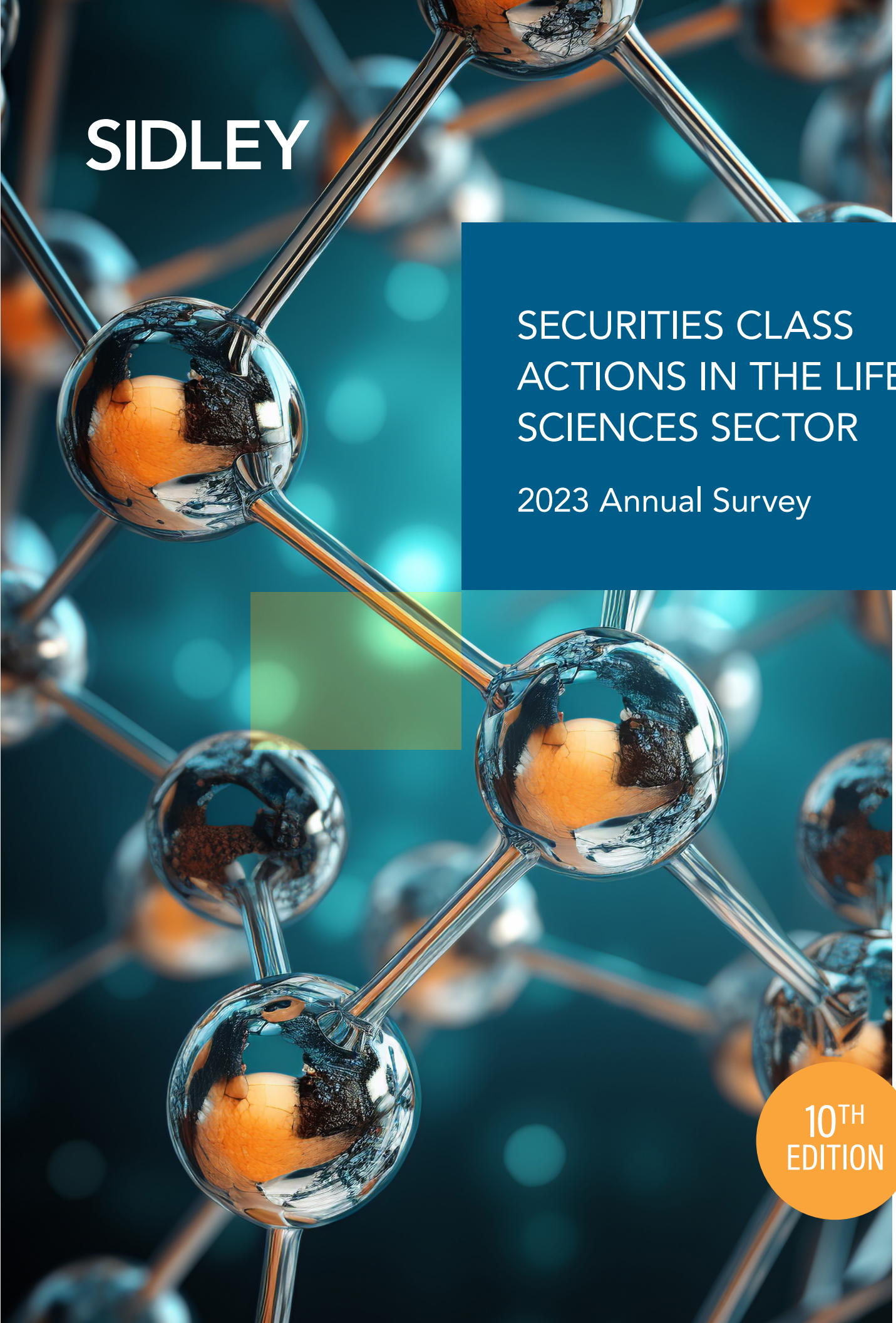

SIDLEY

SECURITIES CLASS ACTIONS IN THE LIFE SCIENCES SECTOR

2023 Annual Survey

10TH EDITION

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Securities Class Actions in the Life Sciences Sector

2023 Annual Survey

INTRODUCTION AND OVERVIEW

In our tenth annual year-in-review survey, we address developments in securities class actions brought against life sciences companies in 2023. We begin with an overview and analysis of trends in federal district court and appellate decisions in these cases. We then provide summaries of the 31 decisions surveyed. Finally, we catalog the new securities class action complaints filed against life sciences companies in 2023.

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 Section 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 Issues & Rights, Ltd.*, 551 U.S. 308, 310 (2007).

DECISIONS ISSUED IN 2023: TRENDS AND ANALYSIS

In this section (pages 3-16), we discuss trends in the reported federal decisions issued in securities actions at the pleading stage (or in two cases, 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 2023. Companies' success rate in 2023 was 68%, a significant increase over the rate in previous years.

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%.

2023: Companies won dismissal in 17 of the 25 decisions issued by the district courts, or 68%.[3]

As in previous years, the success rate was significantly higher for companies with pre-approval drugs and devices than for those with post-approval drugs or devices. Companies prevailed in 80% of the pre-approval cases (12 out of 15) but only 50% of the post-approval cases (five out of ten).

Companies fared well in the appellate courts in 2023, with affirmance of dismissal in five of six cases. The sole reversal occurred in the Biogen case, which involved the controversial 2021 approval of an Alzheimer's disease treatment.

As we discuss more fully below, the volume of new filings fell in 2023, continuing a decline we saw last year. Before 2022, new filings were in the mid- to high-40s range. In 2022 and 2023, new filings dropped to the mid-30s.

2019 – 44 new complaints

2020 – 45 new complaints

2021 – 49 new complaints

2022 – 37 new complaints

2023 – 34 new complaints

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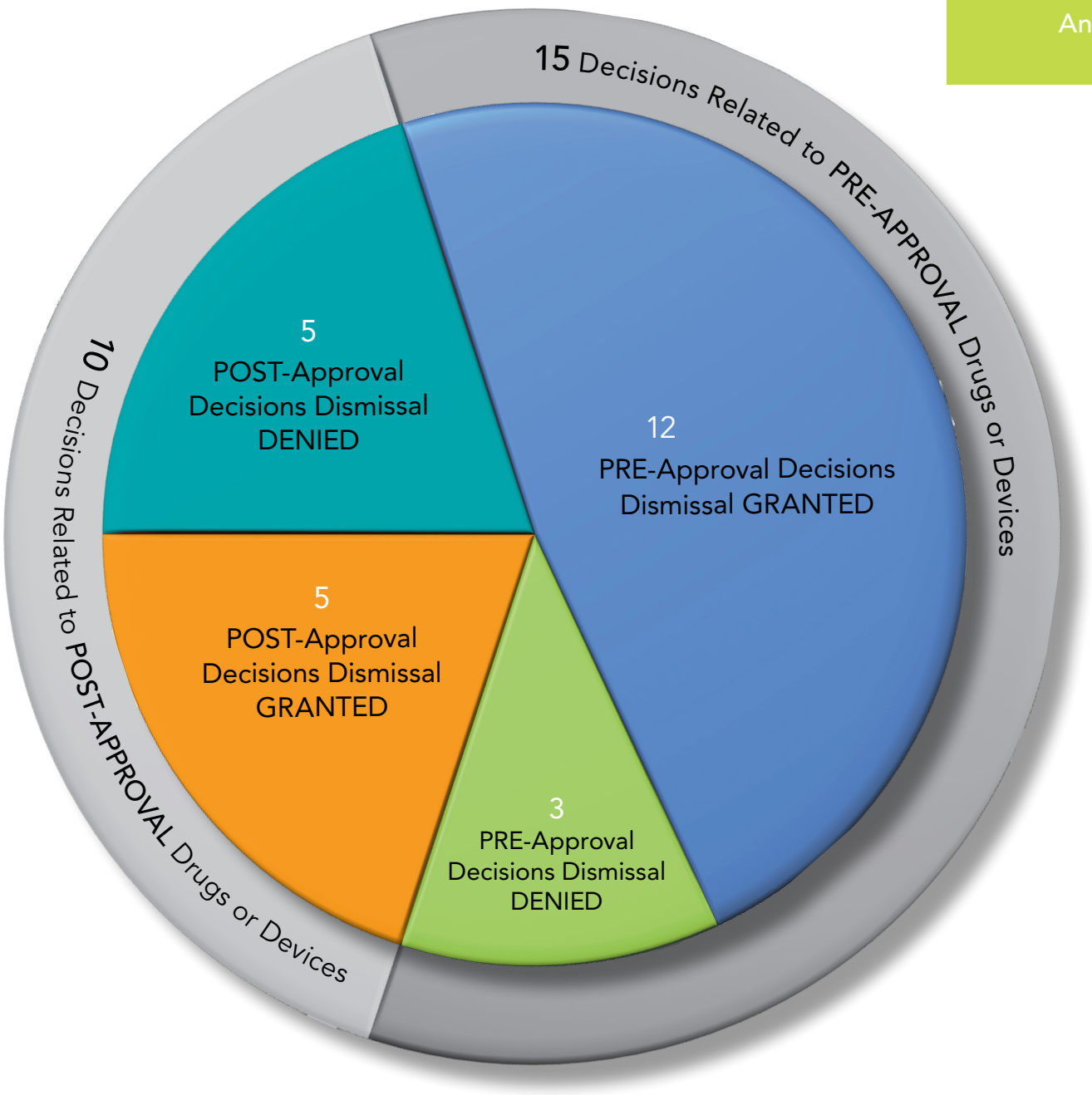
2 Under Section 10(b) (15 U.S.C. § 78j(b)), life sciences companies and their officers may be liable for consciously false or misleading statements they make in virtually any public context, including press releases, earnings calls, investor conferences and SEC filings. Defendants may also be liable for participating in a "scheme" to defraud, although successful scheme claims asserted by private plaintiffs are rare. Several cases discussed in this review also include claims under Sections 11 and 12 of the Securities Act of 1933 in addition to Section 10(b) claims (15 U.S.C. §§ 77k, 77l). Sections 11 and 12 apply only to statements made in connection with new securities offerings—generally, statements in the prospectus and registration statement for an offering. In contrast with Section 10(b), Sections 11 and 12 do not have a scienter requirement.

3 In this section and throughout this review, we use the term "company" to refer collectively to the defendants in securities litigation—both the company and individual officers or directors.



DISTRICT COURT DECISIONS

PRE-APPROVAL DECISIONS

Companies with development-stage drugs or devices won dismissal in 80% of the 2023 cases in the district courts, and prevailed in three of the four cases on appeal. We address developments in three areas.

First, we survey for the third year in a row decisions in cases against companies developing COVID-19-related products. Because the COVID-19 cases arise from events in 2020 and 2021, this chapter of litigation may be nearing its end. Companies prevailed in the 2023 decisions more often than not. In the most significant case, which arose from high-profile failures in manufacturing vaccines, defendants lost their bid for dismissal. Decisions in which companies prevailed, as in past years, show that courts expect investors to be sufficiently familiar with the risks in fast-paced vaccine development that they can discount overly ambitious projections of success.

We next turn to litigation arising from high-profile setbacks in the development of treatments for Alzheimer's disease. In the leading case in this area, the First Circuit reversed a trial court victory for Biogen. The appellate court analyzed the challenged statements as opinions and applied *Omnicare* in a somewhat surprising way. Ultimately, the decision may be best understood as a caution against using categorical terms—"all data"—even in the context of statements qualified as opinions.

Finally, we discuss challenges companies face in communicating about the risk that a product will not be approved. Courts have become increasingly skeptical of arguments by defendants that they would not have invested in a product they knew the FDA would not approve. Courts credit arguments by plaintiffs that such expenditures do not negate an inference of fraud where plaintiffs' theory is that defendants misleadingly downplayed the risk of non-approval. These decisions may weigh in favor of including more detail in communicating about risk—not only in formal risk disclosures but also in discussing interim regulatory communications. On the other side of the ledger, one 2023 decision suggests that defendants may be able to capitalize on the risk and uncertainty inherent in the FDA approval process through creative loss causation arguments.

In the Third Year of Reported COVID-19 Decisions, Manufacturing Issues Continue to Give Rise to the Strongest Claims

In the first three years of the pandemic—2020 through 2022—six or seven new filings per year targeted companies developing COVID-19-related products, principally tests and vaccines. As the cases have worked their way through the courts, the results have been mixed. Decisions on motions to dismiss were evenly split in 2021 and favored defendants in 2022. The 2023 decisions again tilted toward defendants. The 2023 decisions also show, as in previous years, that the strongest claims have arisen from difficulties companies experienced in manufacturing vaccines in 2020 and 2021. A manufacturer experienced the single defeat in the 2023 COVID-19 cases in *Emergent Biosolutions* (29). Vaccine developers succeeded in obtaining dismissal or affirmance of dismissal in *AstraZeneca* (20) and *Ocugen* (27).

Emergent, which arises from high-profile manufacturing failures, is the most significant COVID-19 decision from 2023. Between April and June 2020, long before COVID-19 vaccines had been tested and approved, Emergent obtained manufacturing contracts worth more than $1.5 billion. Its counterparties were both the U.S. government and private vaccine developers, including Johnson & Johnson and AstraZeneca.

Problems arose early. By April 2020, the FDA had already issued a Form 483; in June 2020, the agency told Emergent that it did not consider the company's Bayview facility ready to support commercial operations. Meanwhile, Johnson & Johnson and AstraZeneca flagged problems with contamination, mold, and inadequate training and quality review systems. On July 6, 2020 Emergent nevertheless announced that it was scaling up to produce hundreds of millions of vaccine doses. But audits in the second half of 2020 continued to reveal problems, including the risk of contamination.

On March 31, 2021, the *New York Times* reported that Emergent had voluntarily destroyed batches of vaccines, and that 15 million doses had been contaminated when ingredients for the Johnson & Johnson product were mixed up with ingredients for the AstraZeneca product. The company

responded that the destruction was limited to a single batch. But problems continued, and the government temporarily put Johnson & Johnson in charge of the Bayview facility.

In November 2021, Emergent reported that the government had terminated a major contract. The company also reversed previously recorded revenue. A congressional committee later determined that more than 400 million doses were ultimately destroyed. The committee also concluded that Emergent had hidden evidence of contamination from government investigators, and had failed to remediate multiple deficiencies Johnson & Johnson and AstraZeneca brought to its attention.

In one of only three pre-approval trial court decisions to go against companies in 2023, the District of Maryland denied Emergent's motion to dismiss. The court concluded that most of the company's statements about its manufacturing capabilities were true, but were rendered misleading by the omission of information about the destruction of doses and the FDA's June 2020 communication that it did not believe Emergent was ready to begin commercial operations.

In concluding that plaintiffs had adequately alleged scienter, the court notably rejected two arguments often advanced by drug developers. The first argument was that plaintiffs' theory of fraud was counterintuitive: Emergent would not have "invested immense time, effort, and money in what [it] secretly knew would be a futile effort to manufacture COVID-19 drug substance." The court rejected the argument because it did not accurately capture plaintiffs' theory of fraud. Plaintiffs' theory was not that Emergent knew its efforts would fail but rather that Emergent concealed or downplayed factors bearing on the risk of failure.

Emergent's second scienter argument was that a holistic review of scienter allegations showed that the company "worked in good faith to manufacture vaccine drug substance in response to a pandemic, disclosed the risks, suffered an unfortunate contamination incident, and worked to address it." The court did not question Emergent's good faith in manufacturing vaccines, but concluded that plaintiffs had adequately alleged that "while doing so, [the company] omitted the myriad known deficiencies at Bayview that undercut the success of that endeavor and did so with reckless disregard for how those omissions could mislead investors."

These holdings suggest that securities defendants should take care to refine common scienter arguments. Refined arguments might emphasize (1) that a company would not pour resources into drug development (or any other endeavor) if it did not believe the likelihood of success was sufficiently high to justify the expenditures, and (2) that a company approached drug development and communications with investors about development with the same degree of earnestness and good faith.

Companies were successful in the two other COVID-19 cases that led to decisions in 2023. We have previously reported on *AstraZeneca*, in which plaintiffs faulted the company for not providing more complete information about a vaccine trial while it was ongoing. Some patients were given half-doses not because the protocol called for this but because that was what the manufacturer had provided. Plaintiffs alleged that by not revealing that information until it reported trial results, the company created a false impression that the trial was "on track." The district court granted the company's motion to dismiss in 2022, and the Second Circuit affirmed dismissal in a short unpublished decision in 2023. The district court, in notably crisp terms, rejected plaintiffs' argument that when a company does not disclose adverse facts, investors may reasonably conclude that no such facts exist: "Were that the standard, every omission would be actionable." That is a useful concept and precedent. The Second Circuit's affirmance, though cursory, clinches the value of the district court's decision.

The third 2023 COVID-19 decision is *Ocugen* (27). Ocugen worked on treatments for blindness, but had never had a drug approved, and by 2020 had fallen on hard times. The company reported a going concern qualification in November 2020. The next month, Ocugen switched course dramatically, announcing that it was partnering with Bharat, an Indian biotech company developing an inactivated whole-virion COVID-19 vaccine called Covaxin. While Bharat conducted clinical trials in India, Ocugen took steps to prepare to apply for an Emergency Use Authorization (EUA) based on the Indian trial data. Ocugen projected great success: submission of an application in the first half of 2021, distribution of 100 million doses in the U.S. the same year, and significant revenue from that distribution.

None of that came to pass. In late 2020 and early 2021, the FDA granted EUAs for the Pfizer/BioNTech, Moderna, and Johnson & Johnson vaccines, and issued guidance to companies seeking EUAs for subsequent vaccines. In May 2021, in keeping with FDA instructions, Ocugen provided a "master file" to the agency before submitting an EUA application. The FDA's response was that Ocugen should instead submit a BLA. That deprived Ocugen of the advantages of the expedited EUA process, and the company's stock price fell steeply.

Plaintiffs alleged fraud, attacking Ocugen's highly optimistic projections. Much as in earlier COVID-19 cases in which companies made very confident statements about success during the first months of the pandemic, the court was notably sensitive to circumstances. In this case, that favored the company. The court reasoned that the public gained a heightened awareness of risk in drug development during the pandemic, and that against that background, plaintiffs failed to plead materiality. Reasonable investors, the court held, would understand that forecasts of success in this area are speculative, and that they amount to no more than puffery. "[I]n the height of an unprecedented global pandemic, reasonable investors would certainly appreciate that FDA approval and vaccine distribution was a 'risky endeavor' even if Defendants omitted a caveat to this effect. Accordingly, any reasonable investor would be able to discern Defendants' projections related to vaccine distribution as immaterial puffery."

