2022 Year in Review

Securities Litigation Against Life Sciences Companies

GOODWIN

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Introduction — Summary of 2022 Trends, Themes, and Takeaways

We are proud to present our seventh annual Securities Litigation Year in Review publication, in which we analyze data for securities class actions filed nationally against publicly traded pharmaceutical, biotechnology, medical device, and healthcare product and services companies (collectively referred to herein as "life sciences companies") and summarize important decisions issued by courts in 2022 in key jurisdictions in these cases. These cases are typically filed by shareholders, on behalf of a putative class, seeking to recover investment losses after a company's stock price drops following the disclosure of a setback or problem experienced by the company with respect to its drugs or products, such as negative feedback from or action by the FDA, clinical trial delays, suspensions or terminations, negative clinical data results, adverse events experienced by patients, or manufacturing problems. Plaintiffs typically assert claims under Sections 10(b) and 20(a) and Rule 10b-5 of the Securities Exchange Act of 1934 (the 1934 Act) based upon allegedly false and misleading statements or omissions made by the company and its officers, and/or, if the alleged misstatements or omissions are made in connection with a registered securities offering, under Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (the 1933 Act).

Securities Class Action Filings Across All Industries in 2022

For the second consecutive year, in 2022, the number of new securities class action filings in federal and state courts declined, falling from 218 filings in 2021 to **208 filings in 2022** — a 5% drop from 2021 and 43% lower than the previous five-year average of 362 filings.[1] As in 2021, this decline was largely due to a dramatic drop (61%) in M&A-related class action filings, but it was also due to a 8% decline in federal "core" class action filings alleging Rule 10b-5 claims under the 1934 Act.[2] Filings related to special purpose acquisition company (SPAC) transactions, cryptocurrency, or the COVID-19 pandemic represented more than a third of all core federal class action filings in 2022.[3] With respect to SPACs, core filings in 2022 decreased by 27% relative to 2021 — but were still fourfold the 2020 total,[4] likely attributable to the enormous volume of SPAC initial public offerings and transactions over the past few years. As in 2020 and 2021, there also were a significant number of COVID-19-related class action filings — *i.e.*, filings against companies that were particularly impacted by the pandemic or companies involved in the development of products (*e.g.*, therapeutics, vaccines, and testing products) to address COVID-19 — reaching a new annual high (20 filings) in 2022.[5] Core filings related to cryptocurrency more than doubled in 2022, to a record 23 filings.[6] After declining in 2020 and 2021, the total number of 1933 Act filings in connection with registered offerings rose 43% in 2022, potentially in response to the surge of IPOs in 2021 and the subsequent stock market declines.[7] The majority of these 1933 Act filings —

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[1] Cornerstone Research, Securities Class Action Filings 2022 Year in Review (the Cornerstone Report), at 1, 4, available at Securities Class Action Filings 2022 Year in Review (cornerstone.com).

[2] Cornerstone Report, at 1, 4.

[3] Cornerstone Report, at 2, 5.

[4] Cornerstone Report, at 2.

[5] Cornerstone Report, at 2, 5.

[6] Cornerstone Report, at 2, 9.

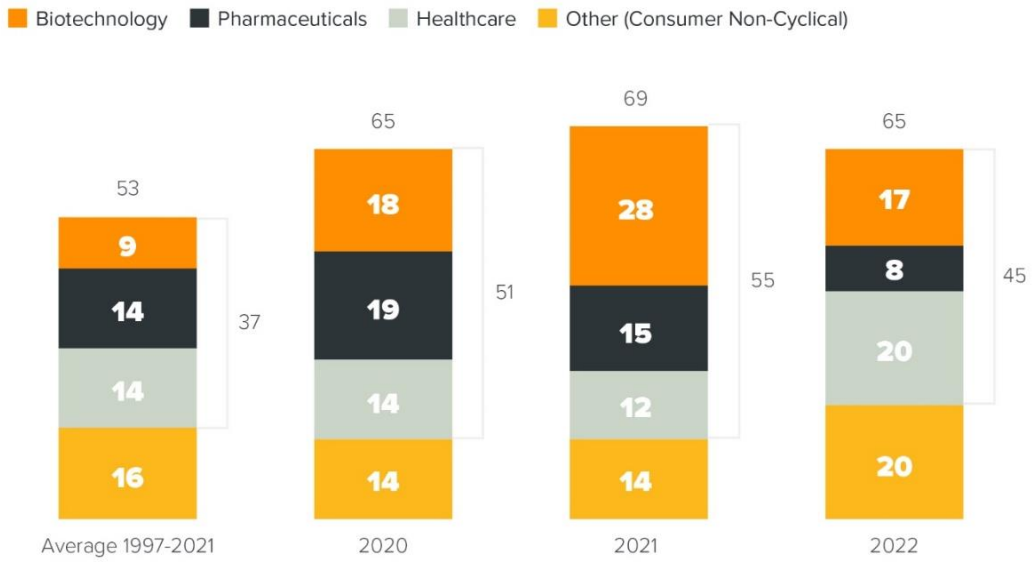
[7] Cornerstone Report, at 1, 4, 27.

76%, the highest percentage since 2014 and as compared to 37% in 2020[8] — were exclusively filed in federal courts, presumably due to exclusive federal forum selection provisions in corporate charters or bylaws many Delaware corporations have implemented requiring 1933 Act claims against them to be filed in federal courts, the validity of which provisions has been upheld by the Delaware Supreme Court and various other state courts since March 2020.[9]

Securities Class Actions Filed Against Life Sciences Companies in 2022

While the overall number of cases across all industries declined in 2022, the consumer non-cyclical sector, primarily composed of life sciences companies, once again had by far the greatest number of securities class action filings in 2022 compared to other sectors.[10] This is likely due to the inherently volatile nature of the stock prices of life sciences companies and the many event-driven disclosures made by such companies and, thus, the continued focus by the plaintiffs' bar on life sciences companies. As depicted in **Figure 1** below, there were 60-plus core federal filings against companies in the consumer non-cyclical sector in 2020, 2021, and 2022, compared to the 1997-2021 average of 53 filings.

