

Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies

2018 Edition

Dechert
LLP



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Introduction

Although 2018 saw a slight decrease in class action securities litigation on the whole, life sciences companies were, once again, popular targets of such lawsuits. Prudent life sciences companies should continue to take heed of the results of last year's decisions and filings to ensure that they are aware of the recent developments in the law as well as filing trends.

In 2018, plaintiffs filed a total of 86 class action securities lawsuits against life sciences companies. While the filings in 2018 represented a 2% decrease from the previous year, it was still more than a 3.5 times increase from only five years prior. Of these cases, the following trends emerged:

- Consistent with historic trends, the majority of suits were filed in the Second, Third and Ninth Circuits, with a decrease in suits filed in the Third Circuit, and the District of New Jersey in particular. The Third Circuit managed to remain in the top three because the District of Delaware saw a 250% increase in filings due to merger litigation.
- Three law firms were associated with more than half of the filings against life sciences companies: Glancy Prongay & Murray LLP (17 complaints), Pomerantz LLP (17 complaints), and The Rosen Law Firm (16 complaints).
- A roughly equal numbers of claims were filed in the first half of 2018 as in the second half, with 26 complaints filed in the first quarter alone.
- Six cases were filed against non-U.S. issuers headquartered in three countries: three are headquartered in Ireland, two are headquartered in Canada and one is headquartered in Israel.

An examination of the types of cases filed in 2018 reveals continuing trends from previous years, with some additional developments.

- About 20% of claims involved alleged misrepresentations regarding product efficacy and safety, with many of these cases involving alleged misrepresentations regarding negative side effects related to leading product candidates, which could at times impact the likelihood of FDA approval.
- About 14% of the claims arose from alleged misrepresentations regarding regulatory hurdles, such as the timing of FDA approval or the sufficiency of applications submitted to the FDA.
- Approximately 30% of the claims alleged unlawful conduct in both the United States and abroad, including illegal kickback schemes, anticompetitive conduct, and inadequate internal controls in financial reporting.
- About a third of the claims involved alleged misrepresentations of material information made in connection with proposed mergers, sales and other transactions.

In addition to an increase in filings, courts throughout the country issued a large number of decisions in 2018 involving life sciences companies, including:

- Claims that arose in the development phase, such as cases involving products failing clinical trials that are required for FDA approval or products not approved by the FDA, all of which resulted in dismissal.
- Claims that were independent of or arose after the development process, with which defendants also tended to have success in dismissing the claims.
- Claims based on the financial management of life sciences companies, which generally split between plaintiff- and defense-friendly outcomes.

Given the numbers from this and recent years' filings, there is no indication that the filings of securities claims against life sciences companies are going to slow down any time soon. The decisions this year resulted in mixed outcomes, with 40 opinions decided in favor of defendants, 10 opinions denying motions to dismiss, and 15 opinions in which only partial dismissals were achieved. Accordingly, in 25 of the 65 decisions in 2018 that Dechert reviewed, the plaintiffs' claims were allowed to proceed. These numbers illustrate how life sciences companies remain attractive targets for class action securities fraud claims and thus companies should continue to stay abreast of recent developments and implement best practices to reduce their risk of being targeted.

Life sciences companies remain popular targets for securities fraud litigation

In recent years, life sciences companies have increasingly been targets of securities fraud lawsuits, and 2018 was no exception. This survey is intended to give a comprehensive overview of life sciences securities lawsuits in 2018. First, we analyze the number of cases filed, including trends relating to the location filed, types of companies that are targeted, and parallels between the underlying claims. Next, we analyze the life sciences securities decisions rendered in 2018 and how they impact the legal landscape of these types of claims. Finally, we set forth issues and best practices life sciences companies should consider to reduce the risk of being subject to such suits.

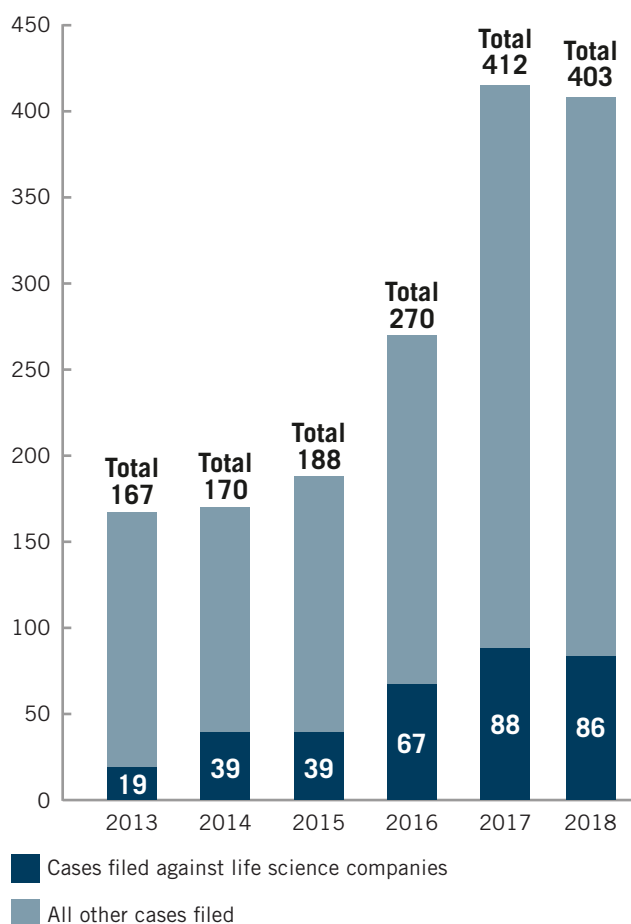
Slightly Decreased Filings

The number of securities fraud class action lawsuits in general has been increasing steadily over the last few years, but it seems to have reached a plateau in 2018. After five consecutive years of steady growth, the total number of securities fraud class action lawsuits filed in 2018 took a slight downturn, topping out at 403 – 9 less than the 412 securities fraud suits filed by the end of 2017.¹ However, the 2018 total is still 236 more than the 167 total class action securities complaints filed in 2013, a mere five years ago.²

As the number of securities lawsuits has decreased slightly, so too has the number of such lawsuits involving life sciences companies. A total of 86 class action securities lawsuits were filed against life sciences companies in 2018, a 2.3% decrease from 2017's 88 actions, but still more than a 350% increase from 2013's 19 actions.³

Figure 1

Number of class action securities fraud cases filed from 2013–2018 (Total cases filed compared to cases filed against life science companies)



1. Throughout this survey, data from prior years is derived from Dechert LLP's 2017 survey on the same topic. David Kistenbroker, Joni Jacobsen, Angela Liu, Dechert Survey: Developments in securities fraud class actions against U.S. life sciences companies, Dechert LLP (Feb. 1, 2018). The number of securities fraud class actions filed and decided in 2018, as well as the number of those brought against life sciences companies, are based on information reported by the Securities Class Action Clearinghouse in collaboration with Cornerstone Research, Stanford Univ., Securities Class Action Clearinghouse: Filings Database, SECURITIES CLASS ACTION CLEARING HOUSE (last visited January 28, 2019). This survey includes litigation and cases involving drugs, devices, deal litigation, and hospital management.

2. 403 represents an increase of 141.3% from 2013's 167 filings; see also Cornerstone Research, Securities Class Action Filings: 2018 Year in Review.

3. 86 is a decrease of 2.3% over 88 and an increase of 353% over 19.

The decreased number of filings in 2018 did not result in a corresponding decrease in the number of dispositive court decisions. Based on our research, in 2018, there were a total of 65 class action securities fraud dispositive decisions involving life sciences companies.⁴

Filing trends

Over the past year, the number of class action securities fraud claims filed against life sciences companies experienced a decrease in number, just missing last year's total by only two filings. In 2018, one out of every five securities fraud class action suits was brought against a life sciences company.⁵ While the number of filings slightly decreased in 2018, common patterns from previous years emerged once again, particularly in relation to when and where suits were filed, and the claims involved. The past year did, however, bring about new and noticeable variations within these larger trends.

