DECHERT SURVEY: DEVELOPMENTS IN SECURITIES FRAUD CLASS ACTIONS AGAINST U.S. LIFE SCIENCES COMPANIES

2019 Edition

Dechert LLP

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