Figure 1: Consumer Non-Cyclical Sector — Core Federal Filings



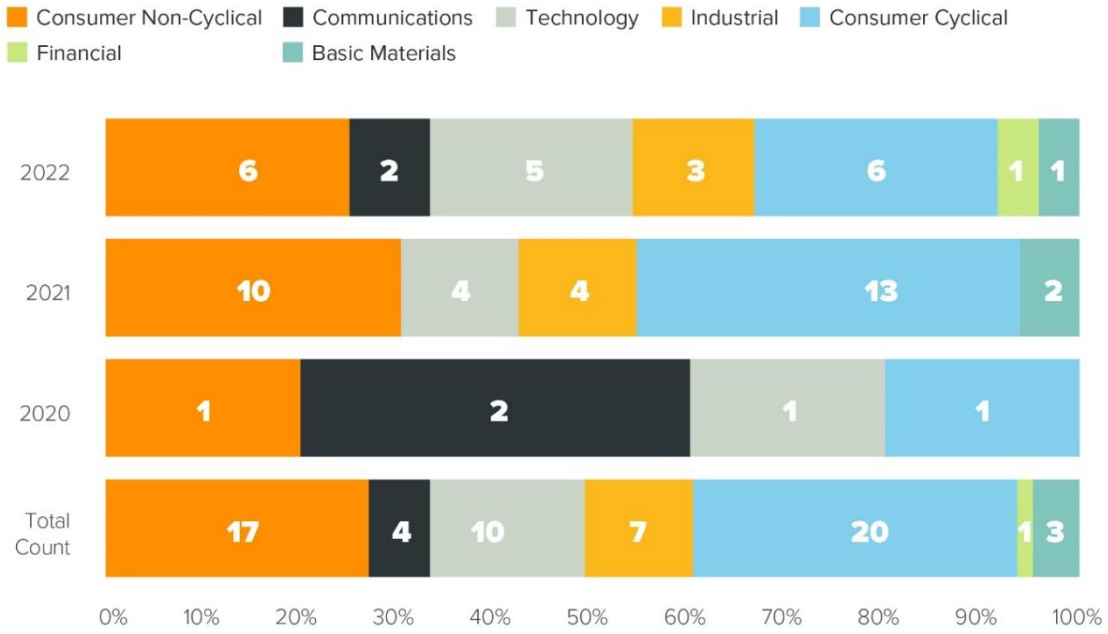
[8] Cornerstone Report, at 4.

[9] *See, e.g.*, *Salzberg v. Sciabacucchi*, 227 A.3d 102 (Del. 2020); *Wong v. Restoration Robotics, Inc.*, 78 Cal. App. 5th 48 (2022), review denied (July 27, 2022).

[10] *See* Cornerstone Report, at 30 (documenting 65 filings against companies in the consumer non-cyclical industry, followed by 28 filings against companies in the consumer cyclical industry).

In addition, as depicted in **Figure 2** below, the consumer non-cyclical sector was one of the two sectors (along with the consumer cyclical sector) most commonly targeted in federal SPAC-related class action filings in 2022, with six total federal class actions filed against life sciences companies.[11]

Figure 2: Filings by Industry — Core Federal SPAC Filings



Consumer Non-Cyclical Sector Core Federal Filings				
	2020-2022	2020	2021	2022
Biotechnology	2	0	2	0
Pharmaceuticals	1	0	1	0
Healthcare	4	0	3	1
Other (Consumer Non-Cyclical)	10	1	4	5
Total Consumer Non-Cyclical Filings	**17**	**1**	**10**	**6**

[11] Cornerstone Report, at 10.

The percentage of cases filed against life sciences companies in 2022 that were dismissed by year-end remained consistent with the year-end dismissal rate from 2021. Specifically, as detailed in **Figure 3** below, showing case status as of December 31, 2022, 11.1% of federal core filings against life sciences companies filed in 2022 were dismissed by December 31, 2022, compared to a 11.1% year-end dismissal rate in 2021 for federal core filings against life science companies filed that year.[12]

Figure 3 : Pharmaceutical, Biotechnology, and Healthcare Subsectors — Core Federal Filings

Year	Filings	Circuit					Case Status				
		1st	2nd	3rd	9th	Other	Percent Dismissed	Percent Settled	Percent Remanded	Percent Ongoing	Percent Trial
2006	25	0	5	3	3	14	44.0%	56.0%	0.0%	0.0%	0.0%
2007	29	0	11	2	7	9	58.6%	41.4%	0.0%	0.0%	0.0%
2008	25	5	5	2	2	11	40.0%	60.0%	0.0%	0.0%	0.0%
2009	22	1	1	2	11	7	36.4%	63.6%	0.0%	0.0%	0.0%
2010	33	3	7	2	15	6	45.5%	51.5%	3.0%	0.0%	0.0%
2011	21	0	5	0	6	10	57.1%	38.1%	4.8%	0.0%	0.0%
2012	28	2	5	5	5	11	57.1%	42.9%	0.0%	0.0%	0.0%
2013	34	2	10	5	11	6	41.2%	58.8%	0.0%	0.0%	0.0%
2014	38	3	8	11	11	5	52.6%	47.4%	0.0%	0.0%	0.0%
2015	42	6	4	5	18	9	52.4%	38.1%	7.1%	0.0%	2.4%
2016	65	5	22	8	20	10	44.6%	46.2%	1.5%	7.7%	0.0%
2017	65	7	17	15	13	13	60.0%	35.4%	3.1%	1.5%	0.0%
2018	56	3	15	11	15	12	53.6%	32.1%	0.0%	14.3%	0.0%
2019	62	3	23	12	11	13	45.2%	35.5%	0.0%	19.4%	0.0%
2020	51	1	12	9	21	8	49.0%	19.6%	0.0%	31.4%	0.0%
2021	55	1	13	9	20	12	20.0%	5.5%	1.8%	72.7%	0.0%
2022	45	2	16	5	10	12	11.1%	2.2%	0.0%	86.7%	0.0%
Average (1997–2021)	37	3	8	5	10	11	45.2%	44.9%	1.0%	8.8%	0.1%

Note: Sectors and subsectors are based on the Bloomberg Industry Classification System. Average figures may not sum due to rounding.

[12] Goodwin 2021 Year in Review: Securities Litigation Against Life Sciences Companies, at 7, available at https://www.goodwinlaw.com/-/media/files/publications/2021-year-in-review--securities-litigation-against.pdf.

As in past years, we have continued to focus our Year in Review on jurisdictions that are epicenters for life sciences companies and, thus, have been among the most active jurisdictions in the country for securities class actions filed against such companies: the First Circuit and District of Massachusetts; the Second Circuit and New York District Courts; the Third Circuit and the District of New Jersey (added to our Year in Review in 2021); and the Ninth Circuit and California District Courts. As in 2021, the Second and Ninth Circuits were particularly active in 2022, accounting for 69% of all core federal class action filings (across all industries) — a 3% decline from 2021 but still significantly higher than the 1997-2021 average of 55%.[13]

In 2022, federal courts in the jurisdictions of our focus once again issued several significant, detailed decisions in securities class actions against life sciences and healthcare companies in various growth stages and their directors and officers. As in prior years, these cases involve disclosures concerning issues that life sciences and healthcare companies often face, including negative clinical trial results, enrollment issues and clinical trial delays, discussions with the FDA, supply and manufacturing issues, drug side effects, adverse events and other safety issues, acquisition-related activity, and future growth prospects and revenue projections. We have highlighted and summarized a selection of key decisions in each of these jurisdictions below.

The decisions in these jurisdictions were a mixed bag in 2022 for life sciences companies. For example, of the decisions resolving motions to dismiss, the majority were favorable to defendants — but nearly a third denied the motion in whole or in part, allowing the case to proceed to discovery. Moreover, nearly a quarter of the decisions granting motions to dismiss gave the plaintiffs another opportunity to replead their dismissed claims, continuing a trend in these jurisdictions — particularly in the federal district courts of California — of giving plaintiffs leeway to amend their deficient pleadings multiple times. Consistent with prior years, of the complaints that were dismissed, most of the dismissals were based on a failure to adequately plead scienter, with a failure to plead a materially misleading statement or omission coming in a close second.

[13] Cornerstone Report, at 31.