The court also rejected plaintiffs' contention that the company knew it would never obtain an EUA. Plaintiffs argued that Ocugen had failed to comply with new FDA guidance on EUAs, and therefore knew that its EUA application would be rejected. But the court held that the FDA guidance was just that—non-binding guidance—and that nothing suggested that a vaccine could not succeed on the EUA pathway unless a company had satisfied every factor in the guidance.

The court's approach to guidance, like its approach to highly optimistic projections, is notably defendant-friendly. Whether either approach will have traction outside the unique context of the pandemic is a different question.

Developments in Alzheimer's Disease Treatments Spawn Difficult Securities Litigation

In 2023, courts continued to work through the fallout of a major and ultimately disappointing development in the treatment of Alzheimer's disease. In 2021, the FDA approved Aduhelm, an Alzheimer's disease drug made by Biogen. Aduhelm had an unusual pre-approval and approval history. In 2015, Biogen commenced two Phase 3 trials of the drug, Engage and Emerge. But in 2019, following a planned interim analysis of the aggregated Engage and Emerge data, the company discontinued both trials on futility grounds.

Biogen then performed a post hoc analysis in which it disaggregated the Engage and Emerge data. That analysis showed that Emerge met its primary endpoint, although Engage did not. This appeared to be related to the timing of protocol amendments. Emerge started later than Engage. As a result, protocol amendments implemented in both trials had a greater impact on Emerge than on Engage. The principal effect of the amendments was to increase the dose available to "carriers"—patients who were predisposed both to Alzheimer's disease and to one of Aduhelm's side effects. The post hoc analysis appeared to show that at a sufficiently high dose, Aduhelm was effective.

The FDA fully supported Biogen's post hoc analysis, and encouraged the company to submit an NDA notwithstanding the fact that the trials had been discontinued for futility. The FDA then scheduled an advisory committee meeting for November 2020. Somewhat unusually, the FDA and Biogen submitted a joint briefing document in advance of the meeting. The briefing document advocated approval, and Biogen's stock price rose the day it was released. The stock fell the next trading day, possibly in delayed response to a dissenting section of the briefing document written by an FDA statistician.

The advisory committee did not return a favorable vote in November 2020. Nevertheless, the FDA approved the drug seven months later, in June 2021, under its Accelerated Approval pathway (which requires a Phase 4 post-approval confirmatory study). The approval was controversial, and Aduhelm's subsequent launch was not a success. A contract with the VA fell through. The launch sites Biogen had targeted were slow to work through pharmacy and therapeutics committee reviews. Medicare decided to cover the drug only in the clinical trial setting. Biogen cut the price of the drug in half. In 2022, the company largely abandoned commercialization.

This saga generated two major pieces of securities litigation, one arising from statements the company made before the November 2020 advisory committee meeting and the other from statements about the launch. As we reported last year, Biogen prevailed in the district court in the first action. But in 2023, the First Circuit reversed in part (*Shash v. Biogen*, page 18). In the second case, concerning the launch, Biogen prevailed in the district court (*Oklahoma Firefighters v. Biogen*, page 33).

The First Circuit's decision is notable in several respects. Reversals are themselves fairly unusual. The reversal rate in securities class actions against life sciences companies is low. Over the ten years in which we have issued this report, the rate is less than 20%.

The First Circuit reversed as to only one challenged statement: "[C]onsistent with the findings from Engage and Emerge, you really need to get to the higher dose. And I think our data are all consistent with that." The First Circuit recognized that this was an opinion statement governed by *Omnicare*, which sets out three ways in which such statements can support a securities claim.[4] Under *Omnicare*, a plaintiff can show that an opinion statement is false if the speaker did not honestly hold the opinion, or if facts embedded in the statement are untrue. A plaintiff can show that an opinion statement is misleading if the speaker omits facts about the basis of the opinion that differ from what a reasonable investor would expect. Courts have recognized that *Omnicare* forecloses claims that an opinion statement is false because it lacks a reasonable basis.[5]

Rather than applying *Omnicare's* three-pronged analysis, the First Circuit focused on a comment in the decision—that reasonable investors will conclude that an opinion "fairly aligns with the information in the issuer's possession at the time."[6] With that as a standard, the First Circuit concluded that plaintiffs had adequately alleged falsity. The challenged statement, the court observed, did not align with *all* data. While some of the post hoc subgroup analyses showed that a higher dose was more effective, others did not.

The First Circuit did not discuss other concepts in *Omnicare*—that defendants who make opinion statements need not disclose every "fact cutting the other way," and that reasonable investors do not expect that "every fact known to an issuer supports its opinion statement."[7] Applying those principles might have changed the legal analysis. The subgroup data that did not support the challenged opinion—"I think our data are all consistent with that"—could be characterized as simply facts cutting the other way. On the other hand, the company's use of the word "all" may have locked in the outcome, regardless of the finer points of *Omnicare's* application. The statement "I think our data are all consistent with that" appears to signal that *no* facts cut the other way. A slightly different formulation—"I think our data are consistent with that," or even "I think our data overall are consistent with that"—may have led to a different outcome.

On other issues, the First Circuit sided with the company and affirmed dismissal. Plaintiffs failed to establish scienter with respect to statements about the drug's efficacy generally: The company's knowledge of the subgroup data did not equate to a belief that the drug was ineffective. More broadly, plaintiffs' theory of bad-faith data manipulation was inconsistent with the FDA's support of the post hoc analysis.

In the end, the First Circuit's decision shows that notwithstanding a decade of experience, courts can apply *Omnicare* in imprecise and unpredictable ways. *Omnicare*'s framework generally favors defendants, but the decision and its progeny also contain concepts that may favor plaintiffs. The First Circuit's decision may also be read as a caution against using terms that leave no wiggle room, even in the context of opinion statements—here, the word "all."

Biogen fared better in the launch case. Plaintiffs there challenged statements about the readiness of sites to begin prescribing, about Medicare coverage, about the VA contract, and about Biogen's collaboration with the FDA leading up to approval. In each instance, the court carefully parsed the nuances of the challenged statements and concluded that there was no inconsistency between those statements and the truths plaintiffs alleged the company had

4 *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015).
5 *City of Dearborn Heights Act 345 Police & Fire Ret. Sys v. Align Tech., Inc.*, 856 F.3d 605, 618-19 (9th Cir. 2017).
6 *Omnicare*, 575 U.S. at 188-89.
7 *Id.* at 189.

concealed. In working through the statements, the court showed a sophisticated understanding of the complicated commercial and regulatory issues surrounding a launch.

The third 2023 decision arising from a failed Alzheimer's disease treatment is *Cassava* (28). Biogen and Cassava exist on opposite ends of the life sciences company spectrum. Biogen has thousands of employees and $10 billion in annual revenue. Cassava has eight or nine employees and has never had a product approved. But like Biogen, Cassava had an Alzheimer's disease drug with an unusual trajectory, in which initially unfavorable results improved on reexamination. And like Biogen, Cassava became enmeshed in securities litigation arising in part from that unusual fact pattern, and was unable to dispose of it at the pleading stage.

Cassava announced in May 2020 that a Phase 2b study of its Alzheimer's drug simufilam failed to meet its primary endpoint. But in reporting complete results in September 2020, the company said that a reanalysis by an "outside lab" had yielded a different outcome: Simufilam "significantly improved an entire panel of validated biomarkers" for Alzheimer's disease.

After the company made additional public presentations and published journal articles, skeptics emerged. Two doctors who held short positions in Cassava's stock filed a Citizens Petition with the FDA, suggesting that the company had manipulated data. The "outside lab" that performed the re-analysis turned out to have been run by the co-inventor of simufilam, who was a Cassava consultant and sat on the company's scientific advisory board. An expert on data manipulation stated in an online post that images Cassava used in its presentations were not originals. The *New York Times* published an article in which experts said they did not trust Cassava's methods or results. *Reuters* reported a DOJ criminal investigation into the matter. Unsurprisingly, Cassava's stock declined through these developments.

Given the wealth of detailed criticism in the public forum, plaintiffs were able to plead with sufficient particularity that the company's positive statements about trial results were misleading by virtue of omitted information. Among other things, plaintiffs presented photographs included in the publicly available critiques.

The court also drew on the widespread nature of the attack on Cassava's data in evaluating scienter:

> Scienter can also be supported by the reaction of the scientific community to the disclosure of Defendants' manipulation of data. Plaintiffs allege that the main reaction of ten prominent scientists to Cassava's research papers was "Oh, my God, how could they get away with this?" (cleaned up)

Cassava's unusual incentive compensation terms further supported an inference of scienter. Cash bonuses were triggered by short-term stock increases.

The search for an Alzheimer's disease treatment, perhaps because of the tremendously high stakes involved, has spawned some unusual and dramatic narratives. The 2023 decisions show how the plaintiffs' bar has been able to capitalize on them.

Challenges in Communicating With Investors About Risk

As noted, courts denied motions to dismiss in only three pre-approval cases in 2023. In two of the three, *ChemoCentryx* (29) and *Emergent* (29), plaintiffs' theory was that the company downplayed risk in communicating with investors. In both cases, the court deemed that theory sufficient as a pleading matter. *Lipocine* (23) provides a counterpoint, and shows how companies may be able to turn concepts of risk to their advantage in analyzing causation.

The plaintiffs in *ChemoCentryx* alleged that the company concealed the risk that the FDA would not approve its NDA. The court's analysis of that risk led to rulings against the company on falsity, materiality, and scienter. Plaintiffs alleged that in reporting to investors about its communications with the FDA, the company omitted specific concerns the agency had raised. The company argued that it had adequately addressed these matters through its risk disclosures, in which it warned that the FDA could interpret trial results differently from the company. The court rejected that argument, holding that "abstract warnings of future risk" are inadequate when specific instances of risk have already become manifest in the present.

The company also argued that its purported misrepresentations were immaterial, since plaintiffs failed to allege that the FDA told it that the safety and efficacy issues it had identified could foreclose approval. The court rejected that argument too. "Regardless of whether Defendants had any indication that the FDA's concerns would fully prevent the drug's approval, those concerns at least increased the risk that the drug would not be approved, would only be approved for a narrower label than the one Defendants predicted, or would not be as widely used…as Defendants suggested." Given these risks, the court concluded that the company had a duty to disclose even interim FDA communications—contrary to the result in many other cases.[8]

Finally, the risk of non-approval was central to the *ChemoCentryx* court's analysis of scienter. Defendants argued that a benign inference was stronger than an inference of deliberate deceit, pointing out that they "would not have dedicated tremendous amounts of resources necessary to develop [the drug] if they knew concerns about the trial would jeopardize regulatory approval." The court rejected the argument:

> Here, 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.

This analysis is very similar to that in *Emergent*, the COVID-19 vaccine manufacturing case discussed above. There too, the company argued that it would not have sunk resources into a project it knew was doomed. And there too, the court held that plaintiffs had adequately pled scienter on a concealment-of-risk theory:

> [T]he Plaintiffs' theory is not that Emergent knew at the outset that the Bayview facility was "doomed to fail" to produce any vaccines…The Plaintiffs' theory is that the Defendants concealed from investors ongoing, serious deficiencies in the Bayview facility's ability to comply with FDA requirements and to safely manufacture, on a large scale, drug substances for vaccines, downplaying risks of contamination and other problems that might spoil a significant amount of the drug substance batches.

Also as in *ChemoCentryx*, the *Emergent* court rejected the company's argument that it had adequately disclosed risk, and in fact had cautioned investors of an even greater risk than the one that came to pass—the risk that it might never manufacture any vaccines at all. The court held that the "risk disclosure may have warned about the possibility that contamination could occur or that no batches would be produced at all, but the omitted deficiencies substantially affect an assessment of how likely that scenario would be."

These holdings pose again a question we discussed in last year's review. Are courts suggesting that companies need not only disclose risks but also characterize the likelihood that the risks will materialize? And if so, how could companies comply with such a directive?

One answer may be that as long as a company discloses the *substance* of a risk, it need not go further to estimate the *severity* of the risk. But in disclosing substance, a company may need to go into considerable detail about ongoing regulatory occurrences. And the notion that a company needs to do this is in tension with well-developed case law holding that companies have no obligation to disclose non-final agency communications.

On the other side of the ledger, *Lipocine* shows that in some cases defendants may be able to use the difficulty in pinpointing risk to their advantage. The company in that case filed three successive NDAs, each followed by a Complete Response Letter (CRL). Plaintiffs attacked statements made between the second and third CRL, alleging that the company concealed the risk that the trial's failure to meet a secondary endpoint would foreclose approval. In an unusual and interesting analysis, the court rejected plaintiffs' theory on loss causation as well as on falsity and scienter grounds.

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8 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"); *Vallabhaneni v. Endocyte, Inc.*, 2016 WL 51260, at *12 (S.D. Ind. Jan. 4, 2016) ("[n]umerous courts have concluded that a defendant pharmaceutical company does not have a duty to reveal interim FDA criticism regarding study design or methodology") (collecting authorities); *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"), *aff'd*, 816 F.3d 199 (2d Cir. 2016).

In analyzing loss causation, the court first rejected plaintiffs' contention that the third CRL was a corrective disclosure that revealed the purported fraud. In the court's view, the CRL was a piece of very bad news, but it was not demonstrably related to fraud.

The court then considered a materialization of risk theory—specifically, "a materialization of risk theory based on a concealed risk that the chances of NDA approval were lower than investors were led to believe." The court rejected the theory on the facts of the case:

> Such a claim, in theory, could satisfy Plaintiffs' obligation to plead loss causation. For example, if [Plaintiffs] alleged facts that showed that Defendants' misrepresentations led investors to believe that the chance of FDA approval were 70%, when the actual chances of approval were only 30%, then loss causation could be shown by alleging that the actual chances of FDA approval were eventually revealed and caused a fall in Lipocine's stock price. The [Plaintiffs], however, allege no such thing.

In reality, no complaint will include such allegations. A company will rarely if ever quantify the likelihood of approval. And even if a company does so, the "actual chances of approval" will never be known; nor will a CRL reveal the "actual chances." The route to loss causation the court offers "in theory" is in reality no route at all.

But the court's analysis does seem to open up a clever loss causation argument in cases where plaintiffs claim that a company underplayed risk. A company may be able to shift to plaintiffs the challenge of spelling out what the actual magnitude of risk was, and how it was ultimately revealed. Plaintiffs will virtually never be able to quantify risk in this way. Whether that is sufficient in itself to win the day is less clear. The inadequacy of the plaintiffs' falsity and scienter allegations in *Lipocine* may have predisposed the court to see a loss causation shortfall as well. Nevertheless, *Lipocine* may provide the foundation for creative loss causation arguments in cases where plaintiffs seek to exploit the risk and uncertainty inherent in the FDA approval process.

Lipocine is finally notable for one exceptionally clear statement in framing the scienter inquiry. Plaintiffs in pre-approval cases often seek to short-circuit the scienter analysis by arguing that they have shown that individual defendants knew about trial data, regulatory communications or other facts allegedly inconsistent with a challenged statement. The *Lipocine* court explained clearly why this is not sufficient in itself:

> In a case, like this one, where fraud is based on an alleged failure to disclose material information, the PSLRA requires more than an allegation that the defendant knew the facts that were allegedly omitted…Instead, to establish scienter in a securities fraud case alleging non-disclosure of potentially material facts, the plaintiff must demonstrate: (1) the defendant knew of the potentially material fact, and (2) the defendant knew that failure to reveal the potentially material fact would likely mislead investors.

That analysis is a good reminder of a critical scienter angle in both pre-approval and post-approval cases.

POST-APPROVAL DECISIONS

Companies with approved drugs or devices won dismissal or summary judgment in 50% of the cases in the district courts, and won affirmance in the two cases on appeal. We discuss developments in two areas: the latest and possibly final chapter in cases arising from an alleged decade-old price-fixing conspiracy among generic drug manufacturers, and the differing approaches courts have adopted in adjudicating cases based on alleged regulatory or statutory violations distinct from federal securities law.

The Generic Drug Price-Fixing Saga Nears Its End with Two Summary Judgment Decisions

2023 marked the end, or close to the end, of an antitrust story we have been covering for the past seven years. Late in 2016, a consortium of state attorneys general filed a complaint alleging a broad conspiracy to fix generic drug prices, naming six manufacturers as defendants. In amended

complaints over the next several years, more states joined the action, more manufacturers were named as defendants, and more generic drugs were swept into the mix.

The public companies alleged to have participated in the conspiracy inevitably became the targets of Section 10(b) litigation. Courts began issuing decisions on motions to dismiss in those cases in 2018 and continued to do so over the next several years. (We reported on these decisions in our 2018, 2019, and 2020 annual reviews.) Companies did not fare well at the pleading stage. Only one manufacturer, Impax Laboratories, ultimately obtained dismissal. Securities litigation against at least a half-dozen other companies proceeded into discovery. Meanwhile, the state AGs' claims, along with many related private actions, were the subject of an MDL proceeding in the Eastern District of Pennsylvania.

Many of the Section 10(b) cases settled, several for hundreds of millions of dollars. Two cases reached summary judgment in 2023, *Mylan* (36) and *Roofer's Pension Fund (Perrigo)* (39). Both cases included significant issues in addition to the alleged antitrust violations. In *Mylan*, the company paid $465 million to resolve claims by the DOJ that it had misclassified a product in order to get more favorable rebate treatment. *Perrigo* arose in the M&A context. The company characterized various aspects of its business favorably while fending off a hostile tender offer (coincidentally, by Mylan), and then made arguably inconsistent representations about the same assets after defeating that offer.

As to the securities claims arising from the alleged generic drug price-fixing conspiracy, Mylan won summary judgment and Perrigo lost narrowly—but may yet prevail. In *Mylan*, the district court had earlier ruled that plaintiffs were required to prove antitrust violations with respect to particular generic drugs. The court rejected plaintiffs' contention that they could prevail on their securities claim by establishing market allocation or price fixing as to the generic drug market as a whole. Plaintiffs sought to meet their summary judgment burden as to only six drugs, and failed as to all of them. The Sherman Act Section 1 "plus" factors plaintiffs identified showed only that the company was operating rationally in an oligopolistic market. The factors did not show an illicit agreement among the manufacturers. "The failure of Plaintiffs to deal with Mylan's explanation of what economic rationality entails in the generic drug market makes it impossible to conclude that 'no reasonable firm would have engaged' in Defendants' course of conduct absent being party to a conspiracy."

