLRA safe harbor for forward-looking statements.

In re Allergan PLC Sec. Litig., 2022 WL 17584155 (S.D.N.Y. Dec. 12, 2022), granting motion for summary judgment. **Product recall**

Allergan manufactures various breast implant products, which are regulated by the FDA as class III medical devices. Breast implants have been associated with a cancer of the immune system called breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL). Reports from as early as 2011 associated BIA-ALCL primarily with "textured" breast implants, of which Allergan's Biocell product is one. Allergan disclosed the possible link between breast implants and BIA-ALCL in its risk disclosures, 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. Allergan's stock fell 7%.

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 BIA-ALCL. The company moved to dismiss and the court granted the motion as to statements in the second and third categories but denied it as to certain statements in the first. Specifically, the court allowed plaintiff to proceed with challenges to statements that purportedly gave investors the false impression that Allergan's implants were no more linked to BIA-ALCL than implants manufactured by other companies.

Allergan moved for summary judgment after discovery was complete, and the court granted the motion. Plaintiffs attacked statements in which Allergan referred to BIA-ALCL in connection with other manufacturers' products; plaintiffs' theory was that users of Allergan's implants experienced the condition at a higher rate than users of competitors' implants. The court rejected that theory, ruling that the challenged statements were not comparative and that Allergan had no duty to disclose information about relative rates of BIA-ALCL. Moreover, the studies plaintiffs cited to show that rates of BIA-ALCL were higher in Allergan's products contained only raw numbers of cases, with no attempt to control for market share or time on the market. Plaintiffs also failed to raise a genuine issue of material fact on loss causation. Plaintiffs were unable to link the product recall that preceded the stock drop with the relative incidence of BIA-ALCL across manufacturers.

15 *Epstein v. Wash. Energy Co.*, 83 F.3d 1136 (9th Cir. 1996).

DISTRICT COURT DECISIONS—MOTION TO DISMISS DENIED

Mart v. Tactile Sys. Tech., Inc., 595 F. Supp. 3d 788 (D. Minn. 2022), denying in part and granting in part motion to dismiss. **Kickbacks; Medicare fraud**

Tactile sells a pneumatic compression device called Flexitouch for the at-home treatment of lymphedema. Flexitouch accounts for 90% of Tactile's revenue, and 25-30% of the company's business is based on payments from Medicare and the VA. In February 2019, Tactile reported that it had been named in a qui tam action accusing it of paying illegal kickbacks and making false Medicare reimbursement claims. Tactile stated that the action lacked merit and had been filed by one of its competitors. The company also noted that the government had declined to intervene in the action. Tactile's stock fell 8%. The qui tam action was later voluntarily dismissed with prejudice. In June 2020, a short seller appeared online with similar accusations of illegal sales practices. The short seller also questioned Tactile's statement about the size of the market for Flexitouch. The company's stock fell 13%.

Investors sued, challenging the company's statements about revenue, legal compliance and the size of the market. The court denied the company's motion to dismiss as to all three groups of statements, although it did not accept all of plaintiff's theories of falsity. With respect to both the company's statements of revenue and its opinion statements about legal compliance, the court largely credited plaintiff's allegations, drawn from the qui tam complaint and the short seller, about alleged kickbacks. The court emphasized the company's awareness of risk in two programs in which kickbacks were allegedly paid. One was a speaker program, in which opinion leaders spoke in luxury settings; the federal government had identified these programs as high risk. The second was a trainer program, in which therapists who trained patients to use Flexitouch at home were purportedly dismissed if they failed to make sufficient referrals. Tactile's own compliance officer had allegedly identified this program as a business risk related to kickbacks. As to the challenged statements about the size of the market, plaintiff adequately pled falsity based on information purportedly contrary to the company's estimate in an article co-authored by its Chief Medical Officer. On the other side of the ledger, the court concluded that plaintiff failed to adequately allege fraud in connection with the assertion that the company submitted false Medicare claims; here, plaintiff did not show that the individual defendants were aware of the purported misconduct. The court then held that plaintiff had adequately alleged scienter with respect to all but two individual defendants based on access to information and stock sales. The court noted that the defendants made their trades under Rule 10b5-1 trading plans but nevertheless assessed whether the trades made under those plans were unusual in timing and amount—and concluded that they were.[16]

Halman Aldubi Provident and Pension Funds Ltd. v. Teva Pharms. Indus. Ltd., 2022 WL 889158 (E.D. Pa. Mar. 25, 2022), denying in part and granting in part motion to dismiss. **Kickbacks; Patient Assistance Program**

Teva sells Copaxone, an injectable drug for the treatment of multiple sclerosis. Teva sponsors a program called Shared Solutions, which was designed to increase patient access to Copaxone and train patients how to administer the drug and obtain insurance coverage. In connection with the program, Teva contracted with a specialty pharmacy, Advanced Care Scripts, which referred Medicare patients to two patient assistance programs (PAPs). Teva in turn made donations to the PAPs to provide co-pay assistance for Copaxone. Anti-kickback regulations permit pharmaceutical companies to donate to PAPs but do not allow them to channel financial support for co-payments on their own products. Approximately 27% of patients taking Copaxone received co-pay assistance from the PAPs, and Teva's donations allowed patients who might otherwise have stopped taking the medication to stay on it. While it was making donations to the PAPs, Teva increased the price of Copaxone from $17,000 to $73,000 per year. In March 2017, Teva received a DOJ subpoena seeking documents related to its PAP donations. When the company

16 Two points in the court's decision are unusual as a technical securities law matter, and both cut against the defendants. First, the court permitted plaintiff to proceed with claims against outside directors under a false statement theory. The court did not discuss whether the directors were "makers" of any challenged statement, which is required under Section 10(b). *Janus Capital Corp. v. First Derivative Traders*, 564 U.S. 135 (2011). While scheme claims generally do not have a maker requirement, the court dismissed the scheme claim against the outside directors and allowed the false statement claim to move forward. Second, the court implicitly recognized a Section 10(b) claim based on an omission that purportedly violated item 303 of Regulation S-K. *See supra* at 28 n.14.

disclosed the subpoena in May 2017, its stock price did not move. In November 2017, Teva reported a decline in Copaxone revenue and lowered its sales and earnings forecasts. The stock fell nearly 20%. In August 2020, the DOJ sued Teva for violations of the False Claims Act, and its stock fell 15%.