First Circuit

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

Plaintiffs alleged that Karyopharm Therapeutics, Inc. (Karyopharm), and certain of its officers violated the 1934 Act by making misleading statements regarding the safety and toxicity of Karyopharm's STORM (Selinexor Treatment of Refractory Myeloma) study. Specifically, plaintiffs challenged two of Karyopharm's public statements, alleging that: (1) its statements that Selinexor's safety profile in the study was "predictable and manageable," and the most common adverse events were "nausea, vomiting, fatigue, and reduced appetite," purposefully omitted information about the prevalence and severity of these adverse events; and (2) its statement that the study was a "significant step in establishing the efficacy and safety" of the drug falsely described Selinexor results as positive. The district court dismissed the complaint for failing to plead facts supporting a strong inference of scienter. On appeal, the First Circuit affirmed on other grounds, holding that Karyopharm's statement that the study represented a "significant step" was nonactionable puffery, expressing "vague optimism about a product's future." Further, the court found that Karyopharm's statements about the predictability and manageability of the drug's safety profile were not misleading because no reasonable investor would interpret those statements to mean the drug was benign; the patients in the test were severely ill and facing a real risk of death from multiple myeloma; and Karyopharm had regularly made other, more fulsome disclosures about Selexinor's safety and the trial's adverse events in the company's Form 10-Ks. Because "it is not a material omission to fail to point out that of which the market is already aware," the court held, plaintiffs did not plausibly allege a material omission.

City of Miami Fire Fighters' & Police Officers' Retirement. Trust v. CVS Health Corp., 46 F.4th 22 (1st Cir. 2022)

Plaintiffs alleged that CVS Health Corporation (CVS Health) and certain of its officers violated the 1934 Act by making material misstatements about the financial health of CVS Health's newly acquired subsidiary, Omnicare, which made up the bulk of the company's long-term care (LTC) business segment. Specifically, plaintiffs alleged that CVS Health's "escalating disclosure of difficulties with the LTC business and write-downs of goodwill came too late," rendering statements made by senior management materially misleading. The district court dismissed the amended complaint in full, holding that plaintiffs failed to allege any materially false or misleading statements. Plaintiffs then moved the district court to reconsider, attaching a proposed second amended complaint, which the district court denied. Plaintiffs appealed both decisions, which the First Circuit affirmed. In particular, the First Circuit emphasized that the amended complaint "fail[ed] to allege sufficiently specific facts about the state of the LTC business at particular points in time to enable us to conclude that any of the goodwill write-downs were too late or that any of defendants' alleged misstatements contradicted the state of that business as it then stood." The court also denied plaintiffs' request to amend given that plaintiffs had not moved to amend after receiving CVS Health's motion to dismiss, and, to the extent that plaintiffs conducted additional investigation during the motion to dismiss briefing, plaintiffs did not alert the court to that investigation or seek to file a new amended complaint until after the decision had issued.

Leung v. bluebird bio, Inc., No. 21-cv-10335-DJC, 2022 WL 1192801 (D. Mass. Apr. 21, 2022)

Plaintiffs alleged that bluebird bio, Inc. (bluebird) and certain of its officers violated the 1934 Act for material misstatements concerning the timeline of bluebird's Biologics License Application (BLA) for its drug product LentiGlobin, developed to treat sickle cell disease. Specifically, plaintiffs alleged that bluebird intentionally misled investors in advance of a capital raise when it disclosed that it had reached "general agreement with FDA" concerning the clinical data package required to support the BLA and that it would seek "accelerated [BLA] approval" for the drug, without disclosing the insufficiency of the application's comparability plan. Plaintiffs further alleged that, despite its knowledge of public FDA guidance concerning comparability plans, bluebird submitted a comparability plan it knew the FDA was "highly likely to reject" given a change in bluebird's manufacturing process. The court granted defendants' motion to dismiss in full, holding that plaintiffs had failed to plead facts supporting an inference of scienter and failed to identify a materially false or misleading statement or omission. The court further found that most of the challenged statements were immunized under the PSLRA's safe harbor. With respect to scienter, the court found that (1) bluebird's officers' statements that the FDA had requested additional comparability data (pushing back the BLA timeline) did not support an inference that defendants intentionally or recklessly disregarded the comparability's plan deficiency; (2) the FDA guidance was not binding and therefore did not put bluebird on notice of an imminent rejection; and (3) the company's upcoming capital raise was insufficient to establish scienter. The court further pointed to bluebird's ample cautionary statements about the possibility that the FDA would respond unfavorably to the BLA, noting that such "full and prompt disclosure . . . further undercut[s] any inference of fraudulent intent." With respect to materially false and misleading statements, the court found that plaintiffs alleged no contemporaneous facts demonstrating that bluebird knew or should have known that the FDA would require additional comparability analysis, and that the alleged misstatements were generally protected as forward-looking statements accompanied by adequate cautionary language.

Shash v. Biogen Inc., No. 21-cv-10479, 2022 WL 4134479 (D. Mass. Sept. 12, 2022)

Plaintiffs alleged that Biogen, Inc. (Biogen) and certain of its officers violated the 1934 Act by making misleading statements concerning Biogen's post hoc analyses of topline data for the Phase 3 clinical trial of the company's Alzheimer's disease treatment, aducanumab. In particular, plaintiffs alleged that defendants' statements concerning the trial's application for FDA approval, specifically about clinical outcomes, dose-dependent responses, and secondary endpoints, were misleading because Biogen manipulated topline results and ignored an alternative post hoc analysis, prepared by the FDA's statistical reviewer, which was inconsistent with Biogen's analysis. The court granted defendants' motion to dismiss in full, finding many of the challenged statements to be nonactionable puffery. It further found the remaining statements to be interpretations of clinical trial data, which amounted to nonactionable statements of scientific opinion, reflecting Biogen's "genuine conclusions" about the Phase 3 data. Finally, the court was unpersuaded by plaintiffs' allegations that Biogen acted with requisite scienter merely because it "must have had knowledge that an alternative or conflicting view existed."

In re Boston Scientific Corp. Securities Litig., No. 20-cv-12225, 2022 WL 17823837 (D. Mass. Dec. 20, 2022)

Plaintiffs alleged that Boston Scientific Corporation (Boston Scientific) and certain of its officers violated the 1934 Act by making misleading statements regarding the commercial success and "viability" of Boston Scientific's valve replacement device, the Lotus Edge. Specifically, plaintiffs alleged that Boston Scientific hid both "technical failures" and lackluster sales from the device's launch and provided investors with materially misleading reassurances that the device was safe, easy to use, and marketable. The court granted defendants' motion to dismiss in part, finding the majority of the challenged statements to be nonactionable puffery. However, the court found that certain statements made by Boston Scientific's CEO, indicating that the device was a strategic investment and "growth driver," were sufficiently alleged to be misleading, in part because the statements were closely followed by an announcement that Boston Scientific was recalling the device. Based largely on this timing, the court held that plaintiffs adequately alleged scienter by demonstrating that the CEO, in his capacity as an executive, knew or would have "paid at least attention to" facts about the product's imminent recall prior to making his statements. Plaintiffs were similarly successful in alleging loss causation for one of the challenged statements, based on a corrective disclosure stating that the recall "set[ ] the company back after it was expected that Lotus Edge would be a 'major growth engine,'" which directly mirrored the CEO's prior statements and precipitated a stock drop.