The court's drug-specific approach was also fatal to plaintiffs' attempt to establish loss causation. To the extent the purported corrective disclosures conveyed new information, none of it related to the six drugs at issue.

The defendants in *Perrigo* also argued that their conduct was simply that of a firm acting rationally in an oligopolistic market. Here, however, the court concluded that plaintiffs had "barely raised just enough facts to show a genuine issue of fact exists on the existence of a price-fixing scheme for generic drugs." That evidence came primarily from one of Perrigo's competitors, Sandoz. Sandoz had entered into a deferred prosecution agreement in which it admitted to price fixing and market allocation agreements with an unnamed company. Plaintiffs submitted an affidavit from a Sandoz executive identifying that company as Perrigo. Plaintiffs also relied on the state AGs' complaint, and in particular on allegations from a Sandoz confidential witness about communications with a Perrigo sales executive, the goal of which was to keep prices elevated. Here too, a Sandoz executive submitted an affidavit connecting the dots. He revealed himself as the confidential witness and verified the allegations about his communications with Perrigo. Plaintiffs submitted other circumstantial evidence to the same effect.

But having prevailed ("barely") in establishing a factual issue on the existence of a conspiracy and Perrigo's participation in it, plaintiffs lost much of their case on scienter. They failed altogether as to the CEO and CFO, who made the challenged statements about competition and the company's generic drug pricing policy. Plaintiffs overstated the executives' involvement in setting prices, and knowledge of pricing did not in any event equate to knowledge of price fixing.

Turning to the corporation, the court stated that "since the Generic Rx Claim against [the two executives] fail[s] for lack of scienter, this Court finds Perrigo's argument that the claim

against it too must fail persuasive." The court nevertheless did not grant summary judgment for the corporation. Plaintiffs had invoked the concept of "corporate" or "collective" scienter, in which the knowledge of a non-speaking non-defendant can theoretically be imputed to the corporation. The *Perrigo* court surveyed the case law applying the corporate scienter concept, noting that some but not all courts require plaintiffs to identify a particular corporate agent with knowledge of the purported fraud. Most significantly, the court noted that plaintiffs had cited no law applying the corporate scienter concept on summary judgment, as opposed to the pleading stage. The court ordered additional briefing on the issue and the parties moved onto a settlement track.

Courts Continue to Grapple with "Claims Within Claims"

The antitrust-related claims, along with others on which courts ruled in 2023, present the recurrent issue of how best to litigate and adjudicate claims premised on alleged violations of laws other than Section 10(b). The catalyst for many post-approval cases is the announcement of a government investigation or other actual or potential regulatory action. As we have discussed in previous reviews, these cases are often complicated by the fact that the outcome of the investigation or regulatory proceeding is unknown when securities litigation commences, and may remain unknown for years thereafter. That may put the court presiding over the securities litigation in the position of ruling on the alleged underlying violation in the first instance, notwithstanding proceedings elsewhere directly addressing the purported wrongdoing. The *Mylan* court summarized this setup well: "The liability theory advanced by Plaintiffs reflects 'claims within claims'—that [Defendants] misled investors by obscuring underlying violations of antitrust law or regulatory law."

The 2023 decisions reflect a range of judicial responses to that situation. This is particularly clear in cases where the alleged underlying misconduct consists of antitrust violations. The claims in *Mylan* were based on two separate sets of alleged antitrust violations—one concerning generic drugs (discussed above) and the other related to the EpiPen, which is one of Mylan's branded products. The plaintiffs in *Perrigo* (also discussed above) alleged that the company had participated in the same purported generic drug price-fixing conspiracy. In a third case, *Dentsply* (38), plaintiffs alleged that the defendant manufacturer knew about, acquiesced in, and profited from antitrust violations by its distributors.

The first set of alleged antitrust violations at issue in *Mylan*—those related to the EpiPen—had by the time of summary judgment been adjudicated in an MDL proceeding. The MDL court granted summary judgment for the defendants. The *Mylan* court treated the MDL court's ruling as persuasive authority, but did not give it claim-preclusive or issue-preclusive effect. The court instead conducted its own summary judgment analysis of the antitrust claims, and ultimately reached the same conclusion as the MDL court.

More generally, the *Mylan* court set out a two-part framework for adjudicating "claims within claims":

> Plaintiffs[] at summary judgment[] must adduce evidence satisfying a double-layered burden of proof in this case: First, Plaintiffs must survive summary judgment as to the substance of their EpiPen competition claims; and second, Plaintiffs must *then* survive summary judgment as to the elements of a securities claim…Plaintiffs must demonstrate that Mylan actually did violate the Sherman Act as a necessary step to establishing their securities fraud claims.

Applying that framework, the court concluded that plaintiffs had failed to satisfy either burden. As noted, the court did not give preclusive effect to the MDL court's ruling, instead conducting its own extensive analysis of the antitrust issues. The result was obviously favorable for the company. Just as obviously, it came at a significant cost. The securities action reached summary judgment more than six years after it was filed, and more than two years after the MDL court had dismissed the underlying EpiPen antitrust claims.

The second antitrust-based claim in *Mylan* was premised on the alleged generic drug price-fixing conspiracy. On this claim, no substantive ruling appears to have been made on the underlying antitrust claims at the time of summary judgment. The generic drug antitrust claims were the subject of a different MDL proceeding, but the *Mylan* court did not cite any ruling in that case. The court analyzed the alleged antitrust violations from scratch and concluded that plaintiffs

failed to prove the existence of a price-fixing or market allocation agreement. The court then considered the claim within a Section 10(b) framework, but rather than addressing scienter, held that plaintiffs failed to establish loss causation.

The court in *Perrigo*, as noted above, reached the opposite conclusion about the same alleged generic drug price-fixing conspiracy. Plaintiffs in *Perrigo did* present a summary judgment issue on the existence of a conspiracy and the company's participation in it. Unlike the *Mylan* court, the *Perrigo* court considered evidence from other proceedings—specifically, proceedings against Mylan's competitor, Sandoz. Like the *Mylan* court, the *Perrigo* court then evaluated the alleged antitrust violations within a Section 10(b) envelope, focusing on scienter. From that perspective, the court gave defendants a partial summary judgment victory. The court dismissed the claims against the individual defendants and strongly suggested that it could ultimately grant summary judgment for the company too on scienter grounds.

The third decision arising from alleged antitrust violations is *Dentsply*, and the court there took a far less technical approach. The *Dentsply* plaintiffs challenged the company's statements about competition and the reasons for revenue growth. Plaintiffs' theory was that the company misleadingly failed to disclose an alleged conspiracy among its distributors to dampen consumer buying power and keep a lower-priced distributor out of the market. Unlike the *Mylan* and *Perrigo* courts, the *Dentsply* court did not analyze the allegations under antitrust law. There was no discussion of a claim within a claim. The court simply concluded that plaintiffs had pled sufficient factual detail about the existence of the alleged conspiracy and the company's acquiescence in and economic benefit from it. The court took at face value plaintiffs' contention that the conduct violated antitrust law.

The courts' approach to the antitrust-based securities claims thus runs the gamut from simple acceptance of the premise that the alleged actions constitute antitrust violations to a full-fledged independent consideration of the claims as a matter of antitrust law, followed by a separate consideration of antitrust violations within a Section 10(b) framework. The latter approach is plainly more favorable for defendants. *Mylan's* explicit framing of claims within claims should be a significant precedent in cases based on alleged underlying violations, not confined to antitrust violations. As a matter of pleading or at summary judgment, plaintiffs can be assigned a "double-layered burden," and defendants will enjoy a double opportunity to dispose of claims.

In addition to the antitrust-based securities claim, the *Mylan* court considered a separate claim based on an alleged regulatory violation. On this issue too, *Mylan* may be a useful precedent. As noted, Mylan paid $465 million to settle a DOJ claim that it had misclassified the EpiPen in order to obtain more favorable rebate treatment. The court declined to view the settlement as evidence of wrongdoing, for both legal and chronological reasons:

> Mylan's settlement agreement is neither admissible nor significantly probative of scienter. Even if this settlement were admissible evidence, it would not be sufficient to alleviate Plaintiffs' proof problems. Since it is from after the class period, it is largely irrelevant in the context of this securities fraud lawsuit: For scienter purposes, it does not matter what Mylan was willing to settle for in 2017; what matters is what Mylan and its agents knew and believed when the challenged statements were made in 2015.

The court similarly rejected plaintiffs' contention that wrongdoing and scienter could be inferred from two Mylan employees' invocation of the Fifth Amendment during depositions taken as part of the DOJ investigation.

As with the antitrust-based claims, the *Mylan* court placed a double burden on plaintiffs for the misclassification claim. In considering whether a violation had occurred in the first place, the court rigorously analyzed the statutory scheme, noting ambiguity created by amendments. In determining at the second step whether any potential violation could serve as the basis of a Section 10(b) claim, the court focused heavily on scienter. That required examining decades-old communications between the company and the FDA on the subject of classification. And that in turn showed both that the company had a reasonable basis to believe that the FDA agreed with its classification, and that the company had sought expert advice on the matter. Ultimately, the court concluded, "[t]here is no evidence in the record to sustain a reasonable

inference that Mylan knew the EpiPen was erroneously classified and misled its shareholders despite this." Given its view of the evidence, the court had little trouble discounting the hefty settlement payment and the invocation of the Fifth Amendment.

Here too, *Mylan* can be an important model for litigating claims within claims. On the classification issue, defendants benefited significantly from the court's willingness to delve deeply into the merits of the alleged underlying violations, rather than being guided by the outcome of the DOJ proceedings.

Trends and Analysis

DECISIONS RELATED TO DEVELOPMENT-STAGE DRUGS OR DEVICES

In this section (pages 17-30), 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 12 of the 15 cases in the district courts.

In the appellate courts, companies won affirmance of dismissal in three of the four cases.

APPELLATE DECISIONS

Emps' Ret. Sys. of the City of Baton Rouge v. Macrogenics, Inc., 61 F.4th 369 (4th Cir. 2023), affirming dismissal. **Phase 3**

Macrogenics developed Margetuximab, a second-line treatment for metastatic breast cancer. In February 2019, the company announced favorable interim results from a Phase 3 trial, reporting that the data showed that the drug had a statistically significant benefit in progression-free survival (PFS) over the standard of care. Macrogenics did not report overall survival (OS) data, which were still maturing. (The OS data would be complete only when all patients in the trial had died.) The company told investors that it would present interim OS data at the upcoming American Society of Clinical Oncology conference (ASCO) in June 2019. The company's stock price rose following its February 2019 announcement, and Macrogenics conducted a secondary public offering shortly thereafter. In May 2019, the company reported initial interim OS data for the first time: The data showed a 1.7 month benefit for Margetuximab over the standard of care, and a 6.8 month benefit for a pre-determined subset of patients who carried a particular allele. The company characterized this as a promising trend. At ASCO in June 2019, the company provided more complete interim data and specified that the OS results did not reach statistical significance. Macrogenics also presented Kaplan-Meier curves for the first time at ASCO; those curves can aid in assessing immature OS data. The company's stock price fell 21%.

Investors sued, challenging Macrogenics' statements about PFS results and interim OS data. The district court granted the company's motion to dismiss on both falsity and scienter grounds, in a decision we reported in our 2021 review. Most significantly, the district court rejected the plaintiffs' contention that Macrogenics assumed a duty to disclose OS results by discussing PFS results. The district court also concluded that plaintiffs failed to plead facts showing falsity as to the statement that OS trends were positive.

The Fourth Circuit affirmed on falsity grounds. Like the district court, the Fourth Circuit held that the company did not assume a duty to disclose OS data, which it viewed as a subject distinct from PFS data. The omission of OS data was not misleading in any event: The company included a detailed risk disclosure cautioning investors that meeting the PFS endpoint did not guarantee that the trial would meet the OS endpoint. The Fourth Circuit also rejected plaintiffs' argument that by referring to positive OS trends, the company assumed a duty to disclose the Kaplan-Meier curves earlier. Plaintiffs claimed that the curves showed a negative trend, but this to the court was a non-actionable dispute over scientific matters. The court concluded that other challenged statements constituted puffery—and were true—and that all statements about trial results were opinions as to which plaintiffs failed to meet *Omnicare*'s requirements. Plaintiffs also brought a Section 11 claim based on the secondary public offering materials, asserting that the company violated Items 303 and 105 of SEC Regulation S-K. The court affirmed dismissal of that claim too. Item 303 requires the disclosure of certain trends—but the company *did* disclose the positive OS trend. Item 105 requires the disclosure of certain risks, and the company complied with this requirement by cautioning investors that OS results were uncertain. Characterizing the company's position generally, the court stated that drug developers "constantly find themselves in the hot seat," seeking capital to fund clinical trials of "ground-breaking, experimental drugs designed to combat the world's deadliest illnesses." Against that background, the court declined to fault companies for "issuing positive and accurate opinions while weighing…competing facts." In dramatic language, the court concluded "[i]t would be a great disservice to stifle biopharmaceutical companies' pursuit of medical advancements by failing to safeguard against an inundation of lawsuits alleging securities-law violations."

Shash v. Biogen, Inc., 84 F.4th 1 (1st Cir. 2023), reversing dismissal in part. **NDA**

Biogen developed aducanumab for the treatment of Alzheimer's disease. The company conducted two Phase 3 trials called Engage and Emerge. Engage began enrollment before

Emerge. Two-thirds of the patients in the trials were "carriers": They had a condition that predisposed them to both the disease and the side effects of aducanumab. These patients were initially given low doses of the study drug. 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 also appeared favorable when limited to carriers 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. Biogen submitted its NDA in July 2020. The company discussed the post hoc analysis with investors and stated in September 2020 "you really need to get to the higher dose," and "I think our data are all consistent with that." The FDA convened an advisory committee, and when the agency released a joint briefing document in November 2020, analysts reported that the document showed that the agency endorsed approval. Biogen's stock rose. 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 then returned a mixed vote; seven months later, the FDA approved the drug under the Accelerated Approval pathway, which requires a Stage 4 confirmatory study.)

Investors sued, challenging Biogen's September 2020 opinion statement that "our data are all consistent" with the conclusion that higher doses were necessary for efficacy. Plaintiffs also challenged numerous statements about dosing and efficacy. The district court dismissed on falsity, scienter, and loss causation grounds in a decision we reported in last year's review. On loss causation, the court concluded that "causation is not tied to when the market reacts to information, but rather when that information became available to the public."

The First Circuit reversed as to the statement "our data are all consistent" and affirmed as to all other statements. The court concluded that what it called the "all data" statement was misleading by omission and hence actionable under *Omnicare*. Data the company did not disclose at the time of the challenged statements showed that only a single subgroup did better on the higher dose: carriers in the Engage study. Noncarriers, who received higher doses from the start, did no better than the placebo group, and carriers in Emerge did slightly *worse* on a critical metric at the higher dose. On scienter, the court concluded that the company's failure to disclose the subgroup data amounted to an "extreme departure from the standards of ordinary care." In the court's view, the company "knew [that it] had subgroup data inconsistent with the 'all data' statement and consciously chose to hold back only the data that was inconsistent with their public claim." (The court did not discuss *Omnicare*'s holding that defendants who make opinion statements—like Biogen's statement "*I think* all our data are consistent with that"—need not disclose all facts cutting the other way.) As to all other challenged statements, however, the court concluded that plaintiffs failed to meet the scienter standard. The company's knowledge of the subgroup data did not equate to a belief that the drug was ineffective. More broadly, plaintiffs' theory of bad-faith data manipulation was inconsistent with the FDA's support of the post hoc analysis. Finally, on loss causation, the court rejected the premise that a stock price decline must follow *immediately* upon the disclosure of bad news. This was inconsistent with case law recognizing that the market may have a delayed reaction to news, and that such a reaction does not foreclose a showing of loss causation.

Golla v. Neovasc, Inc., 2023 WL 2469770 (2d Cir. Mar. 13, 2023), affirming dismissal. **Premarket Approval Application**

Neovasc developed the Reducer, a device for treating refractory angina. The Reducer was approved in the EU. When Neovasc discussed U.S. approval with the FDA, the agency recommended performing an additional blinded study before submitting a Premarket Approval Application. Neovasc disclosed the FDA's comment to investors but submitted its application without conducting additional pre-approval studies; the company instead proposed a post-approval study. The advisory committee reviewing the application voted against approval and the FDA followed the committee's recommendation. The company's stock fell 42%.

Investors sued, claiming that Neovasc misled investors about FDA communications and the strength of its application. The district court granted the company's motion on scienter grounds.

The Second Circuit affirmed in an unpublished decision. Neovasc disclosed the FDA's recommendation that it perform an additional study, and plaintiffs pled no facts suggesting that this recommendation amounted to a requirement. As to scienter, the court rejected plaintiffs' contention that the company knew that the FDA would deny its application. "[T]he more compelling inference is that Neovasc appreciated the FDA's concerns and decided—given its financial instability and the possibility of a study that would cost tens of millions of dollars and [take] years to complete—that submitting a proposal for a post-approval study alongside its application was preferable."

Nandkumar v. AstraZeneca PLC, 2023 WL 3477164 (2d Cir. May 16, 2023), affirming dismissal. **COVID-19 product 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 "remain[ed] on track," using "2-dose studies." 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 trial design did not call for the use of half doses; the company used them only because that was what its contract manufacturer had produced. On November 24, 2020, the head of Operation Warp Speed (the public-private partnership facilitating COVID-19 vaccine development in the U.S.) 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 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%, and fell again after government officials in Europe made unfavorable statements about the vaccine.

Investors sued, claiming that the company failed to timely disclose the use of half doses and the ages of patients in the trial. In a decision we reported in last year's review, the district 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: "[W]ere that the standard, every omission would be actionable." Other statements were non-actionable puffery or were protected by the PSLRA safe harbor for forward-looking statements. Plaintiffs failed to establish scienter for similar reasons.

The Second Circuit affirmed in an unpublished decision. Like the district court, the Second Circuit concluded that plaintiffs had failed to show that the omitted information about half doses and patients' ages rendered the challenged statements misleading. The appellate court also agreed with the district court that plaintiffs failed to establish a strong inference of scienter. The motives they attributed to defendants could be imputed to any company in the market for acquisitions. Plaintiffs also argued that the court could infer that the company had access to information undercutting the challenged statements, but pled no supporting facts. The fact that the company provided more detailed information to the FDA than to the investing public did not create a strong inference of conscious or reckless misdoing either.