Investors sued, challenging Teva's statements about Copaxone's market share, the Shared Solutions program, and legal compliance. Plaintiffs claimed that all statements were misleading in light of Teva's failure to disclose what they alleged was an illegal kickback scheme—that is, ensuring that patients could stay on Copaxone through its donations, profiting from the portion of payments made by Medicare, and then increasing the drug's price. The court denied in part and granted in part the company's motion to dismiss. As to the challenged statements about market share and Shared Solutions, the court credited, as a pleading matter, plaintiffs' theory that the company misled investors by attributing Copaxone's success to brand loyalty and patient and physician choice rather than to the alleged kickback scheme. The court recognized that companies generally have no duty to disclose unadjudicated wrongdoing, but held that once Teva put the source of its revenue at issue, it was required to disclose the purported kickback scheme. Using the same analysis, the court ruled in Teva's *favor* on the challenged legal compliance statements: Those statements did not put the source of Copaxone's success into play. Investors adequately pled scienter based on the significance of Copaxone to Teva's business and the individual defendants' professed expertise about Copaxone and approval of the challenged PAP donations.

On loss causation, the court rejected two of the three alleged corrective disclosures. The first—the disclosure of the DOJ subpoena—caused no losses. The second—the report of decreased sales and lowered guidance—did not correct any challenged statement. But the third—the report of the DOJ's lawsuit—was sufficient. Although it revealed only allegations of unproven misconduct, the court held that the DOJ's complaint provided the market with meaningful information about the alleged kickback scheme.

Strougo v. Mallinckrodt Pub. Ltd. Co., 2022 WL 17740482 (D. N.J. Dec. 16, 2022), denying motion to dismiss. **Medicaid rebates**

Mallinckrodt acquired Questcor in 2014. Questcor's principal product was Acthar, which was approved for the treatment of chronic inflammatory and immune disorders in 1952, and for infantile spasms in 2010. Questcor had raised the price of Acthar dramatically—from $40 per dose in 2001 to $23,000 per dose in 2007. Mallinckrodt continued to raise the price after it acquired Questcor, to $40,000. These price increases had a significant impact on the rebates the company was required to pay under the Medicaid Drug Rebate Program. Rebates are calculated by reference to a drug's average manufacturer price at the time of approval, which is then adjusted for inflation. For drugs approved before 1990, the time of approval is considered to be 1990. Acthar's steep price increases since created very significant rebate liability—unless the relevant approval date was considered to be not 1990 but 2010, when Acthar was approved for infantile spasms. Both Questcor and Mallinckrodt calculated rebates using the 2010 approval date. CMS, which conducts the rebate program, told the company that this was improper, and that the reference date was 1990 rather than 2010. Mallinckrodt disagreed and ultimately filed a declaratory relief lawsuit seeking to stop CMS from using the 1990 reference price to calculate the rebates the company owed. The company's stock price fell 16.5% after news outlets reported that a whistleblower had filed a False Claims Act case and that the DOJ had intervened in the litigation, fell 29% after the CMS litigation was announced, and fell over 25% after the DOJ intervened in another False Claims Act case. In March 2020, the court presiding over the declaratory relief action granted summary judgment for CMS and Mallinckrodt acknowledged that it owed $650 million in rebates. Several months later, the company filed for bankruptcy.

Investors sued, challenging the company's financial statements, its 2019 guidance and its statements about rebates. The court largely denied defendants' motion to dismiss.[17] The court somewhat oddly analyzed scienter before considering whether plaintiffs had adequately pled that any statement was false or misleading. The court concluded that defendants learned about the rebate issue in diligence conducted as part of the Questcor acquisition. The court gave short shrift to defendants' argument that knowing about CMS's position on the rebate issue did not equate to an intent to defraud, particularly as the legal merit of CMS's positions was the subject of the declaratory relief action and was unresolved at the time of the challenged statements. That argument was undercut, in the court's view, by the summary judgment decision against Mallinckrodt and the company's post-judgment settlement of the declaratory relief action and dismissal of its appeal. The court concluded that plaintiffs had also adequately alleged scienter as to the company's 2019 guidance (which was based on rebates calculated using the 2010 reference price). Although the guidance was necessarily forward-looking, plaintiffs had adequately pled actual knowledge of falsity. Plaintiffs had also adequately pled scienter as to the company's financial statements. The court agreed that the GAAP rules at issue, related to contingent losses, required judgment to apply, which made the financial statements matters of opinion. But plaintiffs had satisfied the requirements for challenging opinion statements: They had pled that the defendants lacked a reasonable basis for and did not believe the opinions. The court largely repeated its analysis in concluding that plaintiffs had adequately alleged that the challenged statements were false or misleading. The court then granted the defendants' motion with respect to one limited theory of fraud—that defendants' statements about clinical trials aimed at securing approval for additional indications were misleading insofar as defendants omitted the purported fact that revenue associated with new indications was needed to offset rebate liability.

City of Sterling Heights Police & Fire Ret. Sys. v. Reckitt Benckiser Grp. PLC, 587 F. Supp. 3d 56 (S.D.N.Y. 2022), denying in part and granting in part motion to dismiss. **Unfair trade practices**

A former subsidiary of Reckitt Benckiser, a UK company, manufactured Suboxone Tablets to treat opioid addiction. The FDA approved Suboxone and granted orphan drug exclusivity in 2002. Exclusivity ended in 2009. Around that time, the subsidiary developed Suboxone Film. The subsidiary stated publicly that the Film would be less susceptible to abuse than the Tablets and posed less risk to children. The subsidiary hoped to offset revenue loss from the expiring exclusivity of the Tablet with new sales of the Film. In 2009, the FDA rejected the subsidiary's NDA for the Film because the application did not include an adequate Risk Evaluation and Mitigation Strategy. After the subsidiary resubmitted its NDA with a revised REMS, the FDA approved the NDA for the Film in 2010. In 2012, the subsidiary sent the FDA a notice of discontinuance for the Tablets, citing concerns about pediatric exposure. The subsidiary also filed a petition asking the FDA not to approve *generic* equivalents of the Tablets, citing safety concerns. The FDA disagreed with the company's safety concerns, denied the discontinuance request, and referred the company to the FTC to investigate anticompetitive practices. In 2014, Reckitt "de-merged" the subsidiary that first brought Suboxone to market.