Second Circuit

Arkansas Public Employees Retirement System v. Bristol-Myers Squibb Co., 28 F.4th 343 (2d Cir. 2022)

Plaintiffs alleged that Bristol-Myers Squibb Co. (Bristol-Myers) and certain of its officers violated the 1934 Act by misleading investors to overestimate the prospect of success of a clinical trial for a PD-1 protein checkpoint inhibitor, now called Opdivo. Bristol-Myers conducted this trial to determine whether Opdivo would be more effective than chemotherapy in treating non-small cell lung cancer, based on a population of patients that Bristol-Myers described as "strongly" expressing a second protein, PD-L1. This expression level was relevant because research on PD-1 checkpoint inhibitors shows that the higher a patient's PD-L1 expression, the more effective a checkpoint inhibitor should be as a cancer treatment. The trial ultimately failed to meet its primary goal.

In announcing that its clinical trial failed to meet its primary goal, Bristol-Myers disclosed for the first time that the trial's PD-L1 expression threshold was 5%, and stated that the trial may have had a greater chance of success had this threshold been higher. The district court granted defendants' motion to dismiss, and the Second Circuit affirmed, holding that investors failed to adequately allege a material misstatement or omission or facts giving rise to a strong inference of scienter. Specifically, plaintiffs' allegation that Bristol-Myers misled investors by calling 5% a "strong" expression of PD-L1 was defeated by the fact that there was no industry consensus on what constituted "strong" expression, with various other studies choosing a threshold of 1%, 5%, or 10%. And although Merck & Co.'s successful trial for its PD-1 inhibitor used a 50% threshold for "strong" PD-L1 expression, that was disclosed long after Bristol-Myers had designed its trial. The Second Circuit further held that Bristol-Myers had no duty to disclose every detail of a clinical trial, especially given the commercial sensitivity of this information, and as such the company's nondisclosure of the specific threshold was not a material misstatement. Further, many of the challenged statements were either forward-looking statements about the trial's predicted success, accompanied by cautionary statements, or nonactionable statements of opinion concerning the strength of the trial's design. Finally, the Second Circuit held that there was no showing of scienter, as: (1) there was no industry understanding as to what constituted "strong" expression of PD-L1; (2) sales of shares by individual defendants were made at a similar rate to prior periods or pursuant to stock trading plans; and (3) Bristol-Myers' reaction to the failed trial, including the departure of high-level employees responsible for the trial, was likely to reflect the importance that Bristol-Myers placed on the drug, and not indicative of scienter.

In Re Chembio Diagnostics, Inc. Securities Litigation, 586 F. Supp. 3d 199 (E.D.N.Y 2022)

Plaintiffs alleged that Chembio Diagnostics Inc. (Chembio), certain Chembio officers and directors, and Chembio's underwriters for a secondary public offering violated the 1933 Act and 1934 Act based on allegedly misleading statements regarding the accuracy of Chembio's COVID-19 antibody test made in press releases, conference calls with stockholders, and Chembio's registration statement for the secondary offering. Chembio's test was granted Emergency Use Authorization (EUA) by the FDA, but the EUA was later revoked due to accuracy issues, causing Chembio's stock price to drop. The court granted defendants' motion to

dismiss in part and denied it in part. The court first dismissed the 1934 Act claims for failure to adequately plead a strong inference of scienter, holding that even if the individual defendants were aware of data suggesting the antibody test was not 100% accurate, the facts alleged failed to support an inference that defendants knew the EUA would be revoked. The court further held that plaintiffs' claims under the 1933 Act against Chembio and its directors and executive officers sounded in fraud and therefore required plaintiffs to plead intentionally false and misleading statements in Chembio's registration statement. Holding that the complaint failed to do so for substantially the reasons the complaint failed to plead scienter under the 1934 Act, the court also dismissed the 1933 Act claims against Chembio and its directors and officers. However, the court declined to dismiss the 1933 Act claims against the underwriter defendants — which claims sounded in negligence rather than fraud — for the underwriters' role in preparing the registration statement, because the registration statement contained statements about the test's accuracy that were contradicted by data that could call into question the EUA.

City of Sterling Heights Police & Fire Retirement System v. Reckitt Benckiser Grp. PLC, 587 F. Supp. 3d 56 (S.D.N.Y. 2022)

Plaintiffs alleged that Reckitt Benckiser Group PLC (Reckitt) and certain of its officers violated the 1934 Act by making positive statements about the commercial success of Reckitt's opioid treatment, Suboxone Film, without disclosing that, among other things, Reckitt was engaged in a coercive and deceptive marketing scheme to portray Suboxone Film as safer than and preferable to Suboxone tablets to artificially increase sales. The court granted in part and denied in part defendants' motion to dismiss. It held that, while certain statements at issue in the complaint concerning Reckitt's culture, relationships with physicians and patients, and growth opportunities were nonactionable puffery, other statements, including statements regarding Suboxone Film's commercial success, were rendered misleading by the alleged deceptive marketing scheme. With respect to scienter, the court dismissed claims against certain Reckitt officers for failure to raise a strong inference of scienter, but it held that the complaint adequately pleaded that Reckitt and certain other officers knew facts contradicting their public statements, in light of allegations concerning (1) Reckitt's criminal indictment and $1.4 billion fine; (2) Reckitt's $50 million antitrust settlement with the FTC; (3) the FDA's revocation of Suboxone's orphan-drug designation; and (4) guilty pleas of multiple Reckitt officers, including its CEO. The court held that the complaint adequately pleaded loss causation by plausibly alleging that the stock price drop was related to the alleged misstatements in light of the fact that Reckitt's stock price dropped each time the company disclosed information about government actions. The court rejected defendants' "truth on the market" defense, holding that the public information that defendants argued reflected the market's awareness of the allegedly omitted information did not sufficiently counterbalance the misleading disclosures, including because defendants had publicly denied wrongdoing for years and because specific information about Reckitt's alleged anticompetitive behavior was not publicly known until the announcement of multimillion-dollar penalties resulting from government investigations. Finally, the court rejected defendants' argument that the claims were barred by the statute of limitations for similar reasons.