DISTRICT COURT DECISIONS—MOTION TO DISMISS GRANTED

Zhou v. NextCure, Inc., 2023 WL 4493541 (S.D.N.Y. July 12, 2023), granting motion to dismiss with prejudice. **Phase 1**

NextCure uses a 3D imaging platform to develop immuno-oncology drugs. In a Phase 1 trial, NextCure tested NC318 as a therapy for a variety of cancers, including non-small cell lung cancer (NSCLC). The company conducted its IPO in May 2019, while the trial was ongoing. In August 2019, the company assessed interim results; at that time, 32 of the 43 patients in the

study were evaluable. On November 5, 2019, the company released an abstract, in advance of a medical conference, reporting the interim results. The abstract showed the results of tumor scans for the seven NSCLC patients who had been evaluable in August. Two of the seven had experienced a complete or partial response; the disease control rate was five out of seven. The company also stated in the abstract that it would present updated results at the medical conference four days later. The stock rose 250%. At the November 9 medical conference, the company presented data on a total of 13 NSCLC patients. The results were less favorable than the results for the seven-patient group reported on in the abstract. Only two of the 13 patients had experienced a complete or partial result, and the disease control rate was six out of 13. The stock fell 53%. During an analyst call and in the registration statement for a subsequent stock offering, the company cautioned investors that the purpose of the Phase 1 trial was to study safety and tolerability and to derive a dose for a Phase 2 trial. The Phase 1 trial showed that the drug had potential to treat a variety of cancer types, but was not designed to, and did not, establish efficacy. In January 2020, Eli Lilly terminated a joint development agreement and NextCure's stock fell 8%. In February 2020, another drug developer sued NextCure's CEO, claiming that he had used its confidential information to develop NextCure's 3D platform. The stock price fell further after the company presented a poster summarizing the Phase 1 results and announced that the NSCLC cohort would not advance to Phase 2.

Investors sued, challenging (1) the company's report of tumor scan data in the November 5 abstract, (2) subsequent statements expressing optimism about NC318, and (3) statements about the 3D platform in the registration statements for the IPO and secondary offering. Plaintiffs attacked the statements in the offering documents under both Section 10(b) and Section 11. The court granted the defendants' motions to dismiss as to all statements and all claims. All claims failed on falsity grounds. With respect to the abstract, plaintiffs' theory was that the company had wrongly withheld results from the larger 13-patient group, instead artificially limiting its report to the subset of seven patients to make the results appear more favorable. The court explained that plaintiffs were less than clear about *when* the company was supposed to have obtained the results for the 13-patient group, but that their theory was deficient regardless of alleged timing. If the theory was that the company already had the results in August 2019, it failed because plaintiffs pled no supporting facts. If the theory was that the company obtained the results between August 2019 and the November 5, 2019 publication of the abstract, it failed because the company told investors on November 5 that the results in the abstract were incomplete and would be updated on November 9, a mere four days later. The court also rejected plaintiffs' attack on optimistic statements made after the November 9 conference. Many were non-actionable puffery; the balance were not misleading in light of the company's thorough cautionary statements about the limitations of Phase 1 trials. As to the allegation that the CEO had improperly used confidential information from another company in developing the 3D platform, this was based on unproven allegations from another complaint. Plaintiffs' Section 10(b) claims failed on scienter as well as falsity grounds, and for similar reasons.

Dresner v. Silverback Therapeutics, Inc., 2023 WL 2913755 (W.D. Wash. Apr. 12, 2023), granting motion to dismiss with prejudice. **Phase 1**

Silverback Therapeutics developed SBT 6050 to treat breast, gastric, and non-small cell lung cancers. The company began a Phase 1 trial in July 2020 and conducted its IPO five months later, in December 2020. 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 from patients given the drug as a monotherapy as well as 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 experienced a partial response, while three others had stable disease. The stock fell 23%. In March 2022, the company announced that recent results showed that SBT 6050 did not have sufficient anti-tumor activity when given as a monotherapy, and that an effective dose in the combination therapy caused adverse events too severe for the treatment to be viable. Silverback was accordingly discontinuing SBT 6050, along with another drug with a similar clinical profile. The stock fell 9%.

Investors sued, claiming that in describing interim results, the company misleadingly failed to disclose that (1) the SBT 6050 trial data demonstrated only limited anti-tumor activity, (2) patients given the drug as a combination therapy suffered adverse events, and (3) if SBT 6050 failed, then another of the company's drugs in development would also be discontinued. Versions of the first and third groups of statements appeared in the company's offering materials, and plaintiffs accordingly challenged them under Section 11 as well as Section 10(b). The court granted the company's motion to dismiss as to all statements and all claims. The court concluded that plaintiffs' overall theory of falsity depended on misunderstanding what an "open label" trial is. "Open label" means that providers and patients are aware of the treatment being given. "Open label" does not mean that trial data are immediately collected and reported to the sponsor, as plaintiffs appeared to believe. Even if plaintiffs had been able to plead that defendants knew results in real time, they would not have shown that the challenged statements were misleading. Silverback said that changes in pharmacodynamic markers were "associated" with tumor regression, not that tumor regression had occurred. Nor did Silverback tell investors that it would develop its second drug regardless of SBT 6050's performance. Plaintiffs' scienter allegations also fell short, as they too hinged on plaintiffs' misunderstanding of "open label"; in addition, plaintiffs' confidential witness allegations lacked necessary detail.

Quinones v. Frequency Therapeutics, 2023 WL 2693901 (D. Mass. Mar. 29, 2023), granting motion to dismiss with prejudice. **Phase 2**

Frequency Therapeutics developed FX-322, an injectable treatment for severe hearing loss. The company conducted a Phase 2a clinical trial in late 2020. In discussing inclusion criteria, Frequency stated that all participants had "meaningful word recognition deficits." The company reported disappointing top-line trial results in March 2021: The treatment group did not perform discernibly better than the placebo group. The stock price fell 78%. In reporting the top-line results, Frequency noted that the placebo group had performed better than expected based on previous trials. The company stated that the results may have been driven by bias in the trial design, and some analysts speculated that patients may have been faking worse hearing than they actually had in order to enroll in the trial. When the company reported complete trial results at an investor conference in June 2021, the data suggested that at least one patient may have done just that. A patient on the placebo arm recognized many more words after treatment than at baseline, suggesting that the patient could actually hear better than she reported at baseline.

Investors sued, challenging the company's statements about enrollment criteria and trial design. The court granted the company's motion to dismiss. Plaintiff failed to allege scienter as to any challenged statement, and failed to allege falsity as to all but one statement, repeated on two dates. That statement—which the court held only *may* have been false— was "all subjects have meaningful word recognition deficits." The company's June 2021 report suggested that at least one patient may not have had the required word recognition deficit, which would have made the statement false. Plaintiff failed to allege falsity as to the balance of the statements, in which the company discussed enrollment criteria but did not state that all participants met those criteria. Some of the challenged statements were also protected by the PSLRA safe harbors, or were opinions as to which plaintiff failed to meet *Omnicare*'s requirements. Plaintiff fell short of the scienter standard as to all statements. Plaintiff did not allege that defendants knew (or recklessly disregarded) that patients who failed to meet the enrollment criteria were included in the trial. Executive stock sales were not suspicious in timing or amount, and confidential witness allegations were insufficiently particularized. The court did not discuss whether plaintiff's theory made sense. It is not apparent from the decision why defendants would have believed that allowing a non-qualifying patient to participate in the trial would have helped the company or biased results in its favor. The patient could as easily have been assigned to the control as to the treatment arm—which is indeed what appears to have happened.

Spar v. Celsion Corp., 2023 WL 2069725 (D.N.J. Feb. 6, 2023), granting motion to dismiss without prejudice. **Phase 3**

Celsion developed ThermoDox, a chemotherapy treatment for liver cancer. A 2013 Phase 3 trial called Heat failed to meet its primary endpoint, but a post hoc analysis suggested more

promising overall survival results for patients who received the drug in conjunction with at least 45 minutes of radiofrequency ablation, in which an electrical current heats up a small portion of tissue to destroy cancer cells. In 2014, Celsion began conducting a new Phase 3 trial, Optima, to test that hypothesis. The company made optimistic statements about the promise of Optima as the trial took place over the next five years. In November 2019, the study's Data Monitoring Committee (DMC) performed its first scheduled interim review and determined that the trial should continue. On May 15, 2020, the company announced that the DMC would conduct a second scheduled interim review and expressed optimism about the outcome. Between May 15 and June 9, the stock price ran up from $1.48 to $5.26, after which the company conducted a secondary public offering. On July 13, the company announced the result of the second interim review: The DMC recommended stopping. The stock fell 64%. Two days later, the data were unblinded, and the company stated that there was "but a very slim chance" that the trial would "meet its prespecified target for success." In February 2021, the company announced that it would discontinue the trial.

Investors sued, challenging the company's optimistic statements about the drug's promise and prospects for approval. The court granted the company's motion to dismiss on both falsity and scienter grounds. Critically, the court held, plaintiffs conceded that the trial was blinded at the time of the challenged statements, which wholly undermined plaintiffs' theory of fraud. Many of the challenged statements were also non-actionable puffery or were opinion statements as to which plaintiffs failed to meet the requirements of *Omnicare*. Plaintiffs argued that *Omnicare* dictated that the company should have refrained from expressing positive opinions because the data to support those opinions—unblinded results—were not yet available. The court rejected that reading of *Omnicare*, and further rejected plaintiffs' contention that the company acted recklessly in expressing an opinion in the absence of proven facts. The secondary offering did not enable plaintiffs to clear the scienter hurdle: The desire to raise capital is insufficient to establish a motive to defraud.

Abady v. Lipocine Inc., 2023 WL 2938210 (D. Utah Apr. 13, 2023), granting motion to dismiss with prejudice. NDA

Lipocine developed Tlando, an oral testosterone replacement therapy. The company submitted NDAs in 2016 and 2017, both followed by CRLs. In the second CRL, the FDA identified four deficiencies, one of which was the failure to meet secondary endpoints setting maximum testosterone concentration limits (Cmax). Lipocine submitted a third NDA in May 2019. Between February and November 2019, the company publicly discussed the ways in which it was addressing the deficiencies identified in the second CRL. In November 2019, Lipocine announced its receipt of a third CRL, which cited as a deficiency the failure to meet three secondary Cmax endpoints. The company's stock price fell 71%.

Investors sued, challenging the company's statements about the ways in which it was addressing the deficiencies identified in the second CRL, as well as other statements about the prospects for approval. The court granted the company's motion to dismiss, ruling in its favor on falsity, scienter, and loss causation. With respect to falsity, most of plaintiffs' challenges were defeated by context. Lipocine did not tell investors that it had satisfied the secondary endpoints; rather, the company described its efforts to persuade the FDA that the criteria it had used in reviewing the prior NDA were inapplicable. Other statements were puffery, including the statement that Tlando's performance on the secondary endpoints was generally consistent with that of approved products: Plaintiffs offered no objective criteria with which to assess the alleged falsity of the challenged statement. Still other statements were opinions as to which plaintiffs did not satisfy *Omnicare*'s requirements. This included a statement that a particular subject who exceeded Cmax limitations was ineligible as a protocol violator. Plaintiffs relied heavily on an omission theory but failed to connect the allegedly omitted information with particular challenged statements. On scienter, the court held that a plaintiff does not create the required strong inference by alleging that defendants knew particular material facts: A plaintiff must go further and show that defendants knew that the failure to reveal such facts would mislead investors. Meanwhile, plaintiffs' motive allegations were inadequate because the motive they identified—the need to raise capital—was ubiquitous. When it came to balancing competing inferences, the court found the company's benign inference more compelling than an inference of fraud. The company

persuasively argued that it made the challenged statements to explain to investors how it intended to address the deficiencies noted in the second CRL, and specifically to show the FDA that the secondary endpoint standards it had used were inapplicable. The court finally held that plaintiffs failed to adequately allege loss causation. Plaintiffs' only potentially workable theory was that the third and final CRL showed that the company had overestimated the likelihood of approval. The court suggested that such a theory might suffice if, for example, a company with a 30% likelihood of approval told investors that the likelihood was 70%. Plaintiffs did not, however, plead any facts supporting such a theory. The third CRL revealed only that the drug was not approved—not that the company misrepresented the likelihood of approval.

Gru v. Axsome Therapeutics, Inc., 2023 WL 6214581 (S.D.N.Y. Sept. 25, 2023), granting motion to dismiss without prejudice. **NDA; manufacturing issues**

Axsome Therapeutics developed AXS-07 to treat migraines. In December 2019, the company announced that a Phase 3 trial had established efficacy, and that it intended to file an NDA in the second half of 2020. In November 2020, Axsome announced that it would delay filing until the next quarter, so that it could provide supplemental manufacturing information to ensure a robust submission. The stock price fell 7%. Axsome submitted the NDA in June 2021. In April 2022, Axsome reported that the FDA had told the company that the agency would issue a CRL in light of unresolved manufacturing issues. The stock fell 22%.

Investors sued, claiming that the company's statements about the timeline for submitting an NDA and prospects for approval were misleading in light of undisclosed manufacturing issues. Plaintiff included allegations from a confidential witness who purportedly claimed that in 2021, manufacturing problems led to a supply shortage and hence caused the company to delay a new study planned for April 2021. The court granted the company's motion to dismiss. The lead plaintiff had divested all of his Axsome stock by August 2021. That plaintiff accordingly could not have suffered any loss in connection with the company's April 2022 disclosure that the FDA would not approve the NDA. The court rejected plaintiff's claim that the company's November 2020 announcement, which triggered a 7% decline, constituted a partial corrective disclosure. Plaintiff did not allege facts showing that the company was experiencing manufacturing problems at that time. The company stated publicly only that it wanted to obtain additional manufacturing data to buttress its NDA. As for what was known internally in November 2020, the confidential witness allegations disproved plaintiff's theory of fraud. The allegations showed that even in early 2021, Axsome expected to have sufficient quantities of the drug to support a new study. Manufacturing issues surfaced only thereafter. "Whether the Complaint's deficiency is characterized as no loss causation, no misstatement or omission, or no scienter, the Complaint does not allege facts to suggest that a serious manufacturing problem had emerged and was known to Defendants in November 2020 when the Company announced that it would briefly delay the submission of the NDA into the next quarter."

Chapman v. Fennec Pharm., Inc., 2023 WL 2241992 (M.D.N.C. Feb. 15, 2023), recommending denial of motion for post-judgment relief, 2023 WL 3073652 (M.D.N.C. Mar. 2, 2023), adopting report and recommendation. **NDA; manufacturing issues**

Fennec developed Pedmark to treat hearing loss in children undergoing chemotherapy. Fennec used a third party, Avista, to manufacture the drug substance and another third party, PII, to manufacture the drug product. In July 2020, while Fennec's NDA was pending, the FDA issued a Form 483 identifying multiple serious manufacturing deficiencies, including product contamination. In August 2020, the FDA issued a CRL denying approval based solely on the manufacturing issues. In March 2021, the company told investors that it was making "meaningful progress" in addressing the issues identified in the August 2020 CRL. In May 2021, the company resubmitted its NDA. In September 2021, the FDA issued another Form 483 identifying numerous violations of good manufacturing practices. Fennec did not disclose this. In November 2021, the company reported a second CRL, again based solely on manufacturing deficiencies. The stock fell 8%.

Investors sued, challenging statements about manufacturing and the anticipated timing of approval. Plaintiffs filed their original complaint in early 2021 and challenged only statements

predating the first, August 2020 CRL. The court dismissed the complaint with prejudice. Plaintiffs thereafter moved to vacate the dismissal so they could file an amended complaint challenging statements between the August 2020 CRL and the November 2021 CRL. Plaintiffs also sought to buttress the allegations of falsity in their earlier complaint. The court denied the motion to vacate, concluding that amendment would be futile. Plaintiffs alleged no facts showing that statements the company made between the first and the second CRL were false or misleading. The company stated that it was making meaningful progress and working closely with its manufacturer to address the issues in the August 2020 CRL; plaintiffs alleged nothing to the contrary.[9] Plaintiffs also added allegations from PII employees identifying deficiencies and recalls of drugs made at PII's plant, but were unable to tie any of this to Fennec or its executives. Plaintiffs' newly added allegations about executive compensation did not move the needle either, as they did not distinguish Fennec from any other company with an incentive compensation plan.

Lewakowski v. Aquestive Therapeutics, Inc., 2023 WL 2496504 (D.N.J. Mar. 14, 2023), granting motion to dismiss without prejudice. **NDA/505(b)(2) pathway**

Aquestive developed Libervant, a diazepam-based drug for treating epileptic seizures. Using the 505(b)(2) regulatory pathway, Aquestive sought to show that Libervant was equivalent to an approved diazepam-based treatment, Diastat. At the FDA's direction, Aquestive performed a crossover study comparing 28 patients' responses to the two drugs. In August 2019, Aquestive reported favorable results from the study. Among other findings, five of the 28 patients were non-responders or low responders to Diastat, but no patients were non-responders or low responders to Libervant. Aquestive spoke favorably about the prospects of FDA approval. In September 2020, however, the company announced that the FDA had rejected its NDA because, for 18% of the patients in the crossover study, peak bloodstream diazepam concentration of Libervant was only half as high as peak bloodstream diazepam concentration of Diastat. The company's stock fell 34%.

Investors sued, challenging the company's statements about the crossover trial and the prospects of approval. Plaintiffs' theory was that because a substantial fraction of patients achieved much lower diazepam concentrations with Libervant than with Diastat, those patients were necessarily low responders—which made the company's statements about the trial results false. The court granted the company's motion to dismiss. Most significantly, the term "low responders" had a precise numerical meaning in the context of the crossover trial. It meant that a patient had a blood concentration of diazepam below the threshold of 70 nanograms per mL, which the company had established was a therapeutic dose in previous trials. Plaintiffs did not allege that any patients fell below this numerical threshold. To the extent plaintiffs challenged the determination that 70 ng/mL was in fact a therapeutic dose, this was an opinion as to which plaintiffs failed to meet *Omnicare*'s requirements. The challenged statements about FDA approval were non-actionable puffery, came within the PSLRA's safe harbors for forward-looking statements, and were again opinions as to which plaintiffs failed to satisfy *Omnicare*. Plaintiffs' claims also failed on scienter grounds. Plaintiffs' contention that the company submitted an NDA it knew would fail was counterintuitive, and the fact that the company made a secondary offering during the purported class period was too generic to support a motive for fraud. Notably, plaintiffs cited no company documents or confidential witnesses, relying instead on inadequate conclusions about what defendants "must have known."