In July 2017, Reckitt announced a £318 million charge in connection with DOJ and FTC investigations into alleged anticompetitive conduct at its former subsidiary. The price of the company's American Depositary Shares (ADS) fell 5% and its ordinary shares fell 3%. Disclosures of additional charges in connection with other investigations were followed by stock price drops of 10% (ADS) and 8% (ordinary shares). In February 2019, the company announced a £296 million charge in connection with the investigations, which was followed by a price drop of 10% (ADS) and 8% (ordinary shares). In April 2019, the former subsidiary was indicted for fraudulently marketing Suboxone Film. The stock fell 6% (ADS) and 7% (ordinary shares). In July 2019, a non-prosecution agreement in what the DOJ called the "largest opioid settlement in history" imposed $1.4 billion in penalties. That announcement was followed by an *increase* in stock price. In late 2019, the FDA revoked as improperly granted the initial orphan drug designation of buprenorphine, concluding that the original request failed to establish a reasonable expectation that the costs of developing the drug would not be recovered from U.S. sales. In 2020, the

17 Because the company was in bankruptcy, plaintiffs proceeded solely against ten individual defendants. Several of the individuals were board members and one was an accounting executive. As in the *Tactile* decision (see page 37) the court did not discuss whether those individuals were "makers" of the challenged statements under *Janus*.

subsidiary's CEO pled guilty to violating the FDCA by causing misbranded Suboxone to be introduced into interstate commerce.

Investors sued, alleging that the company's statements about the Film's success were rendered misleading by the failure to disclose anticompetitive and deceptive conduct underlying that success. The court denied in part and granted in part the company's motion to dismiss. First, the court addressed two threshold defenses. It rejected the company's truth-on-the-market argument—the contention that a misstatement is not materially misleading because truthful information is widely available. Although allegations of anticompetitive behavior were publicly known, the company had long denied any wrongdoing. The court also rejected the company's statute of limitations defense. The limitations period is two years, and the Section 10(b) plaintiffs did not bring suit until more than six years after an antitrust action was filed and the *New York Times* ran a front-page article describing safety issues with the Film. But at the pleading stage, the court could not conclude that reasonably diligent plaintiffs would have discovered the relevant facts—including facts needed to establish a strong inference of scienter—more than two years before they commenced the action.

The court then concluded that plaintiffs had sufficiently alleged that certain challenged statements were misleading by virtue of omitted information about anticompetitive conduct. The court credited the plaintiffs' argument that the company had a duty to disclose that information because it had put the reasons for its success "at issue." That argument did not extend to *all* challenged statements, however. Statements about "patient and physician preference" for the Film put the reasons for success at issue and hence were actionable. In contrast, statements of financial results in which the company did not refer to reasons for its success were not actionable. Statements attributing success to "very talented employees," and a "strong culture" were not actionable for a different reason: Although the company put the reasons for its success at issue, the statements were only puffery. The court also dismissed plaintiffs' claim that the company misled investors about the reasons for the de-merger, which plaintiffs viewed as an attempt to isolate the company from the risks posed by its subsidiary. The court further rejected plaintiffs' attack on the company's statements about compliance policies and internal controls. And plaintiffs failed to state a claim based on alleged violations of Item 303, which does not apply to non-U.S. companies. The court credited plaintiffs' scienter allegations against the company and the CEOs of the company and the subsidiary, but dismissed claims against the board chair and CFO, who were not alleged to have known of the marketing strategies at issue.

Franchi v. SmileDirectClub, Inc., —F. Supp. 3d—, 2022 WL 4594575 (M.D. Tenn. Sept. 30, 2022), denying in part and granting in part motion to dismiss. **Sales performance**

SmileDirectClub manufactures clear dental aligners and sells them direct-to-consumer. When the company went public in September 2019, its registration statement described "accelerating growth" as one of the company's strengths. The company also stated that its "primary focus is on delivering an exceptional member experience," that "member satisfaction" was fundamental to its leading market position, and that it had an average rating of 4.9 out of 5 from 100,000 customer reviews on its website. The company further stated that its teledentristry platform provided "convenient access to excellent clinical care," with a network of licensed orthodontists and general dentists. The IPO price was $23 per share. Two months after the IPO, in November 2019, the company disclosed lower than expected quarterly revenue, and its stock fell 20%. In February 2020, an NBC Nightly News report described 1800 complaints against the company, and its stock fell 16%. Later that month, the company announced declining adjusted earnings, and its stock fell 29%. In all, six months after its IPO, the company's stock had fallen to $5.30, a 77% decline.

Investors sued, asserting claims under both Section 10(b) and Section 11 and alleging that the company misled the market by failing to disclose a sudden decline in revenue during the quarter in which the IPO occurred. The court denied the motion to dismiss in large part. The court agreed with plaintiffs that the company had a duty under Item 303 of Regulation S-K to disclose known revenue trends—that is, that revenue, gross profit, and adjusted EBITDA were declining over the course of the quarter. The court rejected the argument that Item

303 does not impose a duty to report intra-quarter developments. Plaintiffs also adequately pled that the company's statements about the standard of care were misleading; the company admittedly did not provide "clinical care." Plaintiffs' challenge to the company's risk warnings was also adequately pled, given the company's failure to disclose complaints by state chapters of the American Dental Association, an investigation for unlicensed practice of dentistry, and the passage of legislation in California that would curtail the company's practices. Plaintiffs also adequately pled scienter in connection with their Section 10(b) claim. Among other things, the court credited plaintiffs' allegation that the company was aware of omitted financial metrics, which it tracked closely. Meanwhile, the company's purchase of $630 million in stock from eight company insiders provided motive. The court granted the company's motion as to several statements. Its reference to "accelerating growth" as part of a graphic demonstrating company strengths was too vague to require the disclosure of specific revenue metrics; similarly, statements about customer satisfaction were non-actionable puffery.