Rice v. Intercept Pharmaceuticals, Inc., No. 21-cv-0036 (LJL), 2022 WL 837114 (S.D.N.Y. Mar. 21, 2022)

Plaintiffs alleged that Intercept Pharmaceuticals, Inc. (Intercept), and certain of its former officers violated the 1934 Act by failing to disclose information material to the safety, continued use, and regulatory approval of

Ocaliva, a drug used to treat liver disease. Specifically, plaintiffs alleged that, during the class period, Intercept disclosed that the FDA had accepted Intercept's NDA for Ocaliva for the treatment of a common nonalcoholic steatohepatitis but failed to disclose safety risks known to Intercept and identified by the FDA, instead only generally disclosing that Intercept was in discussions with the FDA. The court granted in full defendants' motion to dismiss. As to statements made before May 2020, plaintiffs alleged that Intercept failed to disclose adverse events in patients using Ocaliva, but the court held that the complaint did not plausibly allege that this nondisclosure was material, as these were discrete, low-threshold adverse events not necessarily connected to the use of the drug, nearly all of which were publicly available on the FDA's adverse event database. As to Intercept's alleged failure to disclose an FDA safety investigation, the court held that the potential risk identified was not material, as the FDA classified this only as a potential risk to investigate further, with no conclusion about a plausible link to the drug. The court found that this information was especially immaterial as the FDA investigation was focused on a different subset of liver disease than the subset for which Intercept was seeking FDA approval. The court additionally found that plaintiffs failed to specifically allege facts rendering other statements that Intercept made materially false or misleading. The court also found that plaintiffs failed to adequately plead scienter, as (1) the timing of stock sales was not unusually timed, nor did such sales result in unusual profit; and (2) any misrepresentations as to safety risk, even if they did demonstrate scienter, were not material. Finally, the court found that plaintiffs had failed to plead loss causation, as they failed to allege any facts connecting the nondisclosure of safety risks or the FDA investigation with the decline in Intercept's stock price.

In re AstraZeneca PLC Securities Litig., No. 21-cv-722, 2022 WL 4133258 (S.D.N.Y. Sept. 12, 2022)

Plaintiffs alleged that AstraZeneca plc (AstraZeneca) and certain of its officers violated the 1934 Act by making statements that misleadingly failed to disclose certain information about AstraZeneca's Phase 2/3 clinical trial for the company's COVID-19 vaccine candidate, including information about alleged dosing and trial design issues, patient population issues, and the likelihood of FDA approval of the vaccine. The court granted defendants' motion to dismiss for failure to adequately plead an actionable misrepresentation, holding that (1) AstraZeneca had no generalized duty to disclose every negative fact during an ongoing clinical trial; (2) AstraZeneca did not mislead investors about the patient population or dosing by disclosing general facts about the trial; (3) AstraZeneca's general positive comments about the vaccine trial, including that the trial was on track and that the company pledged to "follow the science," were nonactionable puffery; and (4) AstraZeneca's optimistic statements about regulatory approval were forward-looking and accompanied by cautionary language. The court held that, while AstraZeneca's COVID-19 vaccine was later shown to be less effective than other vaccines, the complaint did not plead with particularity anything beyond nonactionable allegations of fraud by hindsight.

Cachia v. BELLUS Health Inc., No. 21-cv- 02278, 2022 WL 4367444 (S.D.N.Y. Sept. 21, 2022)

Plaintiff alleged that BELLUS Health Inc. (Bellus) and certain of its officers and advisors violated the 1933 Act and 1934 Act by misleading investors about the design, enrollment, and potential for success of a Phase 2 clinical trial for a drug to treat chronic cough. Specifically, plaintiff alleged that Bellus failed to disclose that its trial enrolled patients with a lower cough frequency than competitors' trials — an alleged design flaw creating a

high risk that Bellus' trial would fail — in order to generate investor support and raise funds in connection with Bellus' initial public offering in the US.

The court granted defendants' motion to dismiss in its entirety, holding that plaintiff did not identify any false statement or omission that made any statement misleading. The court noted that, "as a matter of law," a plaintiff "cannot use hindsight and securities laws as tools to 'second guess how clinical trials [were] designed and managed.'" Further, the court found, Bellus' public filings did in fact disclose the ways in which the company's trial was similar to and different from those of competitors in design and enrollment criteria, so investors "had the information to discern the differences between the trials and determine whether investing in Bellus was prudent." The court also held that Bellus' statements about the anticipated results of the trial were speculative, nonactionable statements of opinion qualified by adequate cautionary language. Finally, the court held that plaintiff failed to plead scienter, as: (1) plaintiff's contention about Bellus' need for fundraising was general, and "attenuated" from FDA approval for the drug at issue, which would be far in the future regardless of Phase 2 trial results; and (2) there was no indication that Bellus did not believe its clinical trial would be successful.

In re Allergan PLC Securities Litigation, No. 18-cv-12089, 2022 WL 17584155 (S.D.N.Y. Dec. 12, 2022)

Plaintiffs alleged that Allergan PLC (Allergan) and certain of its officers violated the 1934 Act by making false and misleading statements that gave investors a false impression that Allergan's textured breast implants — which were recalled from the European market at the end of the class period, leading to a decline in Allergan's stock price — were no more linked to a rare form of cancer (BIA-ALCL) than textured implants manufactured by other companies. The court had previously, in 2019, denied in part defendants' motion to dismiss. In this decision, following discovery, the court granted defendants' motion for summary judgment in full and dismissed the case for failure to present evidence that: (1) defendants made any false or misleading statement; (2) any alleged misstatements were material; and (3) the alleged misstatements caused plaintiffs' losses. First, the court held that plaintiffs failed to demonstrate that any of the statements at issue were false or misleading. Specifically, the court found that certain of the statements were not comparative in nature and would not have been perceived by reasonable investors to suggest that Allergan's textured breast implants were safer than those manufactured by other companies; Allergan's statements did not create a duty to disclose the relative incidence of BIA-ALCL for its product versus competitor products; plaintiffs failed to show that Allergan's textured breast implants had not been used safely for years; the studies relied on by plaintiffs to show that Allergan's textured breast implants were more dangerous than those of other manufacturers did not speak to the relative incidence of BIA-ALCL, only to total reported cases by manufacturer; and defendants were not on notice of a subsequent recall at the time of the statements. Second, the court held that plaintiffs failed to present evidence that any of the alleged misstatements were material, including because textured implants represented less than 1% of Allergan's total revenue, and BIA-ACLC is rare relative to the total number of women receiving breast implants and is rarely fatal. Finally, the court held that plaintiffs failed to demonstrate loss causation because the recall that led to the stock price decline was based on concerns about textured implants as a category, not on the safety of Allergan's textured implants relative to those of other manufacturers.

Third Circuit

Lungu v. Antares Pharma Inc., No. 21-1624, 2022 WL 212309 (3d Cir. Jan. 25, 2012)

Plaintiffs alleged that Antares Pharma Inc. (Antares) and three senior officers and directors violated the 1934 Act by making materially false and misleading statements relating to product safety during the FDA approval process of Xyosted, the company's treatment candidate for testosterone replacement therapy. Plaintiffs alleged that four statements were misleading in light of adverse events suffered by patients: (1) that Xyosted was a "virtually painless treatment"; (2) that "the most common adverse reactions (incidence ≥5%) were, among other things, increased hypertension" and one reported case each of worsening depression, vertigo, and suicide; (3) that "nothing unusual" occurred with the FDA's review of Xyosted; and (4) that "anyone … diagnosed with testosterone deficiency" is the "perfect candidate for Xyosted and that there isn't any particular patient population . . . that we're excluding." The district court dismissed the complaint in full and the court of appeals affirmed, holding that none of these statements were actionably misleading. First, the court held that the existence of potential adverse reactions did not implicate the statement that Xyosted is a virtually painless treatment. Second, the court held that defendants disclosed the risk of hypertension and were not under any duty to disclose the rate of hypertension (including how much greater than 5% the risk of hypertension was), suicide, or any other adverse reaction. Moreover, plaintiffs failed to allege that Xyosted actually caused depression. Third, the court held that the statement that nothing unusual occurred during the FDA's review was an opinion about the timing of Xyosted's regulatory milestones and did not speak to the content or substance of the FDA's review, and there was no reason to believe Antares' CEO did not genuinely believe what he was saying. Finally, the court held that the statement that "anyone" would be "the perfect candidate" was nonactionable corporate puffery, and the statement that there was no patient population "that we're excluding" was immaterial because it did not alter the total mix of relevant information available to a reasonable investor.