Shapiro v. TG Therapeutics, Inc., 652 F. Supp. 3d 416 (S.D.N.Y. 2023), granting motion to dismiss with prejudice. **sNDA and BLA; adverse event reporting**

TG Therapeutics made UKONIQ, which had been approved for the treatment of specific kinds of lymphoma. The company conducted trials of the approved drug in combination with a second drug, Ublituximab, for the treatment of a wider variety of cancers. The company also studied Ublituximab as a standalone treatment for multiple sclerosis. Throughout the trials, TG Therapeutics reported adverse events and serious adverse events through the FDA's Adverse Event Reporting System. The company submitted an sNDA for the combination treatment (called

9 The statements postdating the first CRL were also challenged in a separate Section 10(b) class action in the same district, *Fisher v. Fennec Pharmaceuticals, Inc.*, on which we reported in our 2022 review. The *Fisher* court dismissed that complaint. The *Chapman* court noted this but nevertheless analyzed the newly challenged statements afresh (rather than applying claim or issue preclusion), explaining that it had to assess the amended complaint as a whole, accounting for the challenges to both the pre-August 2020 and post-August 2020 statements.

U2) and a BLA for standalone Ublituximab. In November 2021, the company announced that the FDA was convening an advisory committee to review the sNDA and the BLA; the stock fell 35%. In April 2022, the company announced that it had withdrawn its application for approval of U2 and was shuttering its oncology division. The stock fell 22%. In May 2022, the company reported delays in the approval process for standalone Ublituximab; the stock fell 15%. Finally, in June 2022, the FDA withdrew its prior approval of standalone UKONIQ; the stock fell 12%.

Investors sued, challenging TG Therapeutics' statements about the drugs' safety and prospects for approval. The court granted the company's motion to dismiss. The court rejected as an initial matter the plaintiffs' contention that the company had omitted adverse event information. Although that information did not appear in TG Therapeutics' press releases, the company reported it through the FDA adverse event database, and that was sufficient. Meanwhile, the challenged statements about prospects for approval were forward looking and came within both the cautionary language and the actual knowledge safe harbors of the PSLRA. The statements about safety were opinions governed by *Omnicare*'s framework. Plaintiffs argued that they had satisfied *Omnicare*'s requirements by challenging factual statements embedded in the opinions. Without resolving the issue of falsity, the court rejected plaintiffs' attack on those statements on scienter grounds. Plaintiffs failed to establish a strong inference of scienter by way of motive and opportunity allegations (which may be sufficient in the Second Circuit). Plaintiffs argued that the executives had a motive to secure FDA approval because this would trigger incentive compensation. But this provided no incentive to conceal adverse events from *the market* (as opposed to the FDA). Plaintiffs similarly failed to establish a strong inference of scienter by means of circumstantial evidence. Plaintiffs alleged that defendants knew about adverse events, but that does not equate to knowledge that the drugs were unsafe.

In re Bristol-Myers Squibb Co. CVR Sec. Litig., 2023 WL 2308151 (S.D.N.Y. Mar. 1, 2023) granting motion to dismiss without prejudice. **BLA; contingent value rights**

In connection with its 2019 merger with Celgene, Bristol-Myers issued $6.4 billion in contingent value rights (CVRs). The CVRs would pay out if the FDA approved three legacy Celgene products by specified deadlines. Two were approved on time, but the third, Liso-cel, missed the December 31, 2020 approval deadline by five weeks—which rendered the CVRs worthless. Initially, Liso-cel appeared to be on track for a timely approval. Celgene submitted portions of the Liso-cel BLA before the merger, and BMS submitted the final Chemistry, Manufacturing and Controls (CMC) portion in December 2019, less than a month after the merger. In March 2020, however, the FDA directed BMS to supplement the CMC, and then deemed BMS's responsive submission a major amendment. That pushed the target approval date to November 2020. The FDA's inspection was then delayed, possibly as a result of the pandemic. After an inspection revealed regulatory deficiencies, BMS submitted a remediation plan on December 23, 2020. Approval followed in February 2021, too late for the CVRs to vest.

Investors sued, accusing BMS of slow-rolling approval and challenging BMS's statements about the likelihood of approval in its offering documents and merger proxy filings under Sections 11 and 14(a). Plaintiffs also challenged statements post-dating the merger under Section 10(b). The court dismissed the Section 10(b) claim on scienter grounds. Plaintiffs failed to establish the required strong inference of scienter through motive and opportunity allegations. Neither the size nor the structure of the CVR payment supported motive; nor did plaintiffs explain how executive compensation terms established motive. As to circumstantial evidence, plaintiffs failed to show that the individual defendants knew that BMS was purportedly delaying the BLA process. Plaintiffs' confidential witness allegations failed because the witnesses did not interact with the individual defendants. Plaintiffs' "FDA Biologics Expert," meanwhile, could not opine on defendants' states of mind. Ultimately, "the more compelling inference to be drawn from the pleaded facts is that both BMS and the FDA experienced embarrassing, but not 'extreme' setbacks during an unprecedented pandemic."

The court also dismissed the Section 11 and Section 14(a) claims, which had no scienter requirement. The statements in the offering and merger proxy filings were forward looking and came within the meaningful cautionary language safe harbor. The court rejected plaintiffs' contention that the risk disclosures were inadequate because defendants did not tell investors

that they intended to delay approval. This argument went to intent—which is the subject of the actual knowledge safe harbor, not the disjunctive meaningful cautionary language safe harbor. Because plaintiffs could not amend their way around the safe harbor, the court dismissed the Section 11 and Section 14(a) claims with prejudice. By contrast, the court granted plaintiffs leave to amend the Section 10(b) claim.

Richfield v. PolarityTE, Inc , 2023 WL 3010208 (D. Utah Apr. 19, 2023), granting motion to dismiss with prejudice. **Section 361/BLA; Forms 483**

PolarityTE created SkinTE, a regenerative skin tissue product for treating wounds, burns, and scars. The company registered SkinTE as an HCT/P—that is, a human cell or tissue-based product. Under Section 361 of the Public Health Service Act, such products need not be FDA-approved if they meet various requirements, including only minimal manipulation of the cells or tissue. Developers self-register products under Section 361. In 2020, PolarityTE announced a change in regulatory strategy. Although the company continued to believe that its product qualified for treatment under Section 361, it recognized that the FDA could disagree. PolarityTE told investors that it would file an IND application and eventually a BLA. The FDA had earlier announced that, as an exercise in enforcement discretion, it would allow manufacturers to market HCT/Ps under Section 361 until November 2020 even if not in strict compliance with its requirements; it later extended the deadline to May 2021 in light of the pandemic. PolarityTE told investors that it would continue to market SkinTE on a limited basis even after the expiration of the deadline, but noted that this was subject to FDA approval, which could be difficult to obtain. PolarityTE ultimately stopped marketing SkinTE in May 2021 and submitted an IND application in July 2021. The FDA placed a clinical hold on the application in August 2021, and the stock fell 10%. In November 2021, the company reported that it expected to be able to address the issues that had triggered the hold by year-end. The stock again fell 10%. The FDA lifted the hold in January 2022. Separate from registration and approval issues, the company received and disclosed a Form 483 following an inspection in July 2018.

Investors sued, challenging PolarityTE's statements about SkinTE's eligibility for treatment under Section 361 and the company's manufacturing advantages. The court granted the company's motion to dismiss. All but one of the statements about Section 361 eligibility were opinions, and plaintiffs failed to plead facts showing, under *Omnicare*, that the company did not hold the opinions it articulated or that it omitted material facts about the bases for those opinions. Plaintiffs claimed the company knew that the tissue used in SkinTE was more than minimally manipulated, but pled no supporting facts. The single factual statement the company made about Section 361 was that SkinTE was registered under that provision—and this was accurate, given the self-registration mechanism. PolarityTE's statement about marketing SkinTE after the end of the discretionary non-enforcement period was not misleading in light of the company's disclosure that the FDA might not approve its request to do so. As to manufacturing, plaintiffs challenged the company's statements in 2020 and 2021 that a relatively small sample of tissue could generate sufficient volume of product to treat a large open wound. According to plaintiffs, that statement was false in light of the observation in a 2018 Form 483 that the company lacked a "potency assay." But the 2018 Form 483 did not reflect the state of the potency assay at the time of the challenged statements in 2020 and 2021. Meanwhile, the company told investors that it needed to do additional work on the potency assay. More generally, the court found plaintiffs' claims inconsistent with the company's risk disclosures, including disclosures related to clinical holds, the Form 483, and the sunsetting of the enforcement discretion period. "The Court concludes that PolarityTE's extensive disclosures are an independent reason to dismiss all the statements challenged in the complaint."

In re Ocugen, Inc. Sec. Litig., 2023 WL 2351695 (E.D. Pa. Mar. 3, 2023) granting motion to dismiss with prejudice. **COVID-19 vaccine development; EUA**

Ocugen, which developed treatments for blindness, reported a going concern qualification in November 2020. The next month the company switched course dramatically, announcing that it was partnering with Bharat, an Indian biotech company developing an inactivated whole-virion COVID-19 vaccine called Covaxin. While Bharat conducted clinical trials in India, Ocugen took steps to prepare for an EUA application with the FDA based on the Indian trial data. Between

February and May 2021, Ocugen spoke optimistically about submitting the EUA in the first half of the year, distributing 100 million doses, and earning significant revenue in 2021. Ocugen told investors that it had discussed the upcoming EUA with the FDA, which was "fine with the way the interim analysis [was] being done." Ocugen's stock price rose from $1.81 to $15.81 during this period. In June 2021, Ocugen reported that the FDA had recommended that it pursue a BLA rather than an EUA, and its stock fell 28%.

Investors sued, claiming that Ocugen never had a chance of obtaining an EUA for Covaxin and that the company concealed that fact. According to plaintiffs, various guidance documents the FDA issued about EUAs for COVID-19 vaccines foreclosed success. The clinical trial population for Covaxin was not racially diverse, the mechanism was an inactivated vaccine, and the company had not engaged in discussions with the FDA before the late-2020 approval of the Pfizer and Moderna vaccines—all of which the guidance documents identified as issues. The court granted the company's motion to dismiss. The FDA guidance was just that—non-binding guidance—and nothing suggested that a vaccine could not succeed on the EUA pathway unless every factor in the guidance was satisfied. The company's projections about EUA approval, vaccine submission, and revenue were puffery, and plaintiffs' attack on the statements depended on hindsight, in any event. In a few statements, the company suggested that it had received positive feedback from the FDA, but plaintiffs failed to allege contrary facts. On the issue of racial diversity, both the FDA's guidance and the fact that the Covaxin trials were conducted in India were matters of public record. Plaintiffs also alleged a "scheme" under Rule 10b-5(a) and (c), but identified no deceptive acts beyond the challenged statements (which they failed to show were false or misleading). Plaintiffs' insider trading claim against the company's CEO failed for lack of an underlying violation.

DISTRICT COURT DECISIONS—MOTION TO DISMISS DENIED

In re Cassava Scis. Inc. Sec. Litig., 2023 WL 3442087 (W.D. Tex. May 11, 2023), denying in part motion to dismiss. **Phase 2**

Cassava developed simufilam, a drug designed to treat Alzheimer's disease. In May 2020, the company announced that a Phase 2b study of the drug did not meet its primary endpoint. But in reporting final results in September 2020, the company announced a different conclusion: Reanalysis by an "outside lab" showed that simufilam "significantly improved an entire panel of validated biomarkers" for Alzheimer's disease. In February 2021, the company reported results from another trial showing that simufilam may renew cognitive function in Alzheimer's patients; the company also reported that it had reached agreement with the FDA on key elements of a Phase 3 program. In July 2021, the company presented Phase 2b trial data at the Alzheimer's Association International Conference. In August 2021, two scientists who held short positions in Cassava stock filed a Citizen Petition with the FDA raising concerns about the "quality and integrity" of the simufilam studies and identifying anomalies in presentations and journal articles that in their view suggested data manipulation and misrepresentation. Cassava's stock price fell. In November 2021, Cassava stated in a press release that the publisher of one of its journal articles had found no evidence of data manipulation. The stock price rose. Subsequently, an expert on data manipulation posted online that she had reviewed the images at issue and did not believe they were originals. Cassava's stock fell again, and continued to fall after a news report revealed that the SEC and NIH were investigating the data manipulation claims; after the two scientists supplemented their Citizen Petition; after the *New York Times* published an article in which experts stated that they did not trust Cassava's methods or results; and after *Reuters* reported that DOJ had opened a criminal investigation into the matter.

Investors sued, challenging the company's statements about the Phase 2b trial. According to plaintiffs, Cassava misleadingly failed to disclose that (1) the trial suffered from anomalous baseline measurements, (2) the company intentionally removed unfavorable data when presenting results, and (3) the reanalysis was conducted by a Cassava-affiliated scientist and not, as the company had stated, by an "outside lab." The court denied the company's motion to dismiss. Plaintiffs sufficiently pled that the challenged statements were false and misleading

in light of alleged data manipulation, which plaintiffs illustrated with photographic evidence. Plaintiffs also adequately pled scienter, having identified alleged selective reporting, the response of the scientific community, and the company's near-immediate denial of the claims in the Citizen Petition. The structure and timing of an executive cash bonus plan further supported an inference of scienter: Bonuses were triggered by short-term increases in stock price.

Homyk v. ChemoCentryx, Inc , 2023 WL 3579440 (N.D. Cal. Feb. 23, 2023), denying in part motion to dismiss. NDA

ChemoCentryx developed avacopan for the treatment of vasculitis, a rare autoimmune disease. Following a Phase 3 trial, the company announced that study results showed that avacopan was safer than the standard-of-care steroid therapy. As to efficacy, avacopan demonstrated non-inferiority versus prednisone at 26 weeks and superiority at 52 weeks; from this, ChemoCentryx concluded that avacopan could replace steroids. The company stated that its communications with the FDA about its NDA had been straightforward. On May 4, 2021, two days before a scheduled advisory committee meeting, the FDA released its briefing book, which included a history of earlier communications with ChemoCentryx. According to that history, the FDA had told the company that its proposed trial design was inadequate to support a safety comparison. On efficacy, the FDA had told the company that superiority rather than non-inferiority would be needed to show that avacopan could replace steroid treatment. The company's stock fell 45% on publication of the briefing book. The advisory committee vote on May 6, 2021 was evenly split, with those who favored approval recommending a limited label. The total stock drop between May 4 and May 7 was 79%. The FDA ultimately approved avacopan, but only for use in conjunction with steroids, only for patients with severe and active disease, and only with warnings for liver toxicity.

Investors sued, challenging statements about safety, efficacy, trial design, and the company's communications with the FDA. The court largely denied the company's motion to dismiss. Plaintiffs adequately pled that statements about safety were misleading in light of the FDA's undisclosed comments about safety comparisons. The court rejected the company's argument that the safety statements were immaterial in that the FDA did not signal that safety issues would preclude approval. The court's view was that the company had concealed a relevant risk. The same analysis applied to the challenged efficacy statements: Plaintiffs adequately pled that these statements were misleading in light of undisclosed FDA communications, and the fact that the FDA's concerns increased the risk of non-approval established materiality for pleading purposes. Plaintiffs' challenge to the company's statement that avacopan could replace steroids was also adequately pled, given the undisclosed fact that the majority of patients in the trial had steroid prescriptions. Plaintiffs also adequately alleged that the company's characterization of FDA communications was misleading: ChemoCentryx had stated that the FDA did not "highlight[] any particular issues that would have to be discussed." On the other hand, plaintiffs' attack on factual statements about the status of the NDA failed on falsity grounds. The court also dismissed a few challenged opinion statements but held that most were mixed fact/opinion statements as to which plaintiffs had satisfied *Omnicare*'s omission prong. The court reached a similar result on forward-looking and "puffery" statements: A few were non-actionable, but plaintiffs had adequately alleged that concrete factual statements were misleading. The court rejected ChemoCentryx's argument that it had no obligation to disclose interim FDA communications, holding that the company had put the issue in play by favorably characterizing trial results. As to scienter, plaintiffs adequately alleged that the company's CEO both knew the omitted facts and knew that omitting those facts would mislead investors, as the facts undermined the reported safety and efficacy results. "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. This motive is plausible."

In re Emergent BioSolutions Inc. Sec. Litig., 2023 WL 5671608 (D. Md. Sept. 1, 2023), denying in part motion to dismiss. COVID-19 vaccine development; manufacturing issues

Between April and June 2020, Emergent entered into private and government contracts to manufacture COVID-19 vaccines once they had been developed and approved. The private parties were Johnson & Johnson and AstraZeneca; collectively, the contracts were worth over

$1.5 billion. The government and the two private firms conducted a series of inspection audits early in the pandemic. In April 2020, the FDA issued a Form 483; in June, it told Emergent that it did not consider its Bayview facility ready to support commercial operations. Meanwhile, the private firms flagged problems with contamination, mold, and inadequate training and quality review systems. On July 6, 2020 Emergent announced that it was scaling up to produce hundreds of millions of vaccine doses. Subsequent audits in the second half of 2020 identified ongoing problems, including the risk of contamination. In March 2021, the *New York Times* reported that Emergent had voluntarily destroyed batches of the vaccine and that 15 million doses had been contaminated when ingredients for the J&J and AstraZeneca products were mixed up. Emergent's stock fell 13%. The government thereafter placed the Bayview facility in the control of J&J and temporarily halted manufacturing. The stock fell 11%. A congressional investigation followed. The *NYT* published two more articles in June 2021, stating that hundreds of millions of additional doses had been quarantined. In November 2021, Emergent reported that the government had terminated a major contract and canceled the company's participation in a public health emergency program; the company also reversed previously recorded revenue. The stock fell 37%. In 2022, the congressional committee investigating Emergent reported that nearly 400 million doses were ultimately destroyed. The committee also concluded that Emergent had hidden evidence of contamination from government investigators and failed to remediate multiple deficiencies J&J and AstraZeneca had brought to its attention.