In re Boston Sci. Corp. Sec. Litig., 2022 WL 17823837 (D. Mass. Dec. 20, 2022), denying in part and granting in part motion to dismiss. Sales performance

Boston Scientific developed the Lotus Edge transcatheter heart valve, which was used to treat patients suffering from aortic stenosis, a disease caused by the narrowing of the aortic valve. Historically, aortic stenosis was treated by replacing the aortic valve through open-heart surgery. In 2002, surgeons began to successfully use a new method, transcatheter aortic valve replacement (TAVR), in which an aortic valve prosthesis is implanted through a catheter. Boston Scientific's Lotus was one of several TAVR products in the market. In marketing it, Boston Scientific said that the Lotus was easier to use and control than competitors' products. Boston Scientific brought the Lotus to market in Europe in 2013, but the product was subject to a recall in 2017 based on reports of a faulty pin connecting the valve to the delivery system. In February 2019, the company announced plans for a controlled launch of the Lotus among high-risk surgical patients in the U.S., with a full launch in the fall of 2019. In November 2020, after the Lotus had been in the U.S. market for roughly a year, the company announced a voluntary recall and said that it would retire the product platform. The company explained that the Lotus had remained a niche player within the TAVR market and would not be scalable without "a design enhancement." The company's stock fell 8%.

Investors sued, challenging statements about (1) accounts and orders for the Lotus, (2) the simplicity and safety of the product, (3) the product launch, and (4) termination of the product platform. The court denied in part and granted in part the company's motion to dismiss. Plaintiffs adequately pled that statements about the number of accounts opened after launch were misleading, given their allegations that the company was not meeting its account-opening milestones. Plaintiffs also adequately alleged falsity as to fall 2020 statements that the Lotus was an important growth driver, given the company's decision shortly thereafter to end the Lotus program. And plaintiffs adequately pled scienter as to the company's CEO, which could be imputed to the company. On the other side of the ledger, challenged statements about "strong" sales and order rates were non-actionable puffery, as were statements about ease of use. Statements about reorder rates, meanwhile, were too vague to be actionable. The court likewise rejected plaintiffs' claims that defendants did not sufficiently disclose safety information: Plaintiffs failed to establish a duty to disclose. And the court dismissed claims against several individual defendants on scienter grounds.

Decisions
Post-Approval

TABLE OF NEW FILINGS IN 2022

In 2022, 37 new securities fraud class actions were filed against life sciences companies, a drop from the number of new filings we have seen over the past five years.[18]

2018 48 new complaints
2019 44 new complaints
2020 45 new complaints
2021 49 new complaints
2022 37 new complaints

Of the new actions in 2022, 23 were filed against companies with development stage drugs or devices. Nearly 40% of those actions (9 out of 23) arose from setbacks at the final stages of the approval process, after a company has submitted an NDA, sNDA or 510(k) application.

Another six cases involve Emergency Use Applications (EUAs) for COVID-19 tests or treatments. This is consistent with the number of COVID-19-related filings in 2021 (six new filings) and 2020 (seven new filings).

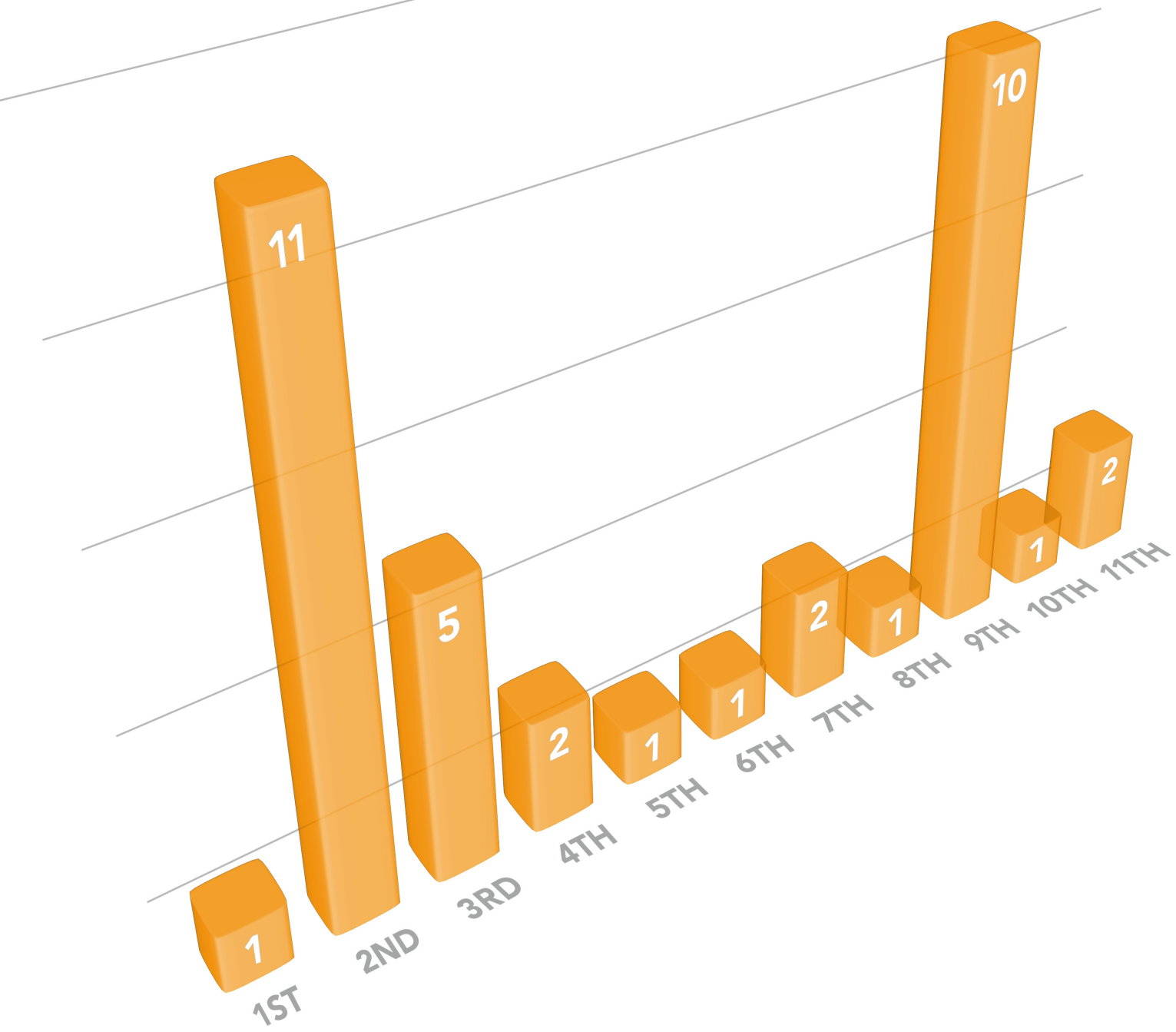
Fourteen actions were filed against companies with mature products. These complaints arise from a range of regulatory and non-regulatory setbacks, clustered around sales forecasts and alleged improprieties in marketing and billing. These 14 new post-approval filings reflect an increase from last year (10 new post-approval filings), but a decrease from earlier years (17 new post-approval filings in both 2019 and 2020). Two of these cases involve COVID-19 products.