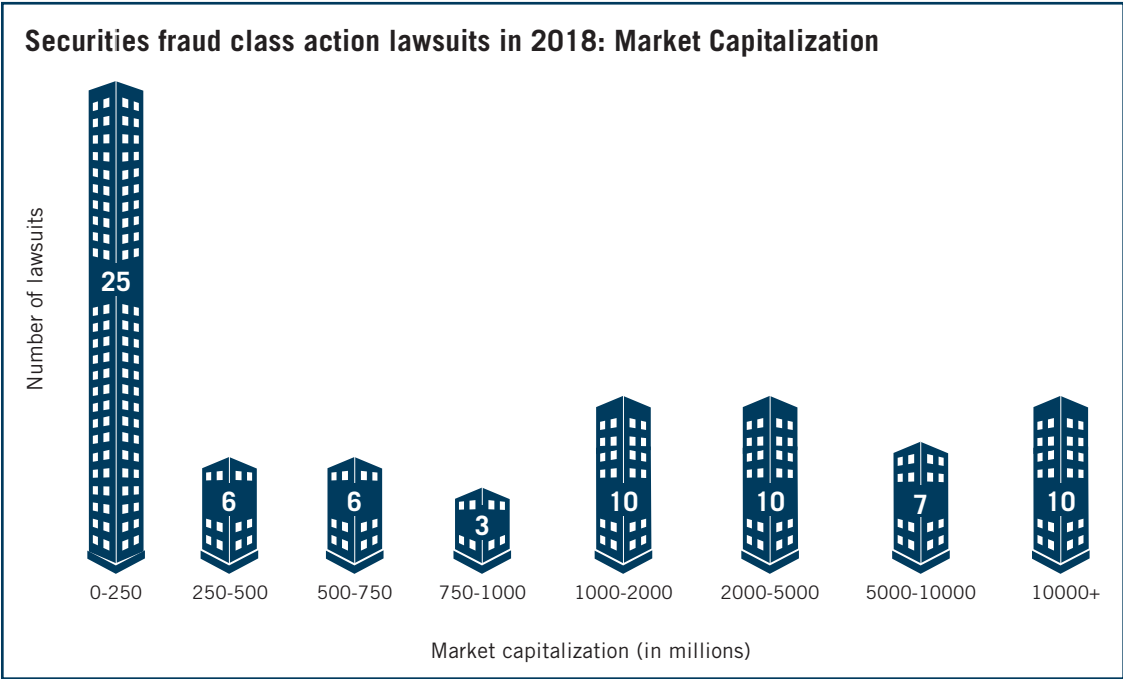


4. The 65 decisions were handed down in 64 different securities class action cases. The cases were compiled by filtering all Securities Class Action Clearinghouse filings by Healthcare and identifying cases that involved potentially dispositive orders between January 1 and December 31, 2018. In many cases, amended complaints were filed following motions to dismiss being granted. Numerous other cases concluded with settlements, voluntary dismissals before any court order, and similar dispositions in 2018; these are not included in the tally.

- **Rise in claims against large cap companies.** In 2018, about 60% of the life sciences companies named in class action securities fraud complaints had a market capitalization of US\$500 million or over.⁶ This is a new filing trend that emerged in 2018.⁷ Most notably, almost half of the total cases filed were against life sciences companies with a market cap of US\$1 billion or more.⁸ Of these complaints, almost half were filed against companies with a market cap of US\$5 billion or more,⁹ making up over a fifth of the total cases filed.¹⁰ Thus, companies with large market capitalizations have become a popular target for class action lawsuits in 2018.

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- 5. 86 filings out of a total of 403 is 21.3%. The 86 filings were tallied by filtering all Securities Class Action Clearinghouse filings by Healthcare, then sorting them by life sciences company named as defendant. Securities Class Action Clearinghouse in collaboration with Cornerstone Research, Stanford Univ., Securities Class Action Clearinghouse: Filings Database, SECURITIES CLASS ACTION CLEARINGHOUSE, (last visited Feb. 1, 2019). The filings include litigation and cases involving drugs, devices, financial management, deal litigation, and hospital management. Cases that were subsequently consolidated or amended were only counted once, unless the subsequent filing received a new docket number, in which case both filings were counted separately.
 - 6. In 2018, 78 different life sciences companies were named in class action securities fraud complaints. Of these, 77 companies had available market capitalization data as of the date of filing. Of those 77 companies, 46 had a market capitalization of US \$500 million or more, or 59.7%. Market capitalization figures are current as of January 25, 2019, and were compiled with Yahoo! Finance and Bloomberg. Yahoo! Finance, YAHOO.COM, (last visited January 18, 2019); Bloomberg, BLOOMBERG, (last visited January 25, 2019).
 - 7. In 2017, 44.3% of class action securities fraud claims against life sciences companies were filed against large cap companies.
 - 8. In 2018, 37 of 77 were filed against these companies, or 48.1%. In 2017, this number was 24 out of 79, or 30.4%.
 - 9. In 2018, 17 of the 37 complaints filed against life sciences companies with a market cap of at least US\$1 billion were against life sciences companies with a market capitalization of US\$5 billion or more, or 45.9%.

Figure 2



- **Shakeup in the distribution of venue in complaints filed in the Third Circuit.** Consistent with historic trends, the majority of the 86 class action securities fraud suits brought against life sciences companies were filed in three federal circuits: the Ninth Circuit with 24, the Third Circuit with 18, and the Second Circuit also with 18. District courts in California had the most filings, with 21 overall and 15 in the Northern District of California alone. New York was once again the second most popular state with 18 total filings, 11 of which were in the Southern District of New York. While nearly half of all cases were brought in the federal district courts in these two states (an increase from 2017), this is still a notable decrease from 2016.¹¹ The Third Circuit, while accounting for the second most filings against life sciences companies in 2018, saw a shift in the distribution of filings among its federal district courts: New Jersey with eight, and Delaware with seven.¹²
- **Three law firms were associated with more than half of filings against life sciences companies.** In 2018, the two firms with the most filings of securities fraud lawsuits against life sciences companies were Glancy Prongay & Murray LLP and Pomerantz LLP. Both were listed as counsel on 17 complaints respectively, or 40% of all cases filed,¹³ and were each selected as lead or co-lead counsel in seven cases. The Rosen Law Firm had the third most filings in 2018, accounting for 16 of the complaints filed, and serving as lead or co-lead counsel in six. In comparison, in 2017, the three firms which filed the most securities fraud suits against life science companies were Levi & Korsinsky, Pomerantz LLP, and The Rosen Law Firm.

10. 17 of 77 is 22.1%.

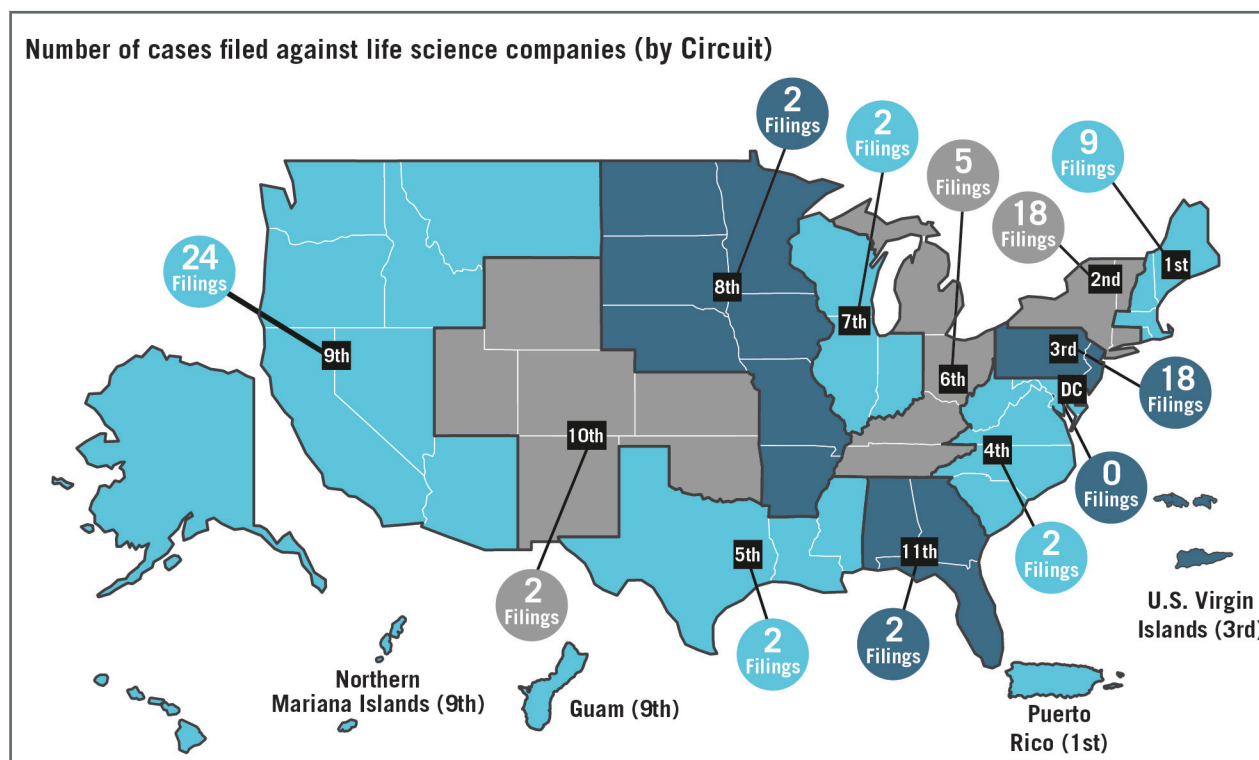
11. In 2016, 36 of 67 cases were filed in district courts in California and New York, or 53.7%. In 2017, this number was 35 out of 88, or 39.8%. In 2018, this number was 39 of 86, or 45.3%.