Investors sued, challenging statements about Emergent's manufacturing performance and abilities as well as financial statements and Sarbanes-Oxley certifications of internal controls. The court granted the company's motion to dismiss as to the latter two categories but largely denied the motion as to the first. Plaintiffs adequately alleged that Emergent's positive statements about manufacturing were misleading, beginning with the July 6, 2020 statement about scaling up production. Most of the challenged statements were factually accurate but were rendered misleading by virtue of omitted facts—that the FDA in June 2020 stated that Emergent was not ready to support commercial operations, and that, starting in early 2021, the company was destroying doses. The court rejected Emergent's argument that it sufficiently alerted investors to these issues by means of its risk disclosures. In those disclosures, Emergent "neglected to mention events that negatively impacted its core mission and business operations—the FDA stating that it did not consider the Bayview facility ready to support commercial operations and the ongoing batch destruction." Plaintiffs also adequately pled that Emergent's statements about dose destruction following the March 2021 *NYT* article were misleading: The company understated the scope of the problem. Plaintiffs created the required strong inference of scienter through confidential witness allegations, references to communications with the FDA about commercial readiness, and the facts about dose destruction reported by the *NYT* and congressional committee. The court rejected Emergent's argument that a holistic review of scienter allegations showed that the company "worked in good faith to manufacture vaccine drug substance in response to a pandemic, disclosed the risks, suffered an unfortunate contamination incident, and worked to address it." The court did not question Emergent's good faith in *manufacturing* vaccines, but concluded that plaintiffs had adequately alleged that "while doing so, [the company] omitted the myriad known deficiencies at Bayview that undercut the success of that endeavor and did so with reckless disregard for how those omissions could mislead investors." The court dismissed the claim against the CFO on scienter grounds, dismissed some statements as non-actionable puffery, and dismissed statements made *before* the critical FDA communications.

DECISIONS RELATED TO POST-APPROVAL DRUGS OR DEVICES

In this section (pages 31-40), we provide detailed summaries of decisions in cases arising from developments at the post-approval stage. As discussed in the "Trends and Analysis" section above, the district court decisions broke evenly. Both plaintiffs and defendants won in five cases.

Defendants also prevailed in the two appellate decisions—*MiMedx*, which may be an important precedent on loss causation, and *iRhythm*, in which the appeal was dismissed on technical grounds.

APPELLATE DECISIONS

MacPhee v. MiMedx Grp., Inc., 73 F. 4th 1220 (11th Cir. 2023), affirming dismissal.
Sales practices; accounting

MiMedx uses human placental tissue to make products for wound care and other medical functions. Distributors sell the company's products to both government customers (the VA and DOD) and private healthcare customers. After MiMedx acquired a proprietary sterilization process in 2012, it enjoyed significant revenue growth over the next four years, meeting or exceeding guidance for 17 straight quarters. In April 2016, the company reported its first revenue miss, and its stock price fell. In December 2016, two former employees filed a lawsuit accusing the company of firing them in retaliation for raising concerns about channel stuffing. The stock price fell again. A series of short seller reports, beginning in September 2017 and alleging improper sales practices, was followed by additional stock declines. In February 2018, the company reported that its Form 10-K would be delayed pending an internal investigation into sales, distribution, and accounting issues. In May 2018, the DOJ announced that a grand jury had returned an indictment of VA employees for conspiracy to commit health care fraud involving benefits they received from MiMedx employees. In June 2018, the company announced that it needed to restate more than five years of financial statements. The CEO, CFO, and COO resigned shortly thereafter. Each of these announcements was followed by a stock decline.

Investors sued, challenging the company's financial reporting as well as statements it made refuting the allegations in the former employees' complaints and short seller reports. The district court dismissed on loss causation grounds and the Eleventh Circuit affirmed. The lead plaintiff sold its stock in February 2018, before the company announced in June 2018 that it would restate its financial statements. Plaintiff argued that numerous statements—by the company itself, by the former employees who sued the company, by short sellers, and by media sources—constituted partial corrective disclosures sufficient to establish loss causation. The court disagreed, analyzing three categories of purported partial corrective disclosures. The first included the company's own statements, which plaintiffs alleged were both corrective and misleading in themselves. The court held that plaintiff could not "have it both ways"—a challenged statement cannot also be a corrective disclosure. The second category consisted of short seller and media pieces; the court held that these could not serve as corrective disclosures because they did not provide new information to the market. The third category included the announcement of government and internal investigations; these were not corrective disclosures because they revealed only a risk that improprieties could later be revealed. The court acknowledged that such announcements may conceivably serve as corrective disclosures if paired with later announcements that disclose actual wrongdoing. Plaintiff sought to pair the February 2018 announcement of the internal investigation with the June 2018 announcement of the restatement. But that pairing, the court held, could not establish loss causation because plaintiff had sold out of the stock before the June disclosure. The court affirmed dismissal on loss causation grounds for all of these reasons, but disagreed with the district court that the loss causation shortfall meant that plaintiff lacked Article III standing. The appellate court explained that loss causation and standing are distinct, and vacated the district court's standing analysis. The appellate court agreed with the district court that plaintiff was not entitled to post-judgment relief under Rules 59(e) and 60, and that the rules governing such relief, rather than the liberal amendment policy of Rule 15, apply after dismissal.

Habelt v. iRhythm Techs., Inc., 83 F.4th 1162 (9th Cir. 2023), dismissing appeal. **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 per patch using Category III Current Procedural Technology (CPT) codes for the Zio XT patch. 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. But after a healthcare policy firm filed a comment urging a lower rate, CMS declined to set a national rate for 2021, leaving rates to be determined regionally. The stock fell 24%. A regional administrator then reduced the average rate to $74-$89, a decrease of roughly 75%. The stock fell 33%. The administrator subsequently revised the rate to $115, but the stock again fell, this time by 40%. When CMS released a proposed rule for 2022, it noted concerns with supply costs and ECG monitoring. The stock fell 9%.

Investors sued, alleging that iRhythm made false or misleading statements about the regulatory price-setting process and the risks it faced. In a 2022 ruling (discussed in last year's review), the district court granted the company's motion to dismiss. Drawing on case law from the public utilities context, the court emphasized that rate-making proceedings are inherently unpredictable, and that investors cannot reasonably rely on predictive statements on this subject.

The lead plaintiff did not appeal the district court's decision, but the putative class member who filed the original complaint did. The Ninth Circuit dismissed the appeal for lack of jurisdiction, concluding that the original plaintiff, Habelt, lacked standing. Habelt did not move to be appointed lead plaintiff and did not participate in the litigation after the lead plaintiff was appointed. As a result, Habelt's claims were extinguished. Habelt's name continued to appear in the caption, but this did not make him a party; the caption was merely the label for the case. Habelt's status as an unnamed member of a not-yet-certified class (as distinguished from a member of a certified class) likewise did not give him standing to appeal.

DISTRICT COURT DECISIONS—MOTION TO DISMISS OR FOR SUMMARY JUDGMENT GRANTED

Oklahoma Firefighters Pension & Ret. Sys. v. Biogen, Inc., 665 F. Supp. 3d 125 (D. Mass. 2023), granting motion to dismiss with prejudice. **Product launch**

The FDA approved Biogen's Alzheimer's disease drug aducanumab (or Aduhelm) in June 2021, after an unusual review process that included post hoc analyses after Phase 3 trials had been discontinued on futility grounds, as well as an advisory committee recommendation against approval. (An earlier lawsuit challenging Biogen's pre-approval statements is discussed on page 18, above.) On the day approval was announced, Biogen reported that 900 sites were ready to begin treatment, that Medicare coverage was "automatically presumed" following approval, and that the company was working to finalize a multi-year contract with the VA. The launch was not a success. Six weeks after approval, only 325 of the 900 sites had completed pharmacy and therapeutics committee (P&T) reviews. Medicare instituted a National Coverage Determination and decided to cover Aduhelm only in the clinical trial setting. Private insurers also denied coverage. The VA contract fell through, and the VA decided not to add Aduhelm to its formulary. In December 2021, Biogen cut the annual price for Aduhelm in half, from $56,000 to $28,000. Biogen's stock price rose $100 on the announcement of approval but fell by that amount and more over the next seven months. Following the announcement that Medicare would not cover the drug, Biogen largely abandoned commercialization.

Investors sued, challenging statements in six categories. The district court dismissed as to all statements on both falsity and scienter grounds. The first group included Biogen's statement that 900 sites were "ready" at the time of approval. Plaintiffs argued that the company's subsequent report that only 325 sites had completed P&T review showed that this was false. But the two announcements were not inconsistent. Biogen defined "ready" to mean logistically capable of infusing and willing to infuse the drug, which was different from completing a P&T review. Reasonable investors would understand that the P&T process could begin only after approval, and would not have been completed on the day approval was announced. The second group of statements concerned testing for the presence of amyloid beta plaque, as the drug was

unlikely to work for patients who did not have this condition. Plaintiffs argued that Biogen's statement that it had taken steps to overcome obstacles to *testing* was misleading in light of the company's failure to disclose obstacles to *collection*. The court rejected the argument, concluding that the two issues were distinct. The third group included statements that Medicare coverage was "automatically presumed." The court concluded that this was accurate as a regulatory matter, and that the company did not say that coverage was guaranteed. The fourth group related to price: Biogen said that it had consulted with a broad group of interested parties in setting the $56,000 price point. The court rejected plaintiffs' contention that this amounted to a representation that those parties *supported* the price; Biogen did not say that. The fifth group of statements concerned the VA contract under negotiation. The court concluded that the fact that negotiations ultimately fell through did not show that the statements were false when made. Finally, the court rejected plaintiffs' attack on Biogen's open letter to the Alzheimer's disease community. Plaintiffs argued that the company represented in the letter that its contacts with the FDA during the review process were appropriate and not out of the ordinary. But that is not what Biogen said, and in any event, the FDA official plaintiffs quoted did not state otherwise. The official said only the that the government should investigate whether Biogen's interactions with the FDA were consistent with policies and procedures. More generally, and with respect to virtually every category, the court faulted plaintiffs for misrepresenting the content of Biogen's statements.

Hattaway v. Apyx Med. Corp., 2023 WL 4030465 (M.D. Fla. June 15, 2023), granting motion to dismiss without prejudice. **Off-label marketing; adverse event reporting**

Apyx obtained 510(k) clearance to market its Renuvion device for cutting, coagulation, and ablation of soft tissue during surgery. The device was not cleared for use in cosmetic surgery, although physicians used it off-label for that purpose and Apyx was seeking to expand clearance to encompass certain cosmetic uses. Apyx included extensive risk disclosures about regulatory compliance generally, and off-market promotion in particular, in its Forms 10-K. In quarterly reports and earnings calls, Apyx spoke optimistically about the growth of its Renuvion business. When asked whether growth might stem from off-label use, Apyx reminded investors that it was prohibited from promoting use in cosmetic surgery and that such use accounted for a small fraction of sales. On March 14, 2022, the FDA issued a Medical Device Safety Communication (MDSC), warning consumers and healthcare providers not to use Renuvion in cosmetic procedures and noting that it had received serious adverse event reports connected with such use. The agency did not retract any previously granted clearances. The stock fell 41%. In an earnings call several days later, Apyx told investors that the MDSC had come as a surprise, and that it believed the catalyst for the FDA's action was an increase in the *absolute number* of adverse event reports—at the same time that use was growing and the *rate* of adverse event reports was falling. Apyx later reported that at the FDA's request, it had revised its messaging to provide stronger warnings against cosmetic use in certain cases. The FDA ultimately granted the label expansion Apyx had requested, clearing Renuvion for limited dermal resurfacing procedures.

Investors sued, challenging the company's financial statements, statements about growth, and risk disclosures. The court granted the company's motion to dismiss on falsity, scienter, and loss causation grounds. Under controlling law, accurate reporting of financial results is not subject to attack on the theory that a company has achieved its results through improper conduct. Optimistic statements about growth were not misleading, given the company's repeated acknowledgment that physicians were using the product off-label. Plaintiffs challenged the company's risk disclosure on the ground that the regulatory risks identified had already occurred, but that was not in fact the case. Apyx disclosed the MDSC as soon as it learned about it, and investors were able to assess the risk of unfavorable regulatory action for themselves, given the public nature of adverse event databases. The court rejected plaintiffs' scienter allegations for similar reasons: Apyx disclosed the risks that eventually materialized, which was inconsistent with the intent to defraud investors. Plaintiffs' confidential witnesses did not connect the company's executives to particular compliance issues at lower levels of the organization, and awareness of general compliance issues could not be equated to an intent to defraud investors when the company disclosed compliance risk. Finally, Plaintiffs failed to establish loss causation. The purported corrective disclosures did not show that any

challenged statement was false or misleading: The announcement of the MDSC showed only the materialization of a disclosed risk.

Sneed v. AcelRx Pharms., Inc., 2023 WL 4412164 (N.D. Cal. July 7, 2023), granting motion to dismiss without prejudice. **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 representations about risk and efficacy, which amounted to misbranding. The promotional materials used the term "Tongue and Done," which the FDA concluded "dangerously undercut" the conditions of use under which it had granted approval. 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 in a decision we reported in our 2022 review, concluding that while the "misbranding allegations [were] serious," plaintiffs had failed to connect the issues the FDA identified with the public statements plaintiffs challenged. Plaintiffs amended their complaint, adding confidential witness allegations and challenging as securities law violations the same customer-facing statements the FDA deemed misbranding. The court again dismissed. The court concluded that plaintiffs had adequately alleged falsity—or at least presented a "close call"—as to the customer-facing advertising statements, as well an executive's oral statement at an analyst presentation using the phrase "Tongue and Done." Plaintiffs' theory was that the company misleadingly omitted information about the limitations on use imposed by the REMS. The company argued that this information was publicly available, and that in any event the individual defendants were not the "makers" of the advertising statements. The court rejected both arguments. Nevertheless, plaintiffs' scienter allegations fell short. Plaintiffs alleged that the individual defendants knew about both the content of the promotional materials and FDA scrutiny, but this did not show, at any time before the FDA issued the warning letter, that defendants intended to deceive investors. Nor did defendants' awareness of warning letters to *other* companies support a strong inference of scienter. The confidential witness allegations, meanwhile, did not show what the individual defendants believed or intended. Moving to statements other than the promotional materials and "Tongue and Done," the court dismissed on falsity grounds. The court also dismissed plaintiffs' claim for scheme liability. Plaintiffs' theory was that the misbranded promotional materials deceived investors into believing that the size and penetrability of the market were greater than they in reality were. But "[p]laintiffs have never provided any plausible factual allegations to support that claim." The court dismissed the scheme claim with prejudice and the balance of the complaint without prejudice.

Turnofsky v. electroCore, Inc., 2023 WL 4527553 (D.N.J. July 13, 2023), granting motion to dismiss without prejudice. **Competition; reimbursement**

electroCore manufactures gammaCore, a device that treats cluster headaches and migraines by stimulating the vagus nerve. The FDA cleared gammaCore for commercial sale in April 2017. In June 2018, the company conducted its IPO, stating in the offering documents that gammaCore's advantages included "ease of use and suitability…without the frequency-of-use restrictions and contraindications associated with other treatments." The company also stated that it had entered into agreements with third-party payers. In May 2019, the company announced that it had missed first-quarter revenue expectations; its stock fell 30%. Later that month, the company announced a restructuring and cost reduction plan, and its stock dropped again. In August 2019, electroCore reported a restructuring charge and restrictions on reimbursement. The stock fell 10%. In September 2019, the company disclosed that the FDA had requested an analysis of clinical data for its 510k submission. The stock fell 23%.

Investors brought both Section 11 and Section 10(b) claims, challenging electroCore's statements about its agreements with third-party payers, physician acceptance of gammaCore, and the financial challenges the company faced. The court dismissed plaintiffs' original consolidated complaint in 2021 (a decision reported in our review for that year), and dismissed the successor

to that complaint in 2023. The Section 11 claims failed on falsity grounds. The company's statements about third-party payers were not misleading in context. Plaintiffs argued that the term "commercial payor" was misleading because the company had entered into contracts only with pharmacy benefit managers (PBMs), and not with insurance companies. But the term "commercial payor" encompasses both PBMs and insurance companies. The court also rejected plaintiffs' attack on the company's statement that an agreement with CVS would give it access to 30 million patients. This was an opinion statement, and while one of plaintiffs' confidential witnesses offered a different opinion (7 million "commercial lives"), that did not establish falsity. Plaintiffs' challenge to statements about physician acceptance and financial performance were also deficient, in part because the company had disclosed relevant risks in these areas. Plaintiffs' Section 10(b) claim failed as to both falsity and scienter. Plaintiffs' scienter allegations amounted to little more than the assertion that the company's executives had "intimate knowledge" of the company's business.

In re Mylan N.V. Sec. Litig., 666 F. Supp. 3d 266 (S.D.N.Y. 2023), granting motion for summary judgement. **Medicaid rebates; antitrust**

Mylan develops and manufactures both generic and brand-name pharmaceuticals, including the EpiPen. Mylan classified the EpiPen as a non-innovator multiple source drug; manufacturers of such drugs receive the most favorable rebate treatment. In 2014, Mylan received a DOJ subpoena in an investigation into the classification of the EpiPen. In 2016, Mylan announced that it had entered into a $465 million settlement with the DOJ over the matter.

Investors sued, alleging that Mylan had made false statements about the classification of the EpiPen. Plaintiffs also alleged that Mylan's EpiPen contracts with PBMs were anticompetitive. Apart from the EpiPen, plaintiffs alleged that Mylan had engaged in a price-fixing conspiracy for generic drugs. In connection with their two antitrust-based theories, plaintiffs challenged broad statements Mylan made about competition in the marketplace and even broader statements about financial success. Plaintiffs alleged that the latter statements were misleading insofar as the company neglected to attribute its success to antitrust violations. The company brought three successive motions to dismiss (covered in our 2018-2020 reports), and the court denied each in part.

The case then proceeded to cross-motions for summary judgment. The court granted the company's motion. The court characterized plaintiffs' case as "claims within claims." With respect to each of plaintiffs' three theories of fraud—relating to EpiPen classification and purported anticompetitive conduct as to both the EpiPen and generic drugs—the alleged securities law violation was premised on an alleged underlying statutory or regulatory violation. As to the EpiPen antitrust theory, the purported underlying violations had been ruled on elsewhere by the time the case reached summary judgment. In MDL proceedings in Kansas, the district court granted summary judgment for the defendants on the antitrust claims, and the Tenth Circuit affirmed. The court in the securities action noted these holdings but also conducted its own substantive analysis of the antitrust issues. The court reached the same conclusion as the MDL court: The PBM contracts were not anticompetitive. The court then applied a securities law framework and held that plaintiffs failed to establish scienter: "[F]our different federal judges have previously looked at the challenged transactions and upheld them." Moving to the EpiPen classification issue, the court held that plaintiffs had failed to show either an underlying violation or scienter. The regulatory record was complicated and murky, and the company had reasonably relied on a communication from CMS agreeing with its classification. Plaintiffs were unable to show that CMS had "actually [] taken an opposing view from that of Mylan." Significantly, the court found that the $465 million DOJ settlement was "neither admissible nor significantly probative of scienter." The court also rejected plaintiffs' argument that a risk disclosure referring to the possibility of government investigations was misleading in light of the undisclosed 2014 DOJ subpoena; read fairly, the disclosure alluded to the possibility of ongoing investigations. Finally, on plaintiffs' claim that Mylan had conspired to fix generic drug prices and engaged in improper market allocation, the evidence showed no more than the behavior of oligopolists. Consistent with its rulings on the motions to dismiss, the court required plaintiffs to establish antitrust violations with respect to specific drugs, not the generic drug marketplace as a whole. Plaintiffs sought to meet their burden as to only six drugs, but failed as to each. The court largely analyzed the evidence as if plaintiffs had asserted an antitrust claim rather than a Section 10(b)

"claim within a claim," although the court also concluded that plaintiffs had failed to establish loss causation under Section 10(b). None of the alleged corrective disclosures revealed plausibly new information about the six drugs at issue.