As in previous years, the new filings are clustered in district courts in the Second, Third and Ninth Circuits. We show these breakdowns in the following three pages.

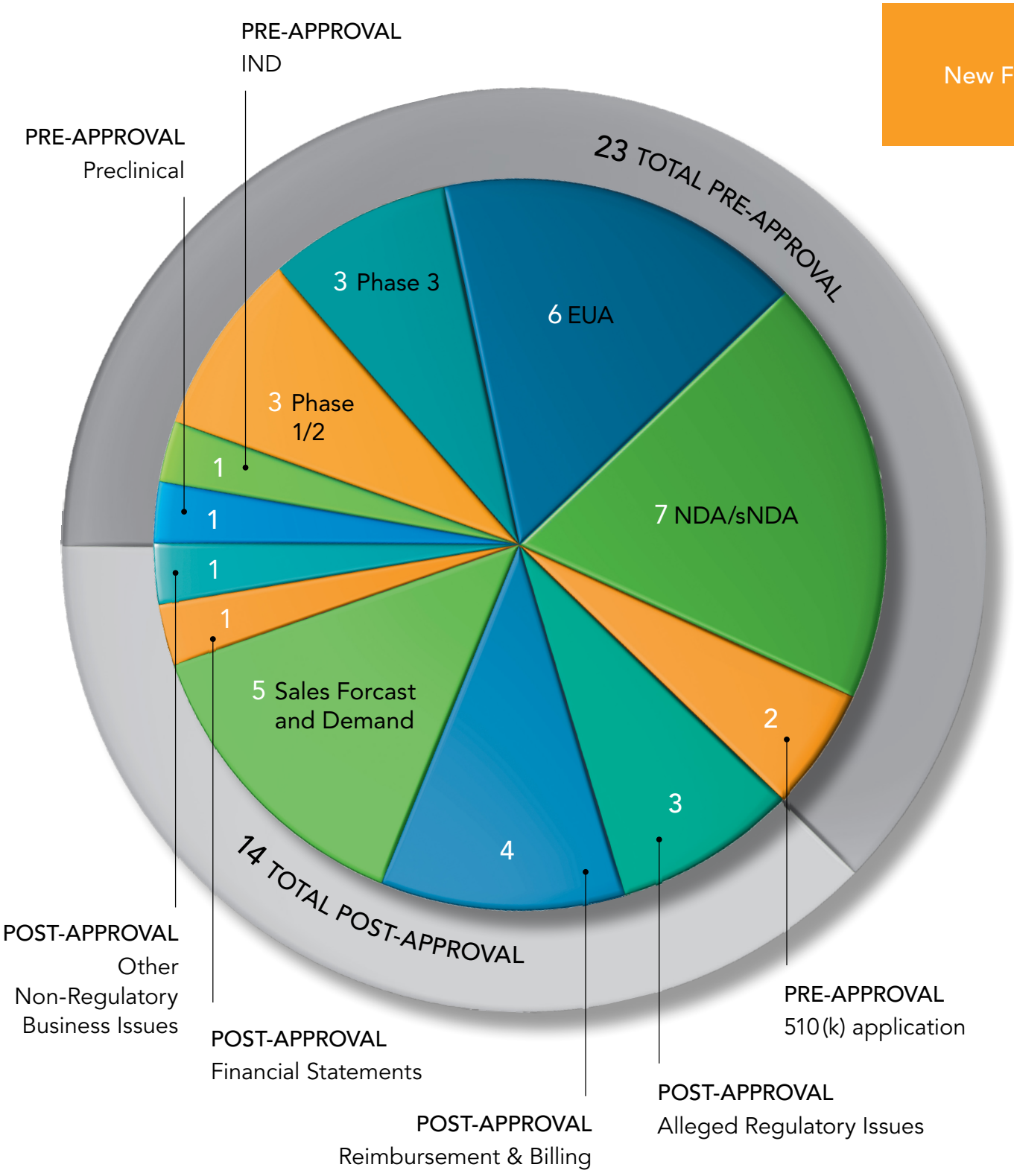
18 We take this figure and list of actions from the Stanford Securities Class Action Clearinghouse. The list includes those cases categorized by Cornerstone Research as within the "healthcare sector" but excludes deal litigation and cases involving hospital management issues unrelated to any drug or medical device. 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.

NEW FILINGS IN 2022 BY CIRCUIT

New Filings



PRODUCT LIFECYCLE		SECURITIES FRAUD CLASS ACTIONS FILED IN 2022
PRE-APPROVAL	Preclinical	1
	IND	1
	Phase 1/2	3
	Phase 3	3
	EUA	6
	NDA/sNDA	7
	510(k) application	2
	TOTAL PRE-APPROVAL	23
POST-APPROVAL	Alleged Regulatory Issues	3
	Reimbursement and Billing	4
	Sales Forecast and Demand	5
	Financial Statements	1
	Other Non-Regulatory Business Issues	1
	TOTAL POST-APPROVAL	14


PRE-APPROVAL
IND
PRE-APPROVAL
Preclinical
23 TOTAL PRE-APPROVAL
3 Phase 3
6 EUA
3 Phase 1/2
1
1
7 NDA/sNDA
1
1
5 Sales Forcast and Demand
2
3
4
14 TOTAL POST-APPROVAL
POST-APPROVAL
Other Non-Regulatory Business Issues
POST-APPROVAL
Financial Statements
POST-APPROVAL
Reimbursement & Billing
POST-APPROVAL
Alleged Regulatory Issues
PRE-APPROVAL
510(k) application

ENOCHIAN BIOSCIENCES INC. 7/26/2022 C.D. Cal.

PRECLINICAL Enochian researched treatments for HIV, hepatitis B, influenza and coronavirus infections. Plaintiffs allege that the company's founder had no post-high school degree but did have a history of crime and fraud; they also allege that the company had entered into related-party transactions with entities controlled by the founder, which exposed it to liability. Stock prices fell after the DOJ announced that the founder had been arrested and charged in a murder-for-hire conspiracy, and fell again after a short seller published a negative report on the founder and the company.

KIROMIC BIOPHARMA, INC. 8/5/2022 S.D.N.Y.

IND Kiromic developed immunotherapy treatments. Plaintiffs allege that the company misleadingly stated in its IPO documents that clinical testing was expected to continue, when in reality the FDA had imposed a clinical hold. Stock prices fell after the company reported the clinical hold and the termination of the CEO for conduct inconsistent with company policy.

SHATTUCK LABS, INC. 01/31/2022 E.D.N.Y.

PHASE 1 Shattuck developed an immuno-oncology treatment. Plaintiffs allege that the company failed to disclose that a Phase 1 trial showed lack of efficacy. Stock prices fell after the company announced that its co-developer had terminated an agreement and a conference poster revealed disappointing results from the Phase 1 trial.

CABALETTA BIO, INC. 2/28/2022 E.D. Pa.

PHASE 1 Cabaletta developed a treatment for mucosal pemphigus vulgaris (an autoimmune skin disease) and Hemophilia A. Plaintiff alleges that the company's favorable statements about the clinical and commercial prospects for its treatment were false or misleading. Stock prices fell after the company reported top-line data from a Phase 1 trial.

HOMOLOGY MEDICINES, INC. 3/25/2022 C.D. Cal.

PHASE 1/2 Homology developed a gene therapeutic to treat phenylketonuria. Plaintiffs allege that the company failed to disclose trial data showing liver toxicity and the failure of some patients to experience an effective dose response. Stock prices fell after the company announced that the FDA would issue a clinical hold.

AKEBIA THERAPEUTICS, INC. 03/14/2022 E.D.N.Y.

PHASE 3 Akebia developed vadadustat, an oral therapy for the treatment of anemia in patients with chronic kidney disease. Plaintiff challenges the company's statements about safety for patients not on dialysis, as well as statements about commercial and regulatory prospects. Stock prices fell after the company reported that vadadustat did not meet a primary safety endpoint in a Phase 3 trial.

AMPIO PHARMACEUTICALS, INC. 08/17/2022 D. Colo.

PHASE 3 Ampio developed Ampion to treat inflammatory conditions, including severe osteoarthritis. Plaintiffs allege that the company falsely stated that the drug demonstrated a statistically significant decrease in pain in a Phase 3 trial. Stock prices fell after the company reported that a second Phase 3 trial had not met its co-primary endpoints.

CENTESSA PHARMACEUTICALS PLC: AMERICAN DEPOSITARY SHARES 09/28/2022 S.D.N.Y.

PHASE 1; PHASE 3 Centessa developed lixivaptan to treat polycystic kidney disease and ZF874 to treat a genetic disorder that can cause lung and liver damage. Plaintiffs challenge statements in the company's offering documents about the safety and clinical and commercial prospects of both drug candidates. Stock prices fell after the company (1) reported Phase 1 results for ZF874, (2) announced its decision to discontinue development of ZF874 after an adverse event, and (3) announced it was discontinuing development of lixivaptan based on Phase 3 observations.

TALIS BIOMEDICAL CORPORATION 1/7/2022 N.D. Cal.

EUA Talis developed the Talis One, a molecular diagnostic device for COVID-19 testing. Plaintiffs challenge Talis's statements about its manufacturing process, the performance and testing of the product, and its EUA submission. Stock prices fell after the company withdrew an initial EUA application. The company then filed a new EUA application, but subsequently announced launch delays and layoffs, after which stock prices fell again. (See report of decision on page 24, above.)

NRX PHARMACEUTICALS, INC. 1/18/2022 D. Del.

EUA NRx develops therapeutics for the treatment of central nervous system disorders and pulmonary diseases, including a COVID-19 drug for respiratory failure. Plaintiff challenges the company's statements about its EUA application for the COVID-19 drug. Stock prices fell after the company announced that the FDA had declined to issue an EUA.

MOLECULAR PARTNERS AG: AMERICAN DEPOSITARY SHARES 7/12/2022 S.D.N.Y.

EUA Molecular Partners developed a COVID-19 treatment and a cancer treatment (the latter in collaboration with Amgen). Plaintiffs challenge the company's statements about the effectiveness and commercial prospects of both drugs. Stock prices fell after the company reported that the COVID-19 treatment did not meet thresholds required to continue Phase 3 enrollment, and fell again after subsequent announcements about the viability of an EUA application. Prices also fell after the company announced that Amgen had returned global rights to the cancer treatment.

HUMANIGEN, INC. 8/26/2022 D.N.J.

EUA Humanigen developed a treatment for "cytokine storm" in patients hospitalized with COVID-19. Plaintiffs challenge the company's statements about the effectiveness of the drug. Stock prices fell after the company announced that the FDA had rejected its EUA application.

EIGER BIOPHARMACEUTICALS, INC. 11/08/2022 N.D. Cal.

EUA Eiger developed a COVID-19 treatment. Plaintiffs allege that the company overstated its expertise in drug development and failed to disclose problems with its Phase 3 study. Stock prices fell after the company announced that the FDA was unable to determine whether the company was likely to meet the criteria for an EUA.