In Re: Amarin Corporation PLC Securities Litigation, No. 21-2071, 2022 WL 2128560 (3d Cir. June 9, 2022)

Plaintiffs alleged that Amarin Corporation, PLC (Amarin), and certain of its officers violated the 1934 Act by making misleading statements in Amarin's announcement of topline results from a Phase 3 trial of its heart disease drug, Vascepa. Plaintiffs asserted three theories of liability, alleging that: (1) the topline results failed to disclose information about the mineral oil placebo in the trial that may have exaggerated the benefits of Vascepa; (2) Amarin put information regarding the mineral oil placebo "in play" and therefore had a duty to disclose further information when announcing the trial's topline results; and (3) Amarin's disclosures in its SEC filings reiterated theoretical risks regarding the mineral oil placebo but failed to disclose that these risks already showed signs of manifesting. The district court dismissed the complaint in full, and the court of appeals affirmed, holding that each of plaintiffs' theories failed. First, the court held that certain opinion statements at issue did not lack a reasonable basis and that Amarin's SEC filings disclosed the risk that mineral oil as a placebo may exaggerate the effect of Vascepa, so the opinion statements could not be a basis for liability. Second, the court held that Amarin's disclosure of the topline results did not put in play the full trial data or additional information about the mineral oil placebo because the disclosures did not make affirmative characterizations regarding the effectiveness of the placebo. Finally, the court held, not only did plaintiffs fail to identify statements in Amarin's SEC filings that were materially false or misleading, but the risk disclosed in these filings had not actually materialized at the time the statements were made.

Paxton v. Provention Bio, Inc., 2022 WL 3098236, No. 21-cv-11613 (D.N.J. Aug. 4, 2022)

Plaintiffs alleged that Provention Bio, Inc. (Provention), and certain officers violated the 1934 Act by making material misrepresentations concerning teplizumab, the company's type 1 diabetes drug candidate, regarding (1) the alleged inadequacy of a bridging study undertaken to demonstrate the biosimilarity of teplizumab manufactured at a facility in Ireland and manufactured at a facility in Seattle; (2) alleged enrollment deficiencies and safety issues in a clinical trial; and (3) alleged manufacturing deficiencies. The court granted defendants' motion to dismiss in full, holding that the complaint failed to adequately plead either a misleading statement or a strong inference of scienter. With respect to the alleged misleading statements, the court held that Provention's statements about the adequacy of the bridging study were statements of opinion for which Provention had a reasonable basis; Provention had no duty to disclose non-final discussions with the FDA; Provention publicly disclosed the enrollment criteria of its clinical trial; Provention disclosed the risks of its reliance on third-party manufacturers; and Provention had no duty to disclose potential safety issues observed by members of an FDA advisory committee because interpretation of data is a question of opinion. With respect to scienter, the court held that the complaint's allegations were conclusory and failed to show that Provention executives knew or were reckless in not knowing about deficiencies at the company's manufacturing facility; and that Provention disclosed the risks at issue, rather than covering them up.

Laasko v. Endo Int'l PLC, 2022 WL 3444038, No. 20-cv-07536 (D.N.J. Aug. 17, 2022)

Plaintiffs alleged that Endo International PLC (Endo) and certain officers violated the 1934 Act by making materially false or misleading statements that failed to disclose the company's alleged campaign to obstruct opioid-related litigation and misrepresented the company's financial condition. The court granted defendants' motion to dismiss in full. First, the court held that the complaint failed to plead any actionable misleading statements. Specifically, statements that Endo was vigorously defending against opioid litigation were not rendered misleading by Endo's alleged discovery misconduct; Endo had no obligation under the securities laws to disclose further details about litigation already in the public domain; and decisions favorable to Endo in the opioid litigation undermined the allegation that the company was not defending itself vigorously. Second, the court held that statements about Endo's liquidity risk and cash reserves were protected because they were forward-looking and accompanied by meaningful cautionary language. Finally, the court held that statements about the company's business, operational, and compliance policies were mere puffery that a reasonable investor would not rely on and/or nonactionable opinion. The court also held that plaintiffs failed to plead facts giving rise to a strong inference of scienter, holding that (1) defendants signing Sarbanes-Oxley certifications, without more, did not establish scienter; (2) allegations that one defendant's bonus and resignation were suspiciously timed were insufficient as the bonus was performance-based and there were no allegations linking his resignation to the alleged fraud; (3) allegations that Endo's discovery violations supported scienter failed for a lack of nexus between defendants' state of mind and the alleged materially false or misleading statements; and (4) allegations of meetings at the highest level during which opioid litigation was discussed were speculative and did not support a core operations theory of scienter.

Ninth Circuit

In re Nektar Therapeutics Securities Litigation, 34 F.4th 828 (9th Cir. 2022)

Plaintiffs alleged that Nektar Therapeutics (Nektar) violated the 1934 Act when it used an allegedly misleading chart based on outlier data from a single patient to tout a 30-fold increase in cancer-fighting cells in a Phase 1 trial for NKTR-214, a modified version of a human protein that activates the body's production of cancer-fighting cells. Nektar subsequently disclosed data from a Phase 1/2 trial that showed a less favorable response rate than the prior Phase 1 trial, causing Nektar's stock price to decline roughly 42%. Anonymous short sellers then released a report claiming that the data in the allegedly misleading chart was skewed by outlier data from a single patient, causing Nektar's stock price to drop by 7%. Plaintiffs argued that Nektar should have excluded the outlier data from the chart or should have affirmatively informed investors that the chart relied on outlier data. The district court dismissed the action with prejudice for failure to adequately plead falsity, scienter, or loss causation. On appeal, the Ninth Circuit affirmed, holding that plaintiffs failed to adequately allege falsity or loss causation. With respect to falsity, the court held that the complaint failed to provide any meaningful context or information about how the chart misled investors. In particular, plaintiffs failed to explain what the chart would have shown without the alleged outlier data or how that would have affected the investing public's assessment of the drug. With respect to loss causation, the court held that plaintiffs failed to allege a "corrective disclosure" that caused the company's stock price to drop. First, the Phase 1/2 results were not a corrective disclosure because they merely showed that results from the different and more comprehensive Phase 1/2 trial were not as promising as those from the more limited Phase 1 trial. Second, the court concluded that the anonymous short sellers' report did not constitute a corrective disclosure because the authors had financial incentives to downplay Nektar's trial drug and convince people to sell Nektar shares, meaning that investors would have taken the report's contents "with a healthy grain of salt." In closing, the court stated, "pharmaceutical companies often suffer setbacks in their clinical trials after earlier testing offered highly promising results. That is the nature of the industry, and — without more — it does not necessarily mean that a pharmaceutical company committed securities fraud."

In re Acadia Pharms. Inc. Sec. Litig., No. 18-cv-01647, 2022 WL 36493 (S.D. Cal. 2022)

Plaintiff alleged that Acadia Pharmaceuticals, Inc. (Acadia), and certain of its officers violated the 1934 Act by making false or misleading statements regarding the safety profile and commercialization of NUPLAZID, which treats hallucinations and delusions associated with Parkinson's disease psychosis (PDP). Specifically, plaintiff claimed that Acadia failed to disclose (1) data concerning serious adverse events and deaths in patients using NUPLAZID; and (2) alleged "kickback" payments that Acadia made to prescribing physicians in connection with the drug's commercialization. The court granted defendants' motion to dismiss each of plaintiff's claims with prejudice, holding that the complaint failed to adequately plead falsity. First, the court reasoned that data showing that users of NUPLAZID experienced adverse events did not mean that the drug had caused those events. As such, plaintiff failed to establish that Acadia's nondisclosure of that data created a misimpression regarding NUPLAZID's then-existing safety profile. The court relied in part on the FDA's reevaluation of the drug, which found "no new or unexpected" risks associated with NUPLAZID. Second, the court found that plaintiff had pleaded no facts to suggest that the alleged kickbacks were not in fact "legitimate payments for services" rendered in connection with Acadia's educational and promotional campaigns. The court noted that

the kickback allegations were the subject of a civil investigative demand, which resulted in the DOJ informing Acadia that it would take no further action. The reasonable inference to be drawn from the investigation's outcome, the court explained, was that the DOJ did not uncover evidence of kickbacks. The court also reasoned that a confidential witness's allegations concerning kickbacks were not supported by facts showing personal knowledge or reliability, and therefore the allegations were conclusory. Finally, the court held that plaintiff failed to raise his claim that certain directors' resignations were related to alleged kickbacks "from possible to plausible." Given that the court had previously granted a motion to dismiss and provided "ample time and opportunity to amend," the court dismissed the complaint without leave to amend.

In re BioMarin Pharmaceutical Inc. Sec. Litig., No. 20-cv-06719, 2022 WL 164299 (N.D. Cal. January 6, 2022)

Plaintiffs alleged that BioMarin Pharmaceutical, Inc. (BioMarin), and several of its executives violated the 1934 Act by making false or misleading statements concerning BioMarin's relationship and interactions with the FDA and the approval timeline for a new gene-based hemophilia therapy, Valrox. Specifically, BioMarin stated publicly that it was "working very closely" and "quite collaboratively" with the FDA and that approval for Valrox was "on track." The complaint alleged that those statements were false or misleading because (1) the entirety of BioMarin's contact with the FDA during the class period was limited to a singular, "deeply worrying" meeting in which the FDA raised concerns about adverse results from Valrox's Phase 3 trials; and (2) BioMarin knew but did not disclose to investors that the FDA's inspection of the company's facility, one of the conditions precedent for final approval, would be delayed. When the FDA ultimately denied accelerated approval of the therapy, BioMarin's share price dropped substantially. As detailed below, the court denied defendants' motion to dismiss and ordered them to answer the complaint.

First, in their motion to dismiss, defendants argued that cautionary language in the company's disclosures brought the challenged statements within the scope of the PSLRA's safe harbor provision. The court rejected this argument, holding that the purported cautionary language was not sufficiently "targeted or tailored" to caution investors that the precise statements that plaintiffs challenged "were qualified, incomplete, untrue, or otherwise misleading," as the PSLRA requires. Specifically, the purported cautionary language merely addressed general concerns such as problems associated with novel gene therapies, new FDA rules, and COVID-19. Second, defendants argued that the alleged misrepresentations regarding the approval process were accurate because BioMarin believed the FDA was going to meet the relevant deadline at the time. The court disagreed, noting that plaintiffs' position was not that the deadline absolutely would not be met, but rather that the statements were misleading because BioMarin projected that approval would be granted despite alleged knowledge of concrete risks that approval would be denied. Third, the court rejected defendants' argument that BioMarin's optimistic statements concerning its relationship with the FDA amounted to nonactionable puffery, because the statements were undergirded by factual assertions such as timelines for approval and inspections. Accordingly, the court denied defendants' motion to dismiss.

Kim v. Allakos Inc., No. 20-cv-01720, 2022 WL 976974 (N.D. Cal. Mar. 31, 2022)

Plaintiffs alleged that Allakos Inc. (Allakos) and certain of its officers violated the 1934 Act by making material misrepresentations concerning the design and administration of Allakos' Phase 2 drug trial relating to AK002, a drug that Allakos was developing to treat diseases including eosinophilic gastritis and eosinophilic gastroenteritis. Plaintiffs' claims arose from a report published by short seller Seligman Investments — which criticized Allakos' drug trial based on interviews with trial investigators and social media posts by trial participants and their families in a private Facebook group — causing a 17% decline in Allakos' stock price. Based on the report, plaintiffs alleged that, contrary to the company's statements, Allakos did not employ a contract research organization (CRO), the drug trial was not properly blinded, and patients were treated inconsistently with steroids. The court dismissed the complaint with leave to amend. The court held that no reasonable investor could have been misled by Allakos' statement that it generally relied on "third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators" to conduct its clinical trials, because Allakos did in fact rely on third parties, if not a CRO. Addressing allegations that the company's description of the trial as a "randomized, double blind, placebo-controlled" study was misleading, the court found that "even if the allegations regarding the alleged failures in methodology were true, these underlying allegations would merely support questioning the efficacy of the study and would not render the company's statements false or misleading." Furthermore, the court held that plaintiffs failed to allege facts sufficient to support the supposed failures in the trial methodology, because the social media posts cited in the report revealed that trial participants could only speculate as to whether they received a placebo, and the fact that some patients experienced reactions was consistent with any other blinded trial. Finally, the court held that plaintiffs' contention that the drug trial's outcome may have been affected negatively by patients' use of steroids was a critique of the design of the study rather than proof of any actionable misrepresentation or omission, because the company disclosed patients' use of steroids.

Habelt v. iRhythm Techs., Inc., No. 21-cv-00776, 2022 WL 971580 (N.D. Cal. Mar. 31, 2022)

Plaintiffs alleged that iRhythm Technologies, Inc. (iRhythm), and certain of its executives violated the 1934 Act by making false or misleading statements concerning risks that iRhythm faced in connection with a regulatory process to set Medicare reimbursement rates for one of the company's products, an ambulatory electrocardiogram device designed to diagnose cardiac arrythmias. After several intervening decisions, the Centers for Medical and Medicaid (CMS) issued a final rule that declined to set a national price for the device but endorsed a rate that was significantly lower than it had been in the past. As a result, iRhythm's share price fell sharply. The court dismissed the complaint with prejudice, finding that amendment would be futile because the complaint's central theory was defective.

Specifically, plaintiffs alleged that defendants' statements were false or misleading because iRhythm failed to disclose certain "threats" and "risks" that the company faced in its attempts to maintain or increase the Medicare reimbursement rates. According to the complaint, the company allegedly knew that, in the past, CMS had rejected pricing proposals similar to the one that iRhythm had submitted to the agency. Defendants argued that the challenged statements were not actionable because they were made in the context of a regulatory proceeding, they were nonactionable puffery, they were not material, and/or they were protected by PSLRA's safe harbor provision. The court agreed with defendants, holding that the challenged statements were not

actionable because they contained adequate warnings and were made within the context of ongoing and "unpredictable" regulatory proceedings. As the court viewed it, plaintiffs' basic theory of the case was that the ultimate outcome of the CMS proceedings was "knowable and absolutely certain," and that defendants therefore knew their pricing proposal to CMS was "destined to fail." Contrary to plaintiffs' theory, the court found that iRhythm had "accurately warned investors" that the company could not "assure any particular outcome" from the proceedings. Accordingly, reliance on the company's statements would be "inherently unreasonable," the court reasoned, and would amount "sheer speculation."

In re Fibrogen, Inc., No. 21-cv-02623, 2022 WL 2793032 (N.D. Cal. July 15, 2022)

Plaintiffs alleged that FibroGen, Inc. (FibroGen), and several of its executives violated the 1934 Act by falsely representing the safety and efficacy data of Roxadustat — FibroGen's flagship drug for treatment of anemia in patients with chronic kidney disease — and falsely assuring investors that the safety data was derived pursuant to FDA-sanctioned analysis. In April 2021, FibroGen issued a public "clarification of certain prior disclosures" concerning safety analyses from Phase 3 trials, which revealed certain "post-hoc" manipulations to Roxadustat's clinical data. Without the manipulations, the clinical data indicated that Roxadustat was less effective and less safe than the placebo and an existing treatment, and carried serious risks of adverse medical events. The company's share price fell by nearly half in two days, and weeks later, upon review of the unmanipulated data, the FDA voted unanimously to deny the NDA for Roxadustat. The court granted in part and denied in part defendants' motion to dismiss.

In their motion to dismiss, defendants argued that alleged misstatements concerning potential FDA approval and whether Roxadustat would receive a "black box" label (the FDA's most severe safety warning) were forward-looking and accordingly inactionable under the PSLRA's safe harbor. The court disagreed because the statements were specifically grounded in existing clinical studies and prior meetings with the FDA. Defendants also argued that several of the challenged statements were simply expressions of corporate optimism, on which investors do not rely. The court disagreed because defendants' expressions of confidence were made in the context of discussing the safety analyses of the existing data and therefore were premised on facts. However, the court granted defendants' motion to dismiss a handful of opinion statements that were "general statements not premised on factual misrepresentations."

Pardi v. Tricida, Inc., No. 21-cv-00076, 2022 WL 3018144 (N.D. Cal. July 29, 2022)

Plaintiffs alleged that Tricida, Inc. (Tricida), and its CEO violated the 1934 Act by making false or misleading statements concerning a meeting with the FDA and the location of Tricida's drug trial relating to veverimer, a drug intended to slow the progression of chronic kidney disease. Specifically, plaintiffs alleged that (1) statements that the drug trial took place in "Europe" failed to disclose that the trial took place in *Eastern* Europe, which carried a risk that the FDA would find that the trial data were not sufficiently representative of the US patient population or medical practice; (2) defendants' description of the study as a "multicenter" study was misleading because defendants knew that data from one clinical site with high enrollment had a disproportionate impact on the trial's results; and (3) defendants disclosed certain information discussed in a meeting with the FDA while omitting discussions regarding whether the trial data was applicable to the US population. The court granted in part and denied in part defendants' motion to dismiss.

With respect to the first category of alleged misstatements, the court held that plaintiffs failed to allege scienter because nothing about the claimed problems relating to the applicability of the foreign clinical data met the high standard of being "so obvious" that defendants must have known that their literally true use of the word "Europe" would be misleading. Similarly, with respect to the second category, there were no allegations supporting a strong inference that defendants intended to mislead or were deliberately reckless in labeling the trial as "multicenter," particularly because the trials were in fact conducted at 47 different sites. However, with respect to the third category of alleged misstatements (concerning the subject of the company's meeting with the FDA), the court held that plaintiffs adequately alleged scienter because once defendants chose to tout allegedly positive discussions with the FDA, they were bound to do so in a manner that wouldn't mislead investors as to potentially negative issues from that same discussion. Accordingly, the court denied defendants' motion to dismiss with regard to the alleged omissions concerning the FDA meeting, while granting plaintiffs leave to amend their other claims.

Sneed v. AcelRx Pharmaceuticals Inc., No. 21-cv-04353, 2022 WL 4544721 (N.D. Cal. Sept. 28, 2022)

Plaintiffs alleged that AcelRx Pharmaceuticals, Inc. (AcelRx), and certain of its investors violated the 1934 Act by omitting information concerning the company's marketing of DSUVIA, an opioid painkiller. The action stemmed from a warning letter from the FDA indicating that two of AcelRx's promotional materials — a banner advertisement and a tabletop display — made "false or misleading claims and representations about the risks and efficacy of DSUVIA" and therefore violated the Federal Food, Drug, and Cosmetic Act. When AcelRx disclosed this letter soon after receipt, the company's stock price fell 8.37%. Pointing to the warning letter, plaintiffs alleged that defendants made false or misleading statements or failed to disclose information indicating that (1) AcelRx failed to implement and/or maintain sufficient disclosure controls and procedures regarding the marketing of DSUVIA; (2) as a result, the company engaged in the misbranding violations; and (3) the company was therefore subject to increased risk of regulatory investigations or enforcement actions. The court granted defendants' motion to dismiss without prejudice, allowing plaintiffs leave to amend.
The court held that plaintiffs failed to allege falsity with respect to many alleged misstatements because the alleged misstatements were not related to the misbranding violations, and plaintiffs' explanation as to how those statements were false or misleading had no connection to the substance of the statements. The court also held that plaintiffs failed to adequately allege scienter, in part because plaintiffs failed to allege that defendants' sales of thousands of shares of stock the day they received the FDA warning letter were "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information."

In re Talis Biomedical Corp. Sec. Litig., No. 22-cv-00105, 2022 WL 17551984 (N.D. Cal. Dec. 9, 2022)

Plaintiffs alleged that Talis Biomedical Corporation (Talis) and certain of its executives and directors violated the 1933 Act and the 1934 Act by making false or misleading statements concerning Talis One, a molecular diagnostic platform for COVID-19 tests. Among other things, plaintiffs challenged certain disclosures concerning (1) the company's application for an Emergency Use Authorization (EUA) from the FDA; (2) the accuracy and functionality of the Talis One platform; and (3) the company's readiness to produce Talis One on a commercial scale. The court dismissed the complaint with leave to amend. The court held that plaintiff failed

to adequately allege that many of the statements at issue were false or misleading because the complaint primarily relied on statements by former employees that were conclusory, based on vague hearsay and rumors, vague or silent as to time period, or opinions without factual support. In addition, the court held that many of the challenged statements were protected by the bespeaks caution doctrine because the company's registration statement included fulsome risk disclosures. Accordingly, the court dismissed the complaint with leave to amend and "encourage[d] plaintiffs to add as much specificity as possible to cure the defects identified in [the court's] order."

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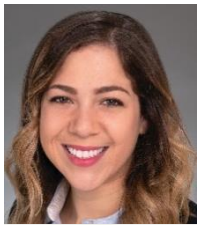

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