DISTRICT COURT DECISIONS—MOTION TO DISMISS OR FOR SUMMARY JUDGMENT DENIED

Zaidi v. Adamas Pharms., Inc., 650 F. Supp. 3d 848 (N.D. Cal. 2023), denying in part motion to dismiss. **Product launch**

Adamas developed and marketed Gocovri, which is used to treat the side effects of levodopra therapy for patients suffering from Parkinson's Disease. Gocovri is an extended-release formulation of amantadine, a generic drug prescribed off-label for the same condition. The benefit of the extended-release formulation is that dosage reaches its maximum concentration in the daytime—when symptoms are most bothersome—but is less concentrated at night. The FDA approved Gocovri on August 24, 2017. In the weeks before approval, the company spoke favorably about physicians' and payers' response to the drug, and stated in particular that it did not expect payers to require that patients undertake a "step through"—that is, to try generic amantadine before agreeing to pay for Gocovri. After approval, the company continued to speak optimistically about these matters, as well as about the rollout of the drug through a specialty pharmacy. But in a March 2019 earnings call, the company revised previous growth estimates and predicted a slowdown in prescriptions. The stock fell 33%.

Investors sued, challenging statements the company made both before and after approval. The court concluded that plaintiffs adequately pled falsity as to statements about favorable physician and payer response to the drug. Plaintiffs cited surveys from the first half of 2017 that allegedly contradicted those statements, suggesting that some physicians saw no difference between amantadine and Gocovri, and that certain payers would impose step through restrictions. Plaintiffs also adequately pled scienter as to the company's pre-approval statements about physician and payer response. By contrast, plaintiffs failed to plead scienter as to the company's post-approval statements on the same subject. After approval, the surveys had become stale, and internal company data did not contradict the challenged statements. For all remaining statements, plaintiffs likewise adequately alleged falsity but failed to create a strong inference of scienter. This included (1) bullish statements about the success of a specialty pharmacy, and (2) risk disclosures identifying the possibility of step through restrictions and delays in payer approval.

In re Mylan N.V. Sec. Litig., 2023 WL 3539371 (W.D. Pa. May 18, 2023), denying in part motion to dismiss. **Manufacturing issues**

Mylan operates several facilities manufacturing generic drugs. In November 2016, the FDA issued a Form 483 after inspecting Mylan's facility in Morgantown, West Virginia. The FDA raised questions about quality control functions and classified the facility as "Voluntary Action Indicated." In March-April 2018, the FDA again conducted inspections of Morgantown and again issued a Form 483, this time directed at manufacturing operations. Mylan submitted a detailed response in May 2018, but also halted production at the facility and recalled at least seven drugs made there. In June 2018, Bloomberg reported on the latter inspection and the company's stock fell 4%. In August 2018, Mylan announced that it had undertaken a remediation plan at Morgantown following the issuance of the Form 483, and the stock fell 7%. In November 2018, the FDA issued a Warning Letter. In February 2019, the company reported declining North American sales, which it attributed to the Morgantown remediation and restructuring. In May 2019, Mylan reported a first quarter loss, again attributing it to the Morgantown restructuring. The stock fell 24%.

Investors sued, challenging the company's statements about regulatory compliance, the quality and reliability of its manufacturing process, the "suitability" of its manufacturing facilities, and the remediation process. The court denied the company's motion to dismiss as to one company statement quoted in a Bloomberg article but granted the motion as to the balance of the challenged statements. The Bloomberg article quoted a company representative stating

that "any explicit or implicit suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of medications we manufacture—for time pressures or any other reason—is simply false." Plaintiffs adequately alleged falsity by reference to confidential witnesses who purportedly asserted that Mylan had cut corners in ways that jeopardized quality. Plaintiffs also adequately alleged collective corporate scienter as to this statement: Senior executives had access to observations and warnings from the FDA that contradicted the statement quoted by Bloomberg. But plaintiffs failed to adequately allege falsity as to any other challenged statement. Some statements were non-actionable puffery. Statements about regulatory compliance were not misleading in light of risk disclosures warning investors of the difficulty of maintaining adequate compliance. Plaintiffs also failed to allege falsity as to opinion statements about the "suitability" of the facilities; those statements related to physical qualities rather than regulatory compliance. Statements about the remediation were not misleading either. The company did not downplay the difficulty of the process and in fact painted a "grim" picture of circumstances at the plant.

Ciarciello v. Bioventus Inc., 2023 WL 7300081 (M.D.N.C., Nov. 6, 2023), denying in part motion to dismiss. **Medicare reimbursements and rebates**

Bioventus sells therapies including hyaluronic acid injections and receives reimbursement from the Centers for Medicare and Medicaid Services. Historically, reimbursement payments were calculated based on wholesale acquisition cost, which did not reflect rebates or discounts. Beginning January 1, 2022, however, Medicare shifted to calculating reimbursements by reference to average sales price. In Bioventus' case, this reduced reimbursements significantly. Separately, under its contracts with third-party payers, Bioventus must pay rebates when an insured patient gets an injection. In the summer of 2021, after an unexpectedly large rebate payout, the company conducted an internal audit of its processes and controls for estimating and managing rebates. The audit identified 12 "red" action items, which required immediate attention and correction. In November 2022, the company reported revenue below expectations, attributing this in part to an unexpectedly large rebate request. The stock fell 58%.

Investors sued, challenging the company's statements about (1) internal controls, (2) revenue reporting and recognition, and (3) Medicare's shift in calculating reimbursement, which the company characterized as "net neutral." In a short opinion, the court denied defendants' motion to dismiss as to plaintiffs' Section 10(b) claim but granted the motion as to the Section 11 claim. Under Section 10(b), plaintiffs adequately pled both falsity and scienter as to all three sets of statements. But under Section 11, the lead plaintiff failed to trace its stock purchase to the challenged registration statement, and thus could not establish statutory standing.

In re Dentsply Sirona, Inc. Sec. Litig., 665 F. Supp. 3d 255 (E.D.N.Y 2023), denying motion to dismiss. **Financial reporting; antitrust**

Dentsply and Sirona merged in February 2016. The combined company, Dentsply Sirona, is the world's largest manufacturer of professional dental products. First Sirona, and subsequently Dentsply Sirona, had exclusive distribution agreements for certain products with Patterson, one of the three principal distributors of dental products. Under the agreements, Patterson was required to make minimum purchases to retain exclusivity. Beginning in 2015, end-user demand was at times lower than the minimum purchase requirements, which Patterson continued to honor. The exclusive distribution agreements expired in September 2017, and Patterson publicly announced in November 2016 that it would not renew the agreements. In May 2017, Dentsply Sirona told investors that it had entered into a new, nonexclusive agreement with Patterson and a second distributor. In an August 2017 earnings call, the company reported an SEC investigation into accounting and disclosures related to transactions with Patterson. During the same call, the company announced a $1.2 billion impairment charge for goodwill and intangible assets. The stock fell 8%. In October 2017, the company announced the resignations of its four top executives, and the stock fell 6%. In May 2018, the company reported that its first-quarter results were impacted by $8 million in dealer inventory reductions, and that it anticipated further destocking of $40 million in 2018. The stock fell 11%. In August 2018, the company announced an additional $1.3 billion impairment charge, as well as actual and anticipated destocking well in excess of the earlier $40 million estimate. The

stock fell 19%. Apart from the company's own announcements, the FTC in February 2018 brought an antitrust action against Patterson and the two other principal distributors, alleging a horizontal agreement to restrain price competition. In December 2020, the SEC announced the issuance of a consensual cease-and-desist order in which it alleged that the company failed to report as a trend the inventory buildup at Patterson and drop-off in end-user demand. The company paid a $1 million fine with no admission of liability.

Investors sued, alleging that the company's sales performance was driven by the minimum purchase requirements in the soon-to-expire agreement with Patterson, and by the antitrust violations of the three dental product distributors, which kept prices elevated. Plaintiffs challenged statements in which the company attributed its financial performance to benign factors and characterized the market as competitive. Plaintiffs also challenged the company's goodwill accounting. The court very largely denied the company's motion to dismiss. Plaintiffs had adequately alleged falsity with respect to the company's attribution of financial performance to sales growth, in light of the unreported inventory buildup at Patterson. Plaintiffs had also adequately alleged a distributor conspiracy: They claimed that the three distributors worked to prevent purchasers from forming dental buying groups (which would have increased their negotiating power) and blocked a rival distributor from entering the market. Plaintiffs also adequately alleged that Dentsply Sirona knew about, acquiesced in, and benefitted from the distributors' conspiracy. (Unlike other courts adjudicating securities claims based on alleged antitrust violations, the court did not analyze the allegations under antitrust law.) In light of the conspiracy allegations, plaintiffs adequately pled that the company's attribution of financial performance to benign factors was misleading. Plaintiffs also adequately alleged falsity as to the company's goodwill accounting. Goodwill estimates are opinion statements governed by *Omnicare*; plaintiffs met *Omnicare*'s requirements for an omission claim insofar as the company failed to account for the unsustainable inventory buildup and alleged distributor conspiracy in calculating goodwill. As to scienter, plaintiffs showed that the company was aware of the inventory buildup and decline in end-user demand by means of reports Patterson was required to provide, and was aware of the alleged distributor conspiracy through emails with the distributors (which plaintiffs presumably drew from the FTC complaint). The resignations of the company's four top executives further buttressed the scienter allegations.

Roofer's Pension Fund v. Papa, — F. Supp. 3d —, 2023 WL 5287783 (D.N.J. Aug. 17, 2023), denying in part motion for summary judgment. **M&A; antitrust**

Perrigo manufactures both branded and generic drugs. In April 2015, Mylan N.V. announced an unsolicited offer to purchase Perrigo for cash and stock. After Perrigo rejected that offer, Mylan proceeded with a tender offer in September 2015. While Mylan's tender offer was pending, Perrigo made statements about its financial health and projected earnings. In November 2015, the tender offer expired with less than 50% of Perrigo's shares tendered. In February 2016, Perrigo reported fourth quarter 2015 revenue below the projections it had made during the tender period, and revised its 2016 earnings guidance downward. The company's stock price fell. In April 2016, the market learned that the CEO was leaving the company, and the stock price fell again. In May 2016, Perrigo announced impairment charges related to problems with its integration of Omega, a recently acquired company. The stock fell 4%. The company announced additional impairment charges in August 2016, and the stock fell 10%. In February 2017, Perrigo announced that it would sell its royalty stream for the drug Tysabri—one of its major revenue generators—for $2.2 billion, substantially less than the value Perrigo had assigned to the asset while Mylan's offer was pending. Perrigo also announced on the same day that it would not timely file its 2016 Form 10-K because it needed to review historical revenue recognition practices for the Tysabri royalty stream (among other issues). The stock fell 12%. In March 2017, Bloomberg reported that Perrigo's generic drug pricing was under investigation by the DOJ, and the stock fell 4%. In May 2017, the company's offices were raided by federal law enforcement, and the stock fell 5%. The company later restated its financial statements for multiple quarters.

Investors sued, claiming that Perrigo had made misrepresentations in four areas in order to discourage shareholders from accepting Mylan's tender offer. Specifically, plaintiffs alleged that Perrigo had (1) inflated its revenues by conspiring with other manufacturers to fix generic drug

prices, (2) misrepresented the success of the Omega integration, (3) misled investors about the value of the Tysabri revenue stream, and (4) misrepresented its organic growth rate. In a 2018 decision (which we discussed in that year's review), the court denied the company's motion to dismiss as to the first two theories, but granted the motion as to the third and fourth.

After several years in discovery, defendants moved for summary judgment. The court largely rejected plaintiffs' antitrust-related claim. Focusing on scienter, the court concluded that plaintiffs had failed to establish that either of the two individual defendants (the former CEO and CFO) knew about alleged price fixing. At most, plaintiffs showed that the executives had some awareness of pricing decisions—but pricing is not the same as price fixing. By contrast, the court concluded that plaintiffs had alleged facts "barely" showing that others at the company knew about the alleged price fixing. This raised the possibility of "corporate scienter"—scienter at the corporate level based on the knowledge of employees or executives other than those who made the challenged statements. But whether that concept applied at summary judgment was unclear, and the court requested additional briefing on the issue. The company did not fare as well on the Omega integration. The court concluded that plaintiffs had established triable facts as to the CEO's statements in April-August 2015 that the acquisition had been "accretive" and that the company "delivered on [its] Omega integration plans." The court declined to grant summary judgment on loss causation; the parties had "both submitted detailed, but conflicting expert reports, making summary judgment inappropriate."

TABLE OF NEW FILINGS IN 2023

In 2023, 34 new securities fraud class actions were filed against life sciences companies, consistent with a decline we saw beginning last year.[10]

2019: 44 new complaints
2020: 45 new complaints
2021: 49 new complaints
2022: 37 new complaints
2023: 34 new complaints

Of the new actions filed in 2023, 16 were filed against companies with development-stage drugs or devices—less than half the total number of filings for the year. That is a deviation from what we see most years, in which well over half the new filings are in the pre-approval space. The reported decisions mirror that trend: Every year, we see more pre-approval than post-approval decisions. We also see a higher success rate for companies in the pre-approval cases every year. As noted above, the success rate in 2023 was 80% in pre-approval cases and 50% in post-approval cases. Although no prediction is certain, these trends may forecast a lower success rate in the decisions overall as the new filings work through the courts in the next year or two.

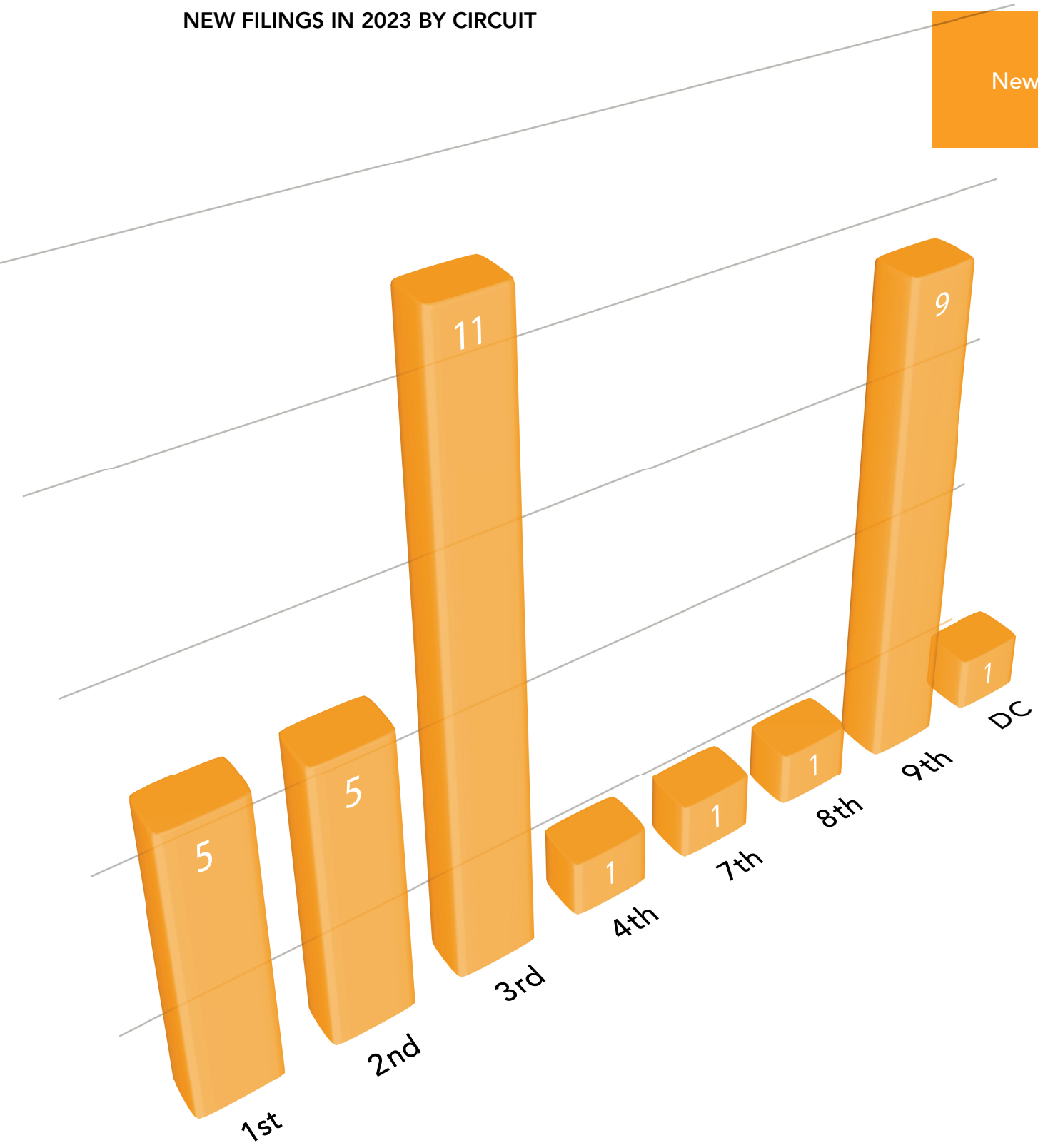
The number of new filings related to COVID-19 products has unsurprisingly tailed off. In 2020 through 2022, we saw six or seven new filings per year, nearly all in the pre-approval (or pre-EUA) stage. In 2023, there were three new COVID-19 filings, one against a company developing a treatment for the disease and two against companies whose sales suffered as the demand for their COVID-19-related products tailed off.