VERU INC. 12/5/2022 S.D. Fla.

EUA Veru developed a drug intended to halt virus replication in hospitalized COVID-19 patients at high risk of acute respiratory distress syndrome. Plaintiffs allege that the company misleadingly suggested that data from its Phase 3 trial were sufficient to support an EUA. Stock prices fell when the Pulmonary-Allergy Drugs Advisory Committee voted against the EUA application.

FENNEC PHARMACEUTICALS INC. 2/9/2022 M.D.N.C.

NDA Fennec developed a treatment for hearing loss in children undergoing chemotherapy. Plaintiff challenges the company's statements about manufacturing and the prospects for approval. Stock prices fell after the company announced that it had received a CRL denying its NDA as a result of manufacturing deficiencies. (See report of decision on page 22, above.)

AXSOME THERAPEUTICS, INC. 5/13/2022 S.D.N.Y.

NDA Axsome develops therapies for central nervous system disorders, including a migraine drug. Plaintiffs allege that the company misrepresented chemistry, manufacturing, and controls issues with the migraine drug. Stock prices fell after the company reported that it expected to receive a CRL.

SPERO THERAPEUTICS, INC. 5/26/2022 E.D.N.Y.

NDA Spero developed an anti-bacterial treatment for urinary tract infections. Plaintiffs allege that the company made false or misleading statements about its Phase 3 trial and NDA. Stock prices fell after the company reported that the FDA had identified deficiencies in its NDA, and fell again when the company announced that it would halt commercialization activities.

VERRICA PHARMACEUTICALS, INC. 6/6/2022 E.D. Pa.

NDA Verrica developed a treatment for molluscum contagiosum, a skin disease. Plaintiffs challenged the company's statements about approval prospects, claiming that the company omitted information about manufacturing deficiencies. Stock prices fell after the company reported that it had received a CRL based on deficiencies in its contract manufacturer's facility. The company resubmitted its NDA, but again received a CRL, and its stock price fell again.

SPECTRUM PHARMACEUTICALS, INC. 12/5/2022 S.D.N.Y.

NDA Spectrum submitted an NDA, under the Accelerated Approval program, for treatment of non-small cell lung cancer in patients with certain mutations. Plaintiffs challenge the company's statements about safety and efficacy data from the Phase 2 trial and the initiation of a Phase 3 confirmatory trial. Stock prices fell after the FDA Oncologic Drugs Advisory Committee released a briefing document with negative safety and efficacy data, as well as the information that the company had not yet enrolled patients in the confirmatory trial.

ABBVIE INC. 4/6/2022 N.D. Ill.

sNDA AbbVie markets Rinvoq for the treatment of rheumatoid arthritis, and submitted an sNDA for other indications. Plaintiff alleges that the company failed to disclose that the FDA would likely require additional safety warnings, which would delay approval. Stock prices fell after the company reported a delay in approval as a result safety concerns with a similar drug. Stock prices fell again after the FDA determined it would require new and updated labeling.

TG THERAPEUTICS, INC. 7/18/2022 S.D.N.Y.

BLA/sNDA TG Therapeutics developed leukemia treatments. Plaintiffs challenge the company's statements about safety, which they allege were misleading in light of an increase in serious adverse events. Stock prices fell after the company reported that the FDA would hold an advisory committee meeting, and fell again after the FDA extended the PDUFA date.

PULSE BIOSCIENCES, INC. 2/16/2022 N.D. Cal.

510(K) Pulse produces the CellFX System for the treatment of lesions, including sebaceous hyperplasia. Plaintiffs allege that the company failed to disclose that the investigational device exemption study evaluating use of the product failed to meet its primary endpoints, which increased the risk that the company's 510(k) application would not be approved. Stock prices fell after the FDA issued an "additional information" letter.

OUTSET MEDICAL, INC. 7/8/2022 N.D. Cal.

510(K) Outset Medical makes Tablo, a home dialysis product. Plaintiffs allege that because the company made significant changes to Tablo, the FDA would likely order the company to cease marketing and selling the product for home use, and would prevent the company from performing the required real-world human testing required for sale. Plaintiffs challenge the company's statements that it would conduct a "human factors" study in accordance with FDA protocol, and about patient data from at-home use. Stock prices fell after the company announced disappointing quarterly results, which analysts attributed in part to the inability to test the product in the home setting. Stock prices fell again after the company announced that a ship-hold had been put in place.

APYX MEDICAL CORPORATION 6/6/2022 M.D. Fla.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Apyx Medical derives the largest share of its revenue from its Advanced Energy products—helium plasma technology used in both cosmetic surgery and hospital surgical markets. Plaintiffs allege that the company failed to disclose that off-label uses were leading to serious adverse events. Stock prices fell after the FDA warned that physicians should stop using certain of the company's devices to treat wrinkles; the devices had not been approved for aesthetic skincare procedures, and the FDA had received multiple reports of life-threatening injuries.

ABBOTT LABORATORIES 8/31/2022 N.D. Ill.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Abbott's Nutritional Products segment manufactures infant formula, nearly half of which was produced at its Sturgis manufacturing facility. Plaintiffs allege that the company misrepresented the safety and commercial viability of its formula. Stock prices fell when, on the same day, the FDA announced an investigation of consumer complaints of infant illness related to formula produced in Sturgis, and Abbott issued a recall of certain products manufactured at the facility. Stock prices fell again after the company closed Sturgis, the FDA released negative reports from its inspections of Sturgis, a whistleblower complaint was made public, and Abbott entered into a consent decree with the FDA.

MEDTRONIC PLC 9/8/2022 D. Minn.

POST-APPROVAL: ALLEGED REGULATORY ISSUES Medtronic developed the MiniMed insulin pump system for the treatment of diabetes. The MiniMed 600 series was established; the company sought approval for the MiniMed 780G model. Plaintiffs challenge the company's statement that the 780G model was on track for approval, alleging that the company knew that the 600 models were subject to recall. Stock prices fell after the company reported an FDA warning letter about the 600 model recall, and fell again after the company announced that approval for the 780G model would be delayed.

NATERA, INC. 4/27/2022 W.D. Tx.

POST-APPROVAL: REIMBURSEMENT AND BILLING Natera produces Prospera, a kidney transplant rejection test, and Panorama, a prenatal test. Plaintiffs challenge the company's statements about both products, claiming that Prospera was not, as the company said, clinically superior to a competitor's products, and that Panorama sales were driven by improper business practices. Stock prices fell after a jury found that the company had falsely marketed Prospera as more accurate than the competitor's test, and a short seller issued a report alleging deceptive sales and billing practices for Panorama.

CAREDX, INC. 05/23/2022 N.D. Cal.

POST-APPROVAL: REIMBURSEMENT AND BILLING CareDx produces a blood test designed to detect whether a patient will reject a kidney after transplant. Plaintiffs allege that the company violated the False Claims Act by billing Medicare for tests that did not meet its reimbursement criteria. Stock prices fell after the company disclosed three government investigations into its practices. Stock prices fell again after the CFO resigned and after the company reported the rate at which tests were rejected for reimbursement.

FULGENT GENETICS, INC. 9/20/2022 C.D. Cal.

POST-APPROVAL: REIMBURSEMENT AND BILLING Fulgent provides COVID-19 molecular diagnostic and genetic testing services. Plaintiffs allege that the company failed to disclose that it conducted unnecessary testing, engaged in improper billing practices and violated the federal Anti-Kickback Statute. Stock prices fell after the company reported that the SEC was investigating its public filings and that the DOJ had issued a civil investigative demand related to allegations of improper billing.

NEOGENOMICS, INC. 12/6/2022 S.D.N.Y.

POST-APPROVAL: REIMBURSEMENT AND BILLING NeoGenomics provides cancer tests and testing. Plaintiffs challenge the company's statement that it offers a "comprehensive menu" of cancer tests, including newer and more advanced iterations, and that its fixed costs have led to increased profitability. Stock prices fell after the company reported an internal investigation into compliance with federal healthcare regulations related to fraud, waste and abuse.

BIOGEN INC. 02/07/2022 D. Mass.

POST APPROVAL: SALES FORECAST AND DEMAND ISSUES Biogen developed Aduhelm, a treatment for Alzheimer's disease. Plaintiff alleges that the company misled investors about the drug's commercial readiness and the company's interactions with the FDA. Stock prices fell after (1) the company disclosed that fewer sites were ready to administer Aduhelm than originally announced; (2) the company reported Aduhelm sales significantly lower than expected; (3) CMS released a draft opinion indicating that Medicare would not cover treatments for most patients; and (4) third-party payors stated that they would not cover Aduhelm based on its price.

ACUTUS MEDICAL, INC. 2/15/2022 S.D. Cal.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Acutus made a product that diagnoses arrhythmias. Plaintiff alleges that the company failed to disclose serious difficulties in its commercial execution of the product. Stock prices fell after the company reported fewer placements than anticipated. Stock prices fell again after the company announced that it was a year behind its expected sales trajectory.

BUTTERFLY NETWORK, INC. 2/16/2022 D.N.J.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Butterfly develops and sells ultrasound imaging devices. Plaintiffs allege that the company failed to disclose losses from inventory purchase commitments. Stock prices fell after the company reported that its inventory balance had grown by 40% over three months. Stock prices fell again after the company adjusted its revenue forecasts downward.

AURINIA PHARMACEUTICALS INC. 4/15/2022 D. Md.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Aurinia produces a treatment for active lupus nephritis. Plaintiff challenges the company's 2022 revenue guidance and claims that the company overstated the product's commercial prospects. Stock prices fell after the company reported 2021 financial results.

CO-DIAGNOSTICS, INC. 08/16/2022 S.D.N.Y.

POST-APPROVAL: SALES FORECAST AND DEMAND ISSUES Co-Dx developed a COVID-19 test for which it received an EUA in April 2020. Plaintiffs challenge the company's statements about demand. Stock prices fell after the company reported that revenue for the second quarter of 2022 had fallen 82% from the prior year period.

DENTSPLY SIRONA INC. 6/2/2022 S.D. Ohio

POST-APPROVAL: FINANCIAL STATEMENT ISSUES Dentsply produces dental supplies. Plaintiff alleges that the company manipulated the way in which it recognized revenue tied to certain rebate and incentive programs. Stock prices fell after the company announced the sudden termination of its CEO, and fell again after the company reported an internal investigation into financial reporting.

TWIST BIOSCIENCE CORPORATION 12/12/2022 N.D. Cal.

POST-APPROVAL: OTHER NON-REGULATORY BUSINESS ISSUES Twist develops synthetic DNA products. Plaintiffs challenge the company's statements about the revolutionary nature of its technology, its plan to build a "factory of the future" in the U.S. and its financial health. Stock prices fell after a short seller issued a report that claiming the company was a "Ponzi-like scheme" and did not have new or innovative technology.

New Filings

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.

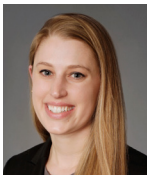
Life Sciences

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.

For more information about our securities litigation capabilities and work for life sciences companies, please contact:

SARA B. BRODY
+1 415 772 1279
sbrody@sidley.com

ROBIN E. WECHKIN
+1 415 439 1799
rwechkin@sidley.com



SARAH A. HEMMENDINGER
+1 415 772 7413
shemmendinger@sidley.com

FRANCESCA E. BRODY
+1 212 839 5372
fbrody@sidley.com

MATTHEW J. DOLAN
+1 650 565 7106
mdolan@sidley.com

KATHRYN L. ALESSI
+1 617 223 0364
kalessi@sidley.com

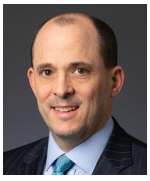
WALTER C. CARLSON
+1 312 853 7734
wcarlson@sidley.com

JIM DUCAYET
+1 312 853 7621
jducayet@sidley.com

YOLANDA C. GARCIA
+1 214 981 3414
ygarcia@sidley.com

YVETTE OSTOLAZA
+1 214 981 3401
yvette.ostolaza@sidley.com

HILLE R. SHEPPARD
+1 312 853 7850
hsheppard@sidley.com



ANDREW W. STERN
+1 212 839 5397
astern@sidley.com