12. In 2018, eight of the 18 filings brought in the Third Circuit were brought in New Jersey district courts, or 44%, and seven of those 18 were brought in Delaware, or 38.9%. In 2017, 13 of the 23 filings in the Third Circuit were

brought in district courts in New Jersey, or 56.5%, and 2 of those 23 were brought in Delaware, or 8.7%.

13. 34 of 86 is 39.5%.

Figure 3



- **About equal numbers of claims were filed in the first half of 2018 as in the second half.** Of the 86 complaints filed against life sciences companies in 2018, 42 were filed in the first half of the year, and 44 were filed in the second half. When broken down by quarter, 26 complaints were filed in the first quarter, 16 in the second, 22 in the third, and 22 in the fourth. This even distribution of filings between the first and the second halves of the year is in contrast with the filing trends in securities fraud class action lawsuits more broadly over the past two years.¹⁴ It seems that this trend is continuing in 2019, as only eight complaints were filed in the first three weeks of 2019.

These figures are generally consistent with historic trends overall, but there were some notable changes in 2018. There was a significant increase in cases filed against companies with market capitalizations of over US\$500 million — with those against companies with market caps over US\$5 billion accounting for over a fifth of the total cases filed. Consistent with recent years, three federal circuits dominated filings in terms of quantity, but the distribution of federal filings among the states within those circuits changed, as federal filings in

New Jersey decreased while Delaware saw a proportional increase. Overall, life sciences companies continue to be a popular target for class action securities fraud claims.

Causes of Action

While there was merely a slight decrease in the total number of filings brought against life sciences companies in 2018, the allegations unique to complaints against life sciences companies were consistent in previous years. Deal litigation was also at the forefront of issues relating to life sciences companies.

Similar to previous years, one group of cases filed against life sciences companies in 2018 involved allegations unique to life sciences companies: misrepresentations regarding product efficacy and safety, especially negative side effects of leading product candidates, which could at times impact the likelihood of FDA approval.¹⁵ Nektar Therapeutics, for example, was sued for its failure to disclose negative test results for a leading drug candidate, NKTR-214.¹⁶ Nektar issued a press release announcing allegedly false results

14. In 2017, 56 of 88 securities fraud class action complaints filed against life sciences companies were filed before the end of June, or 63.6%.

15. Such suits comprised 19 of 86 of the cases filed, or 22.1%.

16. Compl., Mulquin v. Nektar Therapeutics, No. 4:18-cv-06607-HSG ¶¶ 2-5 (N.D. Cal. Oct. 30, 2018).

for a study into NKTR-214, touting its success.¹⁷ A few months later, Nektar filed with the SEC its Form 10-K, which, according to the complaint, similarly advertised the success of NKTR-214.¹⁸ On October 1, 2018, Plainview, a hedge fund, published a report debunking Nektar's statements about the efficacy of NKTR-214, and indicating that NKTR-214 resulted in a 0% objective response rate in its studies, while its studies of nine similar drugs resulted in objective response rates ranging from 15% to 29%.¹⁹ After the release of Plainview's report, Nektar's stock price fell 9.24% and plaintiffs filed suit.²⁰

Another group of complaints unique to life sciences companies arose from alleged misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA.²¹ For example, investors sued CV Sciences, Inc. for allegedly failing to disclose that the company's patent application had been rejected multiple times by the US Patent and Trademark Office.²² CV Sciences' chief pharmaceutical product is a chewing gum meant to treat smokeless tobacco use and addiction.²³ Plaintiffs allege that CV Sciences misled them by stating that the product was patent-pending and

had "a favorable development roadmap for this important combination drug candidate."²⁴ But according to Plaintiffs, in reality, the product was not patent-pending, and the USPTO had already made both its non-final and final rejection of CV Sciences' patent application.²⁵ Citron Research, a securities research firm specializing in identifying fraud, allegedly uncovered CV Sciences' deception and published a report exposing it, leading stock prices to fall more than 60%.²⁶

Another group of complaints alleged other unlawful conduct, including illegal kickback schemes, anticompetitive conduct, and other forms of financial malfeasance.²⁷ Four of these complaints alleged that life sciences companies were involved in anticompetitive and collusive activities.²⁸ Two complaints were brought against the same CEO while he served at two separate companies, alleging that he caused

17. Id. at ¶ 23.

18. Id. at ¶ 25.

19. Id. at ¶ 32-38.

20. Id. at ¶ 39. See also, e.g., Compl., Kakkar v. Bellicum Pharm., Inc., No. 4:18-cv-00338 ¶¶ 2-8 (S.D. Tex. Feb. 6, 2018) (alleging that defendants made false or misleading statements regarding undisclosed risk of encephalopathy for the company's leading drug candidate, causing stock to drop 25.85% when the FDA placed a hold on drug trials following three cases of encephalopathy); Compl., Watkins v. Solid BioSciences, Inc., No. 1:18-cv-10587-MLW ¶¶ 2-8 (D. Mass. Mar. 27, 2018) (alleging that defendants made false or misleading statements in the company's IPO prospectus regarding the efficacy of the company's lead drug candidate, causing stock to drop over 60% when the FDA placed a clinical hold on drug trials after a patient was hospitalized); Am. Compl., Bailey v. Esperion Therapeutics, No. 3:18-cv-11438-RHC-EAS ¶¶ 2-10 (E.D. Mich. Oct. 22, 2018) (alleging that defendants "recklessly disregarded substantial safety and tolerability issues" with its lead drug candidate in inflating expectations about its efficacy, causing stock prices to drop when 14 people died in its Phase 3 clinical trial).

21. Such suits comprised 13 of the 86 cases filed, or 15.1%.

22. Compl., Smith v. CV Sciences, Inc., No. 2:18-cv-01602-JAD-PAL (D. Nev. Aug. 24, 2018) (Amended Complaint filed January 4, 2019).

23. Id. at ¶ 3.

24. Id. at ¶ 26.

25. Id. at ¶¶ 21-24.

26. Id. at ¶¶ 35-37; see also, e.g., Compl., Shi v. Ampio Pharm., Inc., No. 2:18-cv-07476 ¶¶ 24-25 (C.D. Cal. Aug. 25, 2018) (alleging that defendants repeatedly made false statements about the prospects of FDA approval, despite having already failed two pivotal clinical trials and having the third trial declared inadequate); Compl., Tomaszewski v. Trevena, Inc., No. 2:18-cv-04378-CMR ¶¶ 2-6 (E.D. Pa. Oct. 10, 2018) (alleging that defendants misled investors by overstating prospects for FDA approval, causing the stock price to drop 64% when the FDA released a briefing document rebutting defendant's claims); Compl., Odeh v. Immunomedics, Inc., No. 2:18-cv-17645-MCA-LDW ¶¶ 15-24 (D.N.J. Dec. 27, 2018) (alleging that defendants misled investors by overstating prospects for FDA approval).

27. Such complaints comprised 25 of the 86 filings reviewed, or 29.1%. Fifteen of these 25 cases involved allegations of false or misleading statements due to material weaknesses in life sciences companies' internal controls over financial reporting.

28. Consol. Compl., In re Henry Schein, Inc. Sec Litig., No. 1:18-cv-01428-MKB-VMS ¶¶ 3-13 (E.D.N.Y. Sep. 14, 2018) (alleging that defendants artificially inflated the company's stock price by colluding with competitors to fix profit margins, causing shareholders to lose \$2.75 billion in value when the scheme was revealed); Am. Compl., Plymouth County Ret. Sys. v. Patterson Cos., No. 0:18-cv-00871-MJD-SER ¶¶ 2-16 (D. Minn. Nov. 9, 2018) (alleging that defendants artificially inflated the company's stock price by colluding with competitors to collectively boycott purchasing organizations in the dental industry, causing shareholders to lose \$700 million when the FTC filed an antitrust complaint); Compl., Evanston Police Pension Fund v. McKesson Corp., No. 3:18-cv-06525 ¶¶ 2-7 (N.D. Cal. Oct. 25, 2018) (alleging that defendants artificially inflated the company's stock price by colluding with competitors, causing the stock price to drop after the authorities began an investigation); Compl., Boynton Beach General Employees' Pension Plan v. Dentsply Sirona, Inc., No. 2:18-cv-07253 ¶¶ 2-13 (E.D.N.Y. Dec. 19, 2018) (alleging that

a trusted financial magazine to publish positive (but false) articles about companies he owned, and forbade the authors to disclose their compensation.²⁹

Last, and notably, nearly one third of the class action securities fraud claims filed against life sciences companies in 2018 alleged the companies made misrepresentations and omissions in SEC filings related to proposed mergers, sales and other transactions.³⁰ Ignyta, Inc., for example, was sued by stockholders for alleged material misrepresentations and omissions made in a Solicitation/Recommendation Statement requesting that stockholders tender their shares in favor of a merger with Roche Holdings, Inc.³¹ Ignyta is a life sciences company focused on developing and commercializing therapies for treating cancer patients.³² One such therapy Ignyta had in development, entrectinib, had just been fast-tracked in Europe.³³ While developing entrectinib, Ignyta

defendants artificially inflated the company's stock price by colluding with competitors, causing the stock to drop after the SEC announced it was opening an investigation).

29. Compl., *Steinberg v. OPKO Health, Inc.*, No. 1:18-cv-23786-JEM ¶¶ 17-21 (S.D. Fla. Sept. 14, 2018) (alleging that defendants caused Seeking Alpha to publish at least two misleading articles to artificially inflate stock prices, thereby allowing the CEO to receive financial incentives); Compl., *Pepe v. CoCrystal Pharma, Inc.*, No. 2:18-cv-14091-KM-JBC ¶¶ 29-55 (D.N.J. Sept. 20, 2018) (same).

30. Such suits comprised 37 of 86 of the cases filed, or 43.0%. See also Compl., *Kent v. Abaxis, Inc.*, No. 3:18-cv-03834-WHA ¶¶ 31-39 (N.D. Cal. June 27, 2018) (alleging that defendants made material omissions and misrepresentations regarding EBITDA listed in the company's proxy statement asking stockholders to approve a merger); Compl., *Brown v. K2M Group Holdings, Inc.*, No. 1:18-cv-01567-UNA ¶¶ 2-7 (D. Del. Oct. 11, 2018) (alleging that defendants made "incomplete and misleading" statements concerning the company's financial projections, which were developed by the company's financial adviser in rendering the company's fairness opinion in its proxy statement asking stockholders to approve a merger); Compl., *Adlard v. OvaScience, Inc.*, No. 1:18-cv-12332-WGY ¶¶ 2-4 (D. Mass. Nov. 6, 2018) (alleging that defendants made misleading statements concerning the company's financial projections and potential conflicts of interest in the company's proxy statement asking stockholders to approve a merger).

31. Compl., *Wimberly Ventures, LLC v. Ignyta, Inc.*, No. 18-CV-0082 BEN BGS ¶¶ 1-4 (S.D. Cal. Jan. 12, 2018).

32. *Id.* at ¶ 27.

33. *Id.* at ¶¶ 29-30.

34. *Id.* at ¶ 31.

engaged various pharmaceutical companies in discussions regarding the licensing rights of entrectinib.³⁴ Foregoing six written offers for entrectinib's licensing rights, Ignyta entered into an agreement with Roche, under which Roche offered to purchase Ignyta for \$27 per share.³⁵ After having the fairness of the trade approved by Bank of America Merrill Lynch, Ignyta filed a Recommendation Statement with the SEC in which it asked stockholders to approve the sale.³⁶ Stockholders sued Ignyta, alleging the Recommendation Statement made material omissions and misrepresentations that prevented them from making an informed decision whether to tender their shares or seek appraisal.³⁷ The alleged misrepresentations related to Ignyta's financial projections, the sales process culminating in the sale, the valuation performed by the various banks involved, and potential conflicts of interest with Ignyta's insiders.³⁸

The common themes of these complaints show the unique challenges life sciences companies face as issuers, but also the commonalities with securities litigation filings on the whole. First, these filings continue to show that negative side effects in clinical trials can create a claim for securities fraud when management attempts to conceal or downplay these effects, subsequently overstating the trial's results and prospects of FDA approval. The filings also continue to indicate that companies cannot inflate investors' expectations of FDA approval and must ensure that the company's risk disclosures and cautionary warnings are robust, and, as important, that executives' statements regarding the likelihood of approval are measured and in no way misleading. Last, the filings show life sciences companies also face challenges similar to those faced by other issuers, particularly challenges relating to disclosures in the sale or merger of life sciences companies.

While these filings show that life sciences companies face unique challenges when it comes to securities fraud, they also reveal how these companies are still at risk for more common forms of securities fraud claims as well.

35. *Id.* at ¶¶ 31-40.

36. *Id.* at ¶¶ 40-41.

37. *Id.* at ¶ 46.

38. *Id.* at ¶ 47.

39. See *supra* note 4.

2018 Class Action Securities Fraud Decisions in the Life Sciences Sector

In 2018, courts continued the trend of issuing a large number of securities fraud decisions involving life sciences companies. Dechert identified 65 such decisions in 2018, falling into three broad categories: (i) cases involving claims that arose in the development phase, such as cases involving products failing trials that required for FDA approval or products is not approved by the FDA; (ii) cases involving claims that arose independent of or after the development process; and (iii) cases involving financial management of life sciences companies.³⁹ As in 2017, most of these decisions addressed claims based on Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

Court decisions regarding alleged misrepresentations during product development

Although the life sciences space can be incredibly rewarding, life sciences companies continue to face significant risk during the development of a drug or device. If a drug or device performs well during trials and is approved, it may become a success in the market and will thus benefit patients, the company that developed it, and the company's investors. But if a drug or device fails its clinical trials, or if the FDA decides not to approve it, life sciences companies can expect plaintiffs' firms to start mining public filings and building (oftentimes) meritless cases based on alleged mischaracterizations or exaggerations of trial results. More often than not, when the FDA decides not to approve a company's NDA, the company's stock drops and the company faces securities class action lawsuits.

In 2018, courts issued opinions in dozens of securities fraud class actions relating to life sciences companies. Of the 65 opinions we analyzed from 2018, 25 related to alleged misrepresentations that companies made while a drug was being developed. In some cases, stock prices dropped after companies announced that a drug or device performed poorly in a clinical trial, leading to claims that the company misrepresented test results to artificially inflate stock prices. In others, plaintiffs allege that companies

made misrepresentations with respect to the likelihood of a drug or device being approved, including by withholding or mischaracterizing advice or warnings from the FDA during the development process.

Court decisions involving stock drops following clinical trials

Although life sciences companies and investors surely would prefer that all clinical trials were successful, the reality is that sometimes a drug or device that seemed promising at the outset will underperform or fail during clinical trials. When this happens, plaintiffs' firms file securities fraud class action claims to recover for the alleged harm to investors, usually by claiming that the company developing the drug or device somehow misled the public. Fortunately for life sciences companies, courts tend to reject these claims, with all of the cases falling into this category resulting in motions to dismiss being granted. In total, Dechert identified seven district court decisions from 2018 where motions to dismiss claims relating to failed clinical trials were granted,⁴⁰ and three appellate opinions where dismissals were affirmed.⁴¹

40. *Whitehead v. Inotek Pharm. Corp.*, No. 17-CV-10025-LTS, 2018 WL 4732774, at *7 (D. Mass. June 27, 2018) (dismissing claims that the company falsely stated that the performance of a drug and its expectations that trials would be successful and the drug would be approved); *In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 736 (S.D.N.Y. 2018) (dismissing claims that the company's underlying trial data contradicted its top-line data); *Patel v. Seattle Genetics, Inc.*, No. C17-41 RSM, 2018 WL 2359137, at *10 (W.D. Wash. May 24, 2018) (dismissing claims that the company failed to disclose the risk of fatal hepatotoxicity); *Erste-Sparinvest Kapitalanlagegesellschaft MBH v. Seres Therapeutics, Inc.*, No. CV 16-11943, 2018 WL 1567614, at *9 (D. Mass. Mar. 30, 2018) (dismissing claims that the company knew that a clinical trial would fail to achieve its primary endpoint); *Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 501 (S.D.N.Y. 2018) (discussed herein); *In re Stemline Therapeutics, Inc. Sec. Litig.*, 313 F. Supp. 3d 543, 551 (S.D.N.Y. 2018) (dismissing claims that the company failed to disclose that a patient died in a clinical trial from a side effect).

41. *Gregory v. ProNAi Therapeutics Inc.*, No. 18-1061-CV, 2018 WL 6288008, at *3 (2d Cir. Dec. 3, 2018) (refusing to dismiss claims that the company made false and misleading statements about the potential and efficacy of

Defendants frequently defeat securities class action claims by arguing that no misrepresentation was made and that they did not act with scienter, such as in *Tadros v. Celladon Corporation*.⁴² In this Ninth Circuit case, Celladon was developing a heart failure drug that was scheduled to go through clinical trials called CUPID 1 and CUPID 2.⁴³ The plaintiffs alleged that CUPID 1 was fundamentally flawed in design and execution such that its positive results gave investors the false impression that CUPID 2 would likewise be a success.⁴⁴ When CUPID 2 failed to meet its specified end points and Celladon's stock dropped precipitously, investors sued.⁴⁵

The district court granted Celladon's motion to dismiss, and the Ninth Circuit affirmed the decision.⁴⁶ The Ninth Circuit held that Celladon's statements regarding CUPID 1 were not misleading and were already part of the "total mix of information available to investors" because "the alleged flaws underlying the study and the sensitivity analysis were disclosed by defendants in a publicly accessible journal published years before Celladon went public."⁴⁷ The court went on to hold that the plaintiffs did not adequately allege scienter because they "failed to allege specific facts demonstrating that defendants acted with the intent to manipulate the clinical trial or deceive the public" and because "there [was] nothing to suggest that [Celladon's executives] did not believe in the results of the study."⁴⁸

a drug); *Tadros v. Celladon Corp.*, 738 F. App'x 448, 449 (9th Cir. 2018) (discussed herein); *In re Arrowhead Research Corp. Sec. Litig.*, 711 F. App'x 434, 436 (9th Cir. 2018) (affirming dismissal where the company incorrectly stated or implied that one trial's success was indicative that a subsequent trial would also be successful).

42. *Tadros v. Celladon Corp.*, No. 15CV1458 AJB (DHB), 2016 WL 5870002, at *14 (S.D. Cal. Oct. 7, 2016), *aff'd*, 738 F. App'x 448 (9th Cir. 2018).

43. *Id.* at *1.

44. *Id.*

45. *Id.* at *4.

46. *Id.* at *14; *Celladon*, 738 F. App'x at 448-49.

47. *Id.* at 448-49.

48. *Id.* at 449.

Courts also granted motions to dismiss based on alleged misrepresentations that were nonactionable statements of opinion.⁴⁹ In *Nguyen v. New Link Genetics Corporation*, New Link was in the process of developing a drug to treat pancreatic cancer.⁵⁰ New Link conducted a Phase 3 trial for the drug, which used both a control group and an experimental group.⁵¹ New Link told investors that it expected the control group to survive approximately 20 months on average. There were three milestones in the Phase 3 trial that would be reached, based upon a certain number of patients in the experimental group dying. Given that New Link said control group patients were expected to survive for 20 months, investors allegedly believed that if the drug was successful, milestone 1 would be reached shortly after the 20 month mark. When it took much longer for this milestone to be reached, New Link disclosed that it took so long for milestone 1 to be reached because the drug was so effective.⁵² New Link's stock price then dropped, and the plaintiffs sued, alleging that New Link intentionally underestimated the survival statistics for the control group to make it seem as if the drug was more effective than it was.⁵³

The district court granted New Link's motion to dismiss, finding that the survival estimates for the control group "stem[med] from [New Link's] interpretation of previously published studies," which "are essentially no different than opinions" because "[r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions."⁵⁴ The district court noted that "[n]one of the statements referenced in the Complaint suggest that [the defendants] lacked a sincere opinion about the estimated survival rates; to the contrary, the studies the company relied on provided a reasonable foundation from which the company

49. See, e.g., *Biondolillo v. Roche Holding Ag*, No. CV 17-4056, 2018 WL 4562464, at *8 (D.N.J. Sept. 24, 2018); *New Link*, 297 F. Supp. 3d at 501 (S.D.N.Y. 2018).

50. *New Link*, 297 F. Supp. 3d at 478.

51. *Id.* at 479.

52. *Id.* at 479-80.

53. *Id.* at 482.

54. *Id.* at 486 (third alteration in original) (quoting *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 & n.20 (S.D.N.Y. 2011)).

developed its estimates regarding the Control Group's overall survival."⁵⁵ The judge allowed the plaintiffs to amend their complaint one last time, and New Link's current motion to dismiss will likely be decided in 2019.⁵⁶

Decisions from 2018 confirm that plaintiffs bringing securities fraud class actions against life sciences companies for alleged misstatements relating to failed clinical trials have to pass a high bar for their claims to survive a motion to dismiss.

Court decisions arising out of overly optimistic statements regarding FDA approval

In addition to potential litigation if clinical trials are unsuccessful, life sciences companies are increasingly facing litigation when, despite the company's optimism as to chances of approval, drugs and devices are not approved by the FDA. In these cases, plaintiffs allege that life sciences companies made misrepresentations relating to the likelihood

that the drug or device will ultimately be approved or that they misrepresented or mischaracterized communications from the FDA regarding the odds of approval.

Fortunately for life sciences companies, courts in 2018 faced with these types of claims granted more motions to dismiss than they denied. Dechert analyzed nine opinions from 2018 where motions to dismiss were granted,⁵⁷ five opinions where the motions were denied at least in part,⁵⁸ and one appellate opinion reversing the granting of a motion to dismiss.⁵⁹

In *In re Rockwell*, for example, the court dismissed the complaint in part because the plaintiffs failed to allege any actionable misrepresentation.⁶⁰ The court reasoned in part that although the defendants made a number of optimistic statements about the "commercial viability" of a drug, none of the supposed misstatements were worded as guarantees.⁶¹ Moreover, the complaint contained no specific allegations that support an inference that the defendants did not actually

55. *Id.* at 486-87.

56. See *id.* at 501.

57. *Emerson v. Genocera Biosciences, Inc.*, No. CV 17-12137-PBS, 2018 WL 6413145, at *9 (D. Mass. Dec. 6, 2018) (dismissing claims that the company downplayed negative trial results and led investors to believe that a drug was going to complete clinical trials required for FDA approval); *Hirtenstein v. Cempra, Inc.*, No. 16CV1303, 2018 WL 5312783, at *29 (M.D.N.C. Oct. 26, 2018) (dismissing claims that the company did not disclose that a drug posed significant safety risks that concerned the FDA); *Nguyen v. Endologix, Inc.*, No. 2:17-cv-00017-AB-PLA, ECF No. 91, at 13 (C.D. Ca. Sept. 6, 2018) (dismissing claims that the company knew about problems with a device such that the device was not on track for FDA approval); *In re Innocoll Holdings Pub. Ltd. Co. Sec. Litig.*, No. CV 17-341, 2018 WL 4252537, at *11 (E.D. Pa. Sept. 5, 2018) (dismissing claims that the company misled investors and concealed information from the FDA); *In re Egalet Corp. Sec. Litig.*, 340 F. Supp. 3d 479, 515 (E.D. Pa. 2018) (dismissing claims that company failed to disclose to stockholders that the FDA was likely to grant labeling exclusivity to a competitor's drug); *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 766 (S.D.N.Y. 2018) (dismissing claims that the company misled investors concerning the timeline for a commercial launch); *In re Dynavax Sec. Litig.*, No. 4:16-CV-06690-YGR, 2018 WL 2554472, at *9 (N.D. Cal. June 4, 2018) (dismissing claims that a company misled investors because a commercial product launch of a drug was less imminent than investors were led to believe); *In re Rockwell Med., Inc. Sec. Litig.*, No. 16 CIV. 1691 (RJS), 2018 WL 1725553, at *18 (S.D.N.Y. Mar. 30, 2018) (discussed herein); *Hoey v. Insmed Inc.*, No. CV 16-4323 (FLW), 2018 WL 902266,

at *26 (D.N.J. Feb. 15, 2018) (dismissing claims that the company knew that the data supporting an application was unlikely to lead to approval by the EMA).

58. *Shanawaz v. Intellipharma Int'l Inc.*, No. 17-CV-5761 (JPO), 2018 WL 6605426, at *12 (S.D.N.Y. Dec. 17, 2018) (refusing to dismiss claims that the company made misrepresentations relating to, among other things, discussions with the FDA and the contents of an NDA); *In re Spectrum Pharm., Inc.*, No. 16-CV-02279, ECF No. 81, at 50:8-15 (D. Nev. Sept. 26, 2018) (refusing to dismiss claims that the company misled the market concerning the approval process by stating that trial results were statistically significant and by positively spinning the FDA's warning against submitting an NDA); *Cohen v. Kitov Pharm. Holdings, Ltd.*, No. 17 CIV. 0917 (LGS), 2018 WL 1406619, at *9 (S.D.N.Y. Mar. 20, 2018) (refusing to dismiss claims that the company made certain misrepresentations to create a false impression that an NDA would be approved); *In re Heartware Int'l, Inc. Sec. Litig.*, No. 16-CV-00520, ECF No. 45, at 1 (S.D.N.Y. Mar. 16, 2018) (refusing to dismiss claims that the company falsely assured investors that the FDA's concerns that it outlined in a warning letter were resolved; settled for \$54.5 million); *Gerneth v. Chiasma, Inc.*, No. CV 16-11082, 2018 WL 935418, at *8 (D. Mass. Feb. 15, 2018) (discussed herein).

59. *Dougherty v. Esperion Therapeutics, Inc.*, 905 F.3d 971, 984 (6th Cir. 2018) (discussed herein).

60. *Rockwell*, 2018 WL 1725553, at *7.

61. *Id.* at *7-8.

believe their own stated opinions or that they knowingly relied on the false statements regarding the imminent success of the drug.⁶² The court also dismissed based on a lack of scienter, noting, among other things, that the plaintiffs lacked any concrete evidence that the defendants had information contradicting their public statements about the drug.⁶³

In other cases, however, courts refused to grant motions to dismiss because the defendants did not relay information from the FDA to investors concerning odds of approval. In *Gerneth v. Chiasma, Inc.*, for example, the FDA expressed scientific disagreement to Chiasma at a pre-NDA meeting about the efficacy in the Phase 3 trial data for a drug.⁶⁴ Chiasma did not disclose these concerns prior to its initial public offering, and when the FDA later rejected Chiasma's NDA, Chiasma's stock dropped 63%.⁶⁵ The court held that the plaintiffs adequately pled material misstatements or omissions, because even though "the FDA never 'specifically requested that [Chiasma] postpone its NDA submission' due to its concerns stated at the pre-NDA meetings, . . . the allegations reflect 'subjective scientific disagreement over the efficacy of the drug [that] should be disclosed to investors.'"⁶⁶

In another case, *Dougherty v. Esperion Therapeutics, Inc.*, the Sixth Circuit reversed an order granting a motion to dismiss based, in part, on scienter.⁶⁷ In that case, after a meeting with the FDA, Esperion issued a press release stating that the FDA would not require Esperion to conduct a cardiovascular outcomes trial ("CVOT") for a drug, but said that it would have to obtain the meeting minutes from the FDA before it could answer any questions.⁶⁸ After Esperion received meeting minutes from the FDA, it issued another press release, this time saying that per the meeting minutes, the FDA encouraged Esperion to conduct a CVOT.⁶⁹ After market analysts learned that a CVOT would be required, Esperion's stock dropped 48%.⁷⁰

62. Id. at *8.

63. Id. at *13-14.

64. Gerneth, 2018 WL 935418, at *2.

65. Id. at *3.

66. Id. at *5 (alterations in original).

67. Dougherty, 905 F.3d at 983-84.

68. Id. at 976-77.

69. Id. at 977.

70. Id.

The district court granted Esperion's motion to dismiss, holding that the plaintiffs failed to adequately allege scienter because they did not "identif[y] facts demonstrating that Esperion actually understood the FDA's communications [at the meeting] in a way that was different than what was publicly disclosed [in the first press release]."⁷¹ The Sixth Circuit, however, reversed and remanded: "Esperion has offered no innocent inference stronger than Plaintiffs' inference that Esperion knowingly or recklessly made material misrepresentations or omissions in its August communications with investors. Such an innocent inference would require us to believe either that the FDA's meeting minutes do not accurately reflect what took place in the meeting, or that Esperion misunderstood what the FDA intended to require. The former is implausible; the latter supports the plaintiffs' allegation of recklessness."⁷²

Court decisions regarding alleged misrepresentations after product development

Life sciences companies continue to face the risk of liability even after completing the development phase. In 2018, courts issued decisions in at least 13 cases involving fraud claims that arose after the development process. Seven of these decisions ruled in favor of plaintiffs (at least in part). A number of post-development disputes involved misrepresentation of the product's efficacy and/or deficiency,⁷³ or omission of key information relating to sales

71. Dougherty v. Esperion Therapeutics, Inc., 226 F. Supp. 3d 886, 895 (E.D. Mich. 2016).

72. Dougherty, 905 F.3d at 982.

73. See Jackson v. Halyard Health, Inc., No. 16-CV-05093-LTS, 2018 WL 1621539, at *10 (S.D.N.Y. Mar. 30, 2018) (dismissing claims that the company falsely or misleadingly stated and omitted information about deficiencies in its surgical gowns and providing defective gowns to U.S. workers during the Ebola crisis); W. Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc., 299 F. Supp. 3d 1055, 1073-74 (D. Minn. 2018) (denying in part defendants' motion for summary judgment and finding that plaintiffs sufficiently alleged three individual defendants engaged in or controlled a scheme to downplay the product's risk and side effects); SEB Inv. Mgmt. AB v. Endo Int'l, PLC, No. CV 17-3711, 2018 WL 6444237, at *22-23 (E.D. Pa. Dec. 10, 2018) (denying in part defendants' motion to dismiss and concluding that plaintiffs sufficiently pleaded defendants' material misrepresentations and omissions regarding the safety and efficacy of a reformulated drug); Biondolillo v. Roche Holding Ag, No. CV

and revenue.⁷⁴ Other issues unique to the post-development process included failure to comply with FDA regulations, manufacturing issues, and execution of supply contracts.

Once a product reaches the market, it is important for life sciences companies to market the product accurately and comply with any applicable FDA regulations. In *Wang Yan v. ReWalk Robotics Ltd.*, for example, the plaintiffs asserted Securities Act and Exchange Act claims that the defendants disclosed neither ReWalk's failure to comply with the FDA's directive to perform post-market surveillance nor the risks associated with the device that helps persons with spinal-cord injuries walk.⁷⁵ After approving ReWalk's medical device for marketing, the FDA ordered the company to conduct a post-market surveillance survey concerning the risk of serious injury or death in the event of the device's

malfunction.⁷⁶ Due to deficiencies in ReWalk's study plan, the FDA issued a warning letter regarding the company's failure to comply with its directive.⁷⁷ The court disagreed with the plaintiffs and found the allegations mischaracterized the FDA letters, which did not conclude that the ReWalk device was actually dangerous.⁷⁸ Relatedly, the court did not find any misstatements in the registration statement because references to "compelling" clinical data and "breakthrough product" were mere puffery and discussion of intent to conduct further clinical studies were forward-looking statements. The descriptions of post-market surveillance study requirements and regulatory risks were neither inadequate nor misleading.⁷⁹ Thus, the plaintiffs' claims under the Securities Act were dismissed, but the claims under the Exchange Act moved forward so that the parties could submit briefing on whether the plaintiffs had standing after the dismissal of the Securities Act claims. The case is ongoing.⁸⁰

Quality control at manufacturing plants is another area of potential risk and liability for life sciences companies that have moved into the post-development stage. In *Shah v. Zimmer Biomet Holdings, Inc.*, the plaintiffs alleged that the defendants made misrepresentations regarding the company's revenue growth and risks while omitting information about quality system problems at one of the manufacturing facilities.⁸¹ The court denied in part the defendants' motion to dismiss as to the company and its management and directors, finding that the defendants had a duty to disclose the quality issues at the manufacturing facility, which were material, and that these defendants made misrepresentations with the requisite scienter.⁸² Specifically, the court found that under Item 303 of Regulation S-K, the defendants had a duty to disclose the problem and that the defendants should have known that the company could not

17-4056, 2018 WL 4562464, at *8 (D.N.J. Sept. 24, 2018) (dismissing claims that defendants made false and misleading statements regarding the efficacy of breast cancer treatments).

74. See *Shoemaker v. Cardiovascular Sys., Inc.*, 300 F. Supp. 3d 1046, 1055-56 (D. Minn. 2018) (dismissing claims that defendants made material misstatements about illegal kickbacks to health care providers and off-label promotion of medical devices); *Dahhan v. OvaScience, Inc.*, 321 F. Supp. 3d 247, 256 (D. Mass. 2018) (denying dismissal of claims where plaintiffs asserted that defendants misrepresented the demand for a fertility treatment despite increased costs and invasive procedure); *Paciga v. Invuity, Inc.*, No. 17-CV-01005, ECF No. 53, at 12 (N.D. Cal. Sept. 26, 2018) (granting dismissal of claims that defendants made misstatements and omissions about the company's sales growth and revenue guidance and finding that plaintiffs did not sufficiently plead falsity of the statements and defendants' knowledge of information contrary to the statements); *In re Galena Biopharma, Inc. Securities Litigation*, 336 F. Supp. 3d 378, 389 (D.N.J. 2018) (granting dismissal of claims that defendants failed to disclose information such as over-reliance on sales from off-label prescription because there is no private right of action under Item 303 of SEC Regulation S-K and plaintiffs failed to sufficiently plead material omission under Section 10(b) of the Exchange Act); *In re Illumina, Inc. Sec. Litig.*, No. 3:16-CV-3044-L-KSC, 2018 WL 500990, at *5-6 (S.D. Cal. Jan. 22, 2018) (denying in part defendants' motion to dismiss and finding that plaintiffs sufficiently alleged defendants' misrepresentation of earnings projections despite a decline in the sale of one of its genetic sequencing products); *Oklahoma Law Enf't Ret. Sys. v. Adeptus Health Inc.*, No. 4:17-CV-00449, 2018 WL 4352836, at *7 (E.D. Tex. Sept. 12, 2018) (denying in part defendants' motion to dismiss and finding that plaintiffs plausibly claimed that defendants misrepresented information relating to patient acuity, joint ventures, and internal controls).

75. *Wang Yan v. ReWalk Robotics Ltd.*, 330 F. Supp. 3d 555, 561-62 (D. Mass. 2018).

76. *Id.*

77. *Id.* at 562-63.

78. *Id.* at 570-71.

79. *Id.* at 571-72.

80. *Id.* at 572-74.

81. *Shah v. Zimmer Biomet Holdings, Inc.*, No. 3:16-CV-815-PPS-MGG, 2018 WL 4637247, at *6-7 (N.D. Ind. Sept. 26, 2018).

82. *Id.* at *13-14, *17-19.

meet its sales and revenue goals because of the need to remediate the facility.⁸³ Such information was material as they contributed to the revenue miss and stock price decline.⁸⁴ Further, the court declined to find the financial guidance statements made during conference calls or contained in the company's 10-Q filing to fall within the PSLRA's safe harbor provision because the company only provided boilerplate cautionary language and failed to update the language despite changes in circumstances.⁸⁵ The court found that the plaintiffs sufficiently alleged scienter based on the knowledge of two confidential witnesses who provided sufficient facts to show defendants' awareness of the issues and plans to do an overhaul of the facility.⁸⁶ The plaintiffs also presented particularized facts suggesting that the defendants were aware of the problem's consequences based on prior experience and that they attempted to orchestrate a cover-up.⁸⁷ However, the court granted dismissal of claims under Section 12(a)(2) of the Securities Act and for insider trading under Section 20A of the Exchange Act against the defendants who are private equity funds because the plaintiffs failed to sufficiently allege that these private equity defendants sold securities to the plaintiffs or had actual knowledge of any alleged material nonpublic information.⁸⁸ The case is ongoing with respect to the plaintiffs' claims against the company that survived the motion to dismiss.

Life sciences companies can also face risks relating to defendants' representations of substantial supply contracts. In *Costabile v. Natus Medical Inc.*, the plaintiff claimed that the defendants made misrepresentations and omissions regarding a supply contract that Natus Medical Inc.'s subsidiary entered into with the Ministry of Health of Venezuela to provide medical equipment, supplies, and services.⁸⁹ Specifically, it was alleged that the defendants made false and misleading representations regarding the existence of the supply contract and its requirements, as well as the Ministry of Health's default on the prepayments.⁹⁰

83. *Id.* at *12-13.

84. *Id.* at *14.

85. *Id.* at *14-15.

86. *Id.* at *17.

87. *Id.* at *18-19.

88. *Id.* at *20-21.

89. *Costabile v. Natus Med. Inc.*, 293 F. Supp. 3d 994, 1001 (N.D. Cal. 2018).

While the court found certain statements regarding the prepayments false and misleading because, among other reasons, they created an "impression of [the Supply Contract] that differ[ed]. . . from the one that actually exist[ed],"⁹¹ it did not find other statements problematic, noting that the plaintiff failed to sufficiently plead that the supply contract was not executed despite relying on a confidential witness.⁹² In addition, the court did not find scienter in part because there was no showing that the defendant who made the misleading statements was deliberately reckless or intended to mislead investors.⁹³ Indeed, the court noted that any "misleading implication was inadvertent or the result of an oversight."⁹⁴ The court granted dismissal without prejudice, and later in 2018 dismissed the plaintiff's second amended complaint with leave to amend, finding that the plaintiffs failed to allege any additional facts to demonstrate that the statements were misleading or sufficiently plead scienter where there was no showing that the defendants intended to make the allegedly misleading statements.⁹⁵

Court decisions regarding financial management

While life sciences companies must navigate distinct sources of risk in their communications with investors, they also face a range of other issues relating to securities law that are common to companies across industries. In 2018, courts issued 26 decisions in cases involving allegations of financial management, including improper accounting, price fixing, improper sales or marketing practices, Medicare or Medicaid fraud, and disclosures relating to mergers or spin-offs, among other claims. The results varied for life sciences companies facing such allegations, as the courts dismissed 14 such cases (with or without leave to amend), but allowed 12 others to proceed past the motion to dismiss phase.

90. *Id.* at 1003-05.

91. *Id.* at 1011-13.

92. *Id.* at 1010, 1017.

93. *Id.* at 1018-19.

94. *Id.* at 1018.

95. *Id.* at 1021; *Costabile v. Natus Med. Inc.*, No. 17-CV-00458-JSW, 2018 WL 7134363, at *3-6 (N.D. Cal. Dec. 18, 2018).

Several of the cases involved allegations of price fixing. For instance, in *Fleming v. Impax Labs. Inc.*, the plaintiff shareholders alleged that Impax, a generic-drug maker, made false or misleading statements by attributing drug price increases to natural market conditions, instead of collusion.⁹⁶ They also claimed that they were paying artificially inflated prices for their stock because Impax failed to disclose that the company was under a U.S. Department of Justice criminal investigation over possible price fixing in the generic drug market.⁹⁷ In dismissing the case, the court ruled that while plaintiff adequately alleged actionable misstatements with regard to price fixing, the scienter allegations were not sufficient.⁹⁸ Indeed, the court explained that the allegations did not plausibly suggest that the individual defendants directly engaged in unlawful price fixing or approved allegedly collusive activity.⁹⁹ For example, the plaintiffs merely alleged that the company's senior officials "must have known" or controlled the price-fixing scheme given their positions in the company and the timing and severity of the price hikes, but not that they actually did, finding that the plaintiffs thus failed to prove scienter.¹⁰⁰ The court indicated that the plaintiffs should have specifically explained how the individual defendants had personal access to or control over pricing of the drugs, or that the defendants actually orchestrated or knew of the alleged collusive market activity.¹⁰¹ Furthermore, the court found that the plaintiffs failed to plead loss causation: mere existence of a regulatory investigation was insufficient to show cognizable fraud and the plaintiffs failed to identify a corrective disclosure by Impax that was linked to the alleged misstatements and omissions regarding the drug pricing and to Impax's stock drop.¹⁰²

In contrast to the price fixing related allegations in *Speakes v. Taro Pharm. Indus., Ltd.* largely survived the defendants' motion to dismiss.¹⁰³ The plaintiff investors pleaded that Taro and two of its former executives entered into anticompetitive

agreements with Taro's competitors to inflate drug prices and failed to disclose the collusion.¹⁰⁴ Confidential witnesses corroborated that Taro's pricing committee members met with representatives from other pharmaceutical companies at trade conferences.¹⁰⁵ Soon afterward, Taro raised the prices of certain drugs and its competitors followed suit within months.¹⁰⁶ The U.S. Department of Justice subsequently launched investigations and litigation over the dramatic price changes in the generic drug market, issuing a number of grand jury subpoenas to generic drug manufactures including Taro and two of its senior officers.¹⁰⁷ The plaintiffs allege that the disclosure of the subpoenas caused Taro's stock price to fall, and that a subsequent media report about the imminent filing of the first criminal antitrust charges in the Justice Department investigations, mentioning Taro, caused the stock price to drop even further.¹⁰⁸

The court found that the inference of each individual defendant's scienter was sufficiently compelling, based on the confidential witnesses' testimonies about the individual defendants' involvement in pricing decisions, including regular participation in pricing meetings, speaking specifically to pricing issues on earnings calls, and direct communications with the confidential witnesses regarding pricing.¹⁰⁹ Notably, the court refused to require allegations that price fixing was specifically discussed in the pricing meetings.¹¹⁰ Moreover, the court found that the scienter of management-level employees, even those not named as defendants or alleged to have made any misstatements, was attributable to the corporation.¹¹¹ Further, the court concluded that the plaintiffs adequately pled loss causation

96. *Fleming v. Impax Labs. Inc.*, No. 16-CV-06557-HSG, 2018 WL 4616291, at *2 (N.D. Cal. Sept. 7, 2018).

97. *Id.* at *5.

98. *Id.* at *4.

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.* at 4-5.

103. *Speakes v. Taro Pharm. Indus., Ltd.*, No. 16-CV-08318 (ALC), 2018 WL 4572987, at *11 (S.D.N.Y. Sept. 24, 2018).

104. *Id.* at *1-2.

105. *Id.*

106. *Id.* at *2.

107. *Id.*

108. *Id.*

109. *Id.* at *8-9.

110. *Id.* at *9.

111. *Id.* at *9-10.

by alleging that Taro's stock prices fell after the company's disclosure of the subpoenas and after the media report about the criminal antitrust charges to come.¹¹²

Also noteworthy are cases involving Sections 14(a) and 14(e) claims.¹¹³ Under Section 14(a) of the Exchange Act and SEC Rule 14a-9 proxy solicitations may not contain statements that are "false and misleading with respect to any material fact" or omit "any material fact necessary in order to make the statements therein not false or misleading." Similarly, Section 14(e) of the Exchange Act has been interpreted by courts to provide a cause of action for material misrepresentations and omissions made in connection with a tender offer.

In *Campbell v. Transgenomic, Inc.*, plaintiff shareholders alleged that Transgenomic, a biotechnology company aimed at detecting and treating inherited diseases, asked its shareholders to vote in favor of a complex merger transaction by disseminating a materially incomplete and misleading proxy statement.¹¹⁴ In particular, the proxy statement allegedly contained materially incomplete and misleading information concerning: (i) the terms and details surrounding discussions regarding alternative strategic proposals the company received from other parties; (ii) financial projections for the company and the post-merger entity; and (iii) the valuation analyses performed by the company's financial advisor.¹¹⁵ The court, in dismissing the case, found that the plaintiffs failed to make adequate allegations that the

proxy statement contained a false or misleading statement or omission concerning material fact—in this case, that the post-merger entity's revenue distributions data were factually inaccurate.¹¹⁶ The court ruled that although the financial projections could have been more clearly labeled in terms of whether they were for the pre-merger or post-merger timeframe, the oversight was not materially misleading: any mislabeling did not "significantly alter the total mix of information made available" to the shareholders (i.e., the proxy statement in its entirety, numerous financial disclosures and other financial projections, and the financial advisor's fairness opinion), and a reasonable shareholder would not have been misled.¹¹⁷

112. Id. at *10-11.

113. See, e.g., *Campbell v. Transgenomic, Inc.*, No. 4:17-CV-3021, 2018 WL 2063348, at *3 (D. Neb. May 3, 2018) (discussed herein); *Roofer's Pension Fund v. Papa*, No. CV 16-2805, 2018 WL 3601229, at *24 (D.N.J. July 27, 2018) (dismissing claims related to an individual defendant's forward-looking statements about the positive effects of the acquisition of another pharmaceutical company, while declining to dismiss claims related to the defendants' statements regarding the present success of the acquisition); *Plant v. Jaguar Animal Health, Inc.*, 17-CV-04102, ECF No. 42, at 6 (N.D. Cal. Sept. 20, 2018) (dismissing claims that the defendants disseminated a materially incomplete and misleading joint proxy statement to the company's shareholders in connection with a proposed merger).

114. *Campbell v. Transgenomic, Inc.*, No. 4:17-CV-3021, 2018 WL 2063348, at *1-2 (D. Neb. May 3, 2018) (appeal pending at the 8th Cir., No. 18-2198).

115. *Compl., Campbell v. Transgenomic, Inc.*, No. 4:17-CV-3021, 2018 WL 2063348 ¶ 6 (D. Neb. Feb. 17, 2017).

116. *Campbell*, 2018 WL 2063348, at *5-7.

117. Id. at *7.

Minimizing securities fraud litigation risks

Life sciences companies continue to be a popular target for class action securities fraud claims. While the companies discussed above were often successful in defending against these claims, it is better to avoid these suits altogether. The following is a list of practices that life sciences companies should consider in order to reduce their risk of being targeted in a class action securities fraud claim.

- Be alert to events that may negatively impact the drug product lifecycle and be diligent regarding disclosure obligations. Some potentially troubling issues are obvious, e.g., clinical trial failures and FDA rejection. Others, however, are not so obvious, such as manufacturing problems, negative side effects in clinical trials or decreasing revenue from key products due to government regulation and criticism of pricing decisions.
- Review internal processes relating to communications and disclosure about products, including those that are in the developmental stage. Ensure that such processes are well documented and that disclosure decisions are appropriately vetted. The processes should not only cover written disclosures made in press releases or SEC filings, but also any statements made by executives during analyst calls.
- Ensure that public statements and filings contain appropriate “cautionary language” or “risk factors” that are specific and meaningful, and cover the gamut of risks throughout the entire drug product life cycle – from development to production to commercialization.
- Be aware that while remaining silent on an issue does not in and of itself create liability, such omissions must not make the actual statements made misleading in any way.
- Be aware that opinion statements should not conflict with information that would render the statements misleading.
- Develop and publish employee guidelines tailored to specific areas of business operations. Communications by the R&D and marketing departments become subject to particular scrutiny in securities fraud lawsuits filed against life sciences companies.
- Develop and publish an insider trading policy to minimize the risk of inside trades during periods that might help class action lawyers later develop a theory. Class action lawyers aggressively monitor trades by insiders to develop allegations that a company’s executives knew “the truth” and unloaded their shares before it was disclosed to the public and the stock plummeted.

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