Eighteen actions were filed against companies with mature products. This continues a steady increase: We saw only ten such new filings in 2021 and 14 in 2022. This year, the majority of new filings in this area arise from setbacks not unique to life sciences companies, principally sales performance and financial reporting issues. In previous years, we have seen a greater concentration of cases arising from regulatory issues, particularly alleged improprieties in regulated areas of marketing and billing.

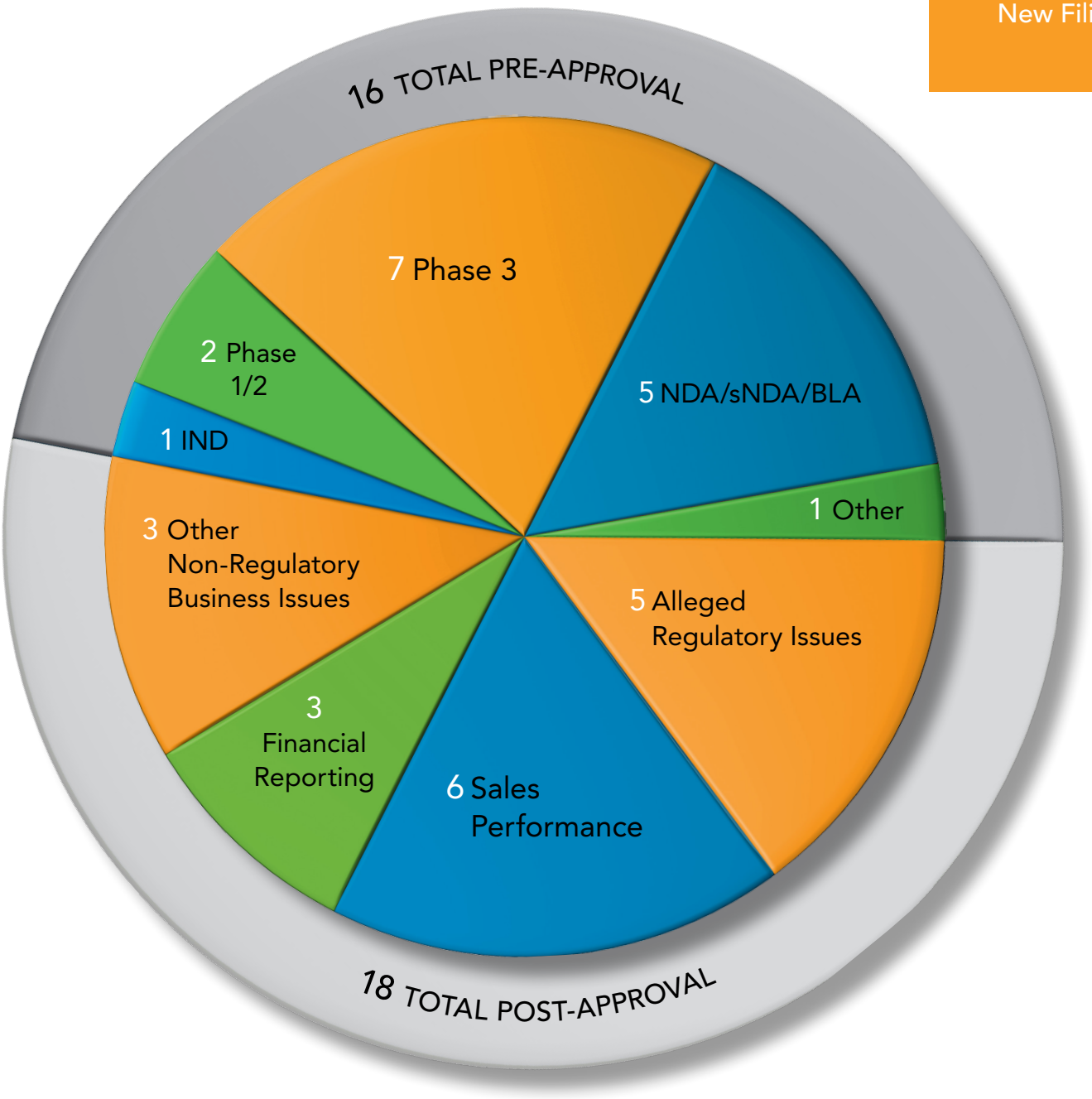
As in previous years, new filings are clustered in district courts in the Third and Ninth Circuits. The First and Second Circuits occupy the next tier. New filings in other circuits are negligible. We show all of these breakdowns on the following 3 pages.

10 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 2023 BY CIRCUIT



PRODUCT LIFECYCLE		SECURITIES FRAUD CLASS ACTIONS FILED IN 2023
PRE-APPROVAL	IND	1
	Phase 1/2	2
	Phase 3	7
	NDA/sNDA/BLA	5
	Other	1
	TOTAL PRE-APPROVAL	16
POST-APPROVAL	Alleged Regulatory Issues	5
	Sales Performance	6
	Financial Reporting	3
	Other Non-Regulatory Business Issues	4
	TOTAL POST-APPROVAL	18



NEW FILINGS IN 2023

FULCRUM THERAPEUTICS, INC. **04/28/2023** **D. MASS**

PRE-APPROVAL: IND Fulcrum develops FTX-6058 to treat sickle cell disease. Plaintiffs challenge the company's statements about the drug's safety and clinical and commercial prospects. Stock prices fell after the company announced that the FDA had issued a full clinical hold, and fell again after the company reported fourth quarter and full year 2022 financial results.

CARIBOU BIOSCIENCES, INC. **02/10/2023** **N.D. CAL.**

PRE-APPROVAL: PHASE 1 Caribou develops CB-010 to treat relapsed or refractory B cell non-Hodgkin lymphoma. Plaintiffs challenge the company's statements about the drug's clinical and commercial prospects. Stock prices fell after Caribou reported results of a Phase 1 trial.

ACELYRIN, INC. **11/21/2023** **C.D. CAL.**

PRE-APPROVAL: PHASE 2 ACELYRIN develops Izokibep, a small protein therapeutic designed to treat hidradenitis suppurativa (skin lesions). Plaintiffs allege the company exaggerated Izokibep's potency and commercial prospects. Stock prices fell after the company announced disappointing top-line results from Part B of the drug's Phase 2b/3 trial.

INVIVYD, INC. **01/31/2023** **D. MASS.**

PRE-APPROVAL: PHASE 2/3 Invivyd develops ADG20, an investigational monoclonal antibody treatment for COVID-19. Plaintiffs challenge the company's statements about the drug's effectiveness against the omicron variant and its commercial prospects. Stock prices fell after Invivyd reported disappointing results in trials testing the drug against the omicron variant.

BIOLINERX LTD. **01/05/2023** **D.N.J.**

PRE-APPROVAL: PHASE 3 BioLineRx reported favorable topline results from the Phase 3 trial of its oncology drug Motixafortide in May 2021. Plaintiffs challenge the company's subsequent statements that it was well-financed as it progressed toward filing an NDA. Stock prices fell after the company reported new financing to support a commercial launch.

NOVOCURE LIMITED **06/19/2023** **S.D.N.Y.**

PRE-APPROVAL: PHASE 3 NovoCure develops Tumor Treating Fields, which it employs in devices using electrical fields to keep cancer cells from multiplying. Plaintiffs challenge the company's report of top-line results in a registrational trial of Tumor Treating Fields as a treatment for non-small cell lung cancer. Stock prices fell after the company reported complete results at a medical conference.

BIOXCEL THERAPEUTICS, INC. 07/07/2023 D. CONN.

PRE-APPROVAL: PHASE 3 BioXcel uses artificial intelligence to develop BXCL501, a treatment for agitation associated with Alzheimer's disease. Plaintiffs challenge the company's statements about protocol adherence and data integrity in a Phase 3 trial. Stock prices fell after the company reported that the trial's principal investigator failed to adhere to the protocol and may have fabricated official correspondence, both of which could jeopardize approval.

RAIN ONCOLOGY INC. 07/14/2023 N.D. CAL.

PRE-APPROVAL: PHASE 3 Rain developed miladmetan, a treatment for the cancer liposarcoma. Plaintiffs challenge the company's statements about safety in its Phase 3 trial and the drug's commercial prospects. Stock prices fell after the company reported that miladmetan did not meet a primary safety endpoint in the Phase 3 trial.

APELLIS PHARMACEUTICALS, INC. 08/02/2023 D. DEL.

PRE-APPROVAL: PHASE 3 Apellis develops SYFOVRE to treat geographic atrophy, a leading cause of blindness. Plaintiffs allege that the company falsely stated that SYFOVRE demonstrated minimal adverse effects and no instances of retinal vein occlusion in Phase 3 trials. Stock prices fell when the American Society of Retina Specialists published a letter highlighting its concerns with SYFOVRE, including concerns that the therapy caused retinal vein occlusion.

INFINITY PHARMACEUTICALS 08/15/2023 D. MASS.

PRE-APPROVAL: PHASE 3 Infinity develops eganelisib, a breast cancer treatment. Plaintiffs allege that the company's statements about its development plans were misleading, claiming that when the company announced a merger, it did not mention the breast cancer treatment. Stock prices fell after the merger announcement.

Y-MABS THERAPEUTICS, INC. 01/18/2023 S.D.N.Y

PRE-APPROVAL: BLA Y-mAbs developed omburtamab, a murine monoclonal antibody treatment for cancer. Plaintiffs challenge the company's statements about the drug's prospects for approval. Stock prices fell after the FDA published its briefing book in advance of an advisory committee meeting, and fell again when the advisory committee voted against approval.

IMMUNITYBIO, INC. 06/30/2023 S.D. CAL.

PRE-APPROVAL: BLA ImmunityBio develops Anktiva, a treatment for bladder cancer. Plaintiffs challenge the company's statements about the drug's third-party manufacturer. Stock prices fell after the company announced that the FDA had rejected its BLA for Anktiva.

BRAINSTORM CELL THERAPEUTICS, INC. **11/01/2023** **S.D.N.Y.**

PRE-APPROVAL: BLA Brainstorm develops a treatment for ALS called NurOwn. Plaintiffs allege that the company understated the risk that the FDA would not approve the treatment, including the risk of continuing with the review process after receiving a Refuse to File letter. Stock prices fell after the company reported its receipt of the Refuse to File Letter, and fell again after an FDA advisory committee voted 17 to 1 that the company had not provided sufficient evidence of efficacy.

ALDEYRA THERAPEUTICS, INC. **07/31/2023** **D. MASS.**

PRE-APPROVAL: NDA Aldeyra submitted an NDA for ADX-2191, which it developed to treat primary vitreoretinal lymphoma. Plaintiffs allege that the company overstated the likelihood of approval by omitting information about the a purported shortfall in the evidence of efficacy. Stock prices fell after Aldeyra announced it had received a CRL citing inadequate evidence of efficacy

OUTLOOK THERAPEUTICS, INC. **11/03/2023** **D.N.J.**

PRE-APPROVAL: NDA Outlook develops ONS-5010 to treat macular degeneration and other eye diseases. Plaintiffs claim that the company overstated the likelihood of approval by omitting unfavorable information about efficacy and manufacturing. Stock prices fell when the company reported that it had received a CRL citing these issues.

CHARLES RIVER LABORATORIES INTERNATIONAL, INC. **05/19/2023** **D. MASS.**

POST-APPROVAL: ALLEGED REGULATORY ISSUES Charles River develops drugs and therapeutics. Plaintiffs allege that the company failed to disclose that it had illegally imported primates for research and was accordingly in danger of regulatory and criminal actions. Stock prices fell after the company reported that it had received a subpoena in the DOJ's investigation into the matter.

KENVUE **10/09/2023** **D.N.J.**

POST-APPROVAL: ALLEGED REGULATORY ISSUES Kenvue sells over-the-counter drugs containing phenylephrine. Plaintiffs challenge the company's statements that it believes its products are effective. Stock prices fell after the FDA published a report concluding that orally administered phenylephrine is not effective as a nasal decongestant.

INTEGRA LIFESCIENCES **09/12/2023** **D.N.J.**

POST-APPROVAL: PRODUCT RECALL Integra manufactures and sells collagen-based devices for wound care, peripheral nerve repair and reconstruction surgery. Plaintiffs challenges the company's statements that a PMA application for an additional indication was on track, as well as statements about its Boston manufacturing facility. Stock prices fell after the company announced a recall of products manufactured at the Boston facility.

SCYNEXIS, INC. 11/07/2023 D.N.J.

POST-APPROVAL: PRODUCT RECALL Scynexis makes a drug that treats fungal infections. Plaintiffs challenge the company's statements about manufacturing and drug supply. Stock prices fell after the company announced product recalls and a clinical hold in light of a cross-contamination issue.

INSPIRE MEDICAL SYSTEMS 12/22/2023 D. MINN.

POST-APPROVAL: REIMBURSEMENT AND BILLING Inspire sells an implantable device used to treat sleep apnea. Plaintiffs allege that the company overstated the reach of a program designed to assist patients in scheduling doctors' appointments needed to facilitate insurance coverage. Stock prices fell after the company reported a revenue miss for 2023.

BAXTER INTERNATIONAL, INC. 07/12/2023 N.D. ILL.

POST-APPROVAL: SALES PERFORMANCE Baxter makes products to treat kidney disease and other chronic medical conditions. Plaintiffs challenge Baxter's statements about the impact of supply chain issues on revenue. Stock prices fell after Baxter reported 2022 revenue below expectations, purportedly the result of supply chain issues.

DANAHER CORPORATION 07/17/2023 D.D.C.

POST-APPROVAL: SALES PERFORMANCE Danaher sold a COVID-19 treatment. Plaintiffs challenge the company's statements about its ability to sustain its 2020-2021 growth. Stock prices fell after the company announced in April 2023 that revenue decreased by 7% from the prior year period as a result of decreased demand for the COVID-19 treatment.

TANDEM DIABETES CARE 09/08/2023 S.D. CAL.

POST-APPROVAL: SALES PERFORMANCE Tandem manufactures an at-home insulin pump. Plaintiffs challenge the company's statements about the accuracy of its sales forecasts. Stock prices fell after the company revised its annual guidance.

DERMTECH, INC. ET AL 10/16/2023 S.D. CAL

POST-APPROVAL: SALES PERFORMANCE DermTech develops and markets non-invasive genomics tests for various skin conditions. Plaintiffs challenge statements about growth prospects, alleging that the company failed to disclose problems it faced in collecting from commercial payers. Stock prices fell after DermTech announced disappointing results for the second and third quarters of 2022, and lowered its projections for the year.

ADAPTHEALTH CORP. 10/24/2023 E.D. PA

POST-APPROVAL: SALES PERFORMANCE AdaptHealth sells home medical equipment. Plaintiffs allege that the company used illicit practices in billing insurers, and that those practices, rather than a growing customer base, drove record sales performance. Stock prices fell after the company disclosed losses and lowered revenue projections.

CATALENT, INC. 02/24/2023 D.N.J.

POST-APPROVAL: SALES PERFORMANCE; FINANCIAL REPORTING Catalent develops and sells drugs and biologics, including COVID-19-related products. Plaintiffs challenge the company's statements about demand for its products as well as its financial reporting. Stock prices fell after Catalent disclosed decreased demand for its COVID-19-related products; after news media reported that release of a COVID-19 vaccine had been delayed by regulators; after the company provided information about excess inventory in reporting quarterly earnings; and after a short seller alleged that the company had overstated revenue.

CUTERA, INC. 05/24/2023 N.D. CAL.

POST-APPROVAL: SALES PERFORMANCE; FINANCIAL REPORTING Cutera makes devices used in medical aesthetics treatments. Plaintiffs challenge the company's financial reporting. Stock prices fell after the company reported preliminary 2022 results; after it announced that its 2023 Form 10-K would be delayed; after it reported the termination of its CEO and executive chairman and resignation of its CFO; and after it released disappointing results for the first quarter of 2023.

BIOVENTUS INC. 01/12/2023 M.D.N.C.

POST-APPROVAL: FINANCIAL REPORTING Bioventus sells therapies including hyaluronic acid injections. Plaintiffs challenge the company's statements about accounting for rebates and preparing for a change in CMS's method of calculating reimbursement. Stock prices fell after the company announced third-quarter 2022 revenue below expectations.

EAGLE PHARMACEUTICALS, INC. 12/11/2023 D.N.J.

POST-APPROVAL: FINANCIAL REPORTING Eagle manufactures PEMFEXY, a metabolic inhibitor used together with chemotherapy to treat certain genomic tumor aberrations. Plaintiffs allege that Eagle inflated revenue by including notes receivable for expired inventory, and failed to disclose internal control issues. Stock prices fell after the company reported that it would file its third-quarter 2023 Form 10-Q late, disclosed issues with inventory expiry, and announced the resignation of its CEO.

AMGEN INC. 03/13/2023 N.D.N.Y.

POST-APPROVAL: TAX ISSUES Amgen develops and sells drugs and other therapeutics. Plaintiffs challenge the company's statements about tax liabilities. Stock prices fell after Amgen disclosed in reporting quarterly earnings that it had received a Notice of Deficiency from the IRS for approximately $7 billion in unpaid taxes.

VIATRIS INC. 05/12/2023 W.D. PA.

POST-APPROVAL: OTHER NON-REGULATORY BUSINESS ISSUES Viatris develops and sells drugs and other therapeutics. Plaintiffs challenge the company's general statements about its business and revenue. Stock prices fell after Viatris announced that it had entered into an agreement to sell its biosimilars business and intended to divest additional assets.

MALLINCKRODT PLC 07/07/2023 D.N.J.

POST-APPROVAL: OTHER NON-REGULATORY BUSINESS ISSUES Mallinckrodt sells specialty pharmaceutical products. Plaintiffs challenge the company's statements about its financial health. Stock prices fell after the Wall Street Journal reported that the company was exploring bankruptcy, and fell again after the company itself disclosed that it was doing so, and that it would not make interest payments on certain bonds.

ILLUMINA, INC. 11/10/2023 S.D. CAL.

POST-APPROVAL: OTHER NON-REGULATORY BUSINESS ISSUES Illumina performs genetic and genomic analysis. Plaintiffs challenge the company's statements about its relationship with a former subsidiary it was re-acquiring. Stock prices fell after the company disclosed that the SEC had requested documents about the acquisition, and fell further after a stockholder filed derivative litigation alleging breaches of fiduciary duty by the board of directors.

ABOUT THE PRACTICE

Securities and Shareholder Litigation

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

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

Life Sciences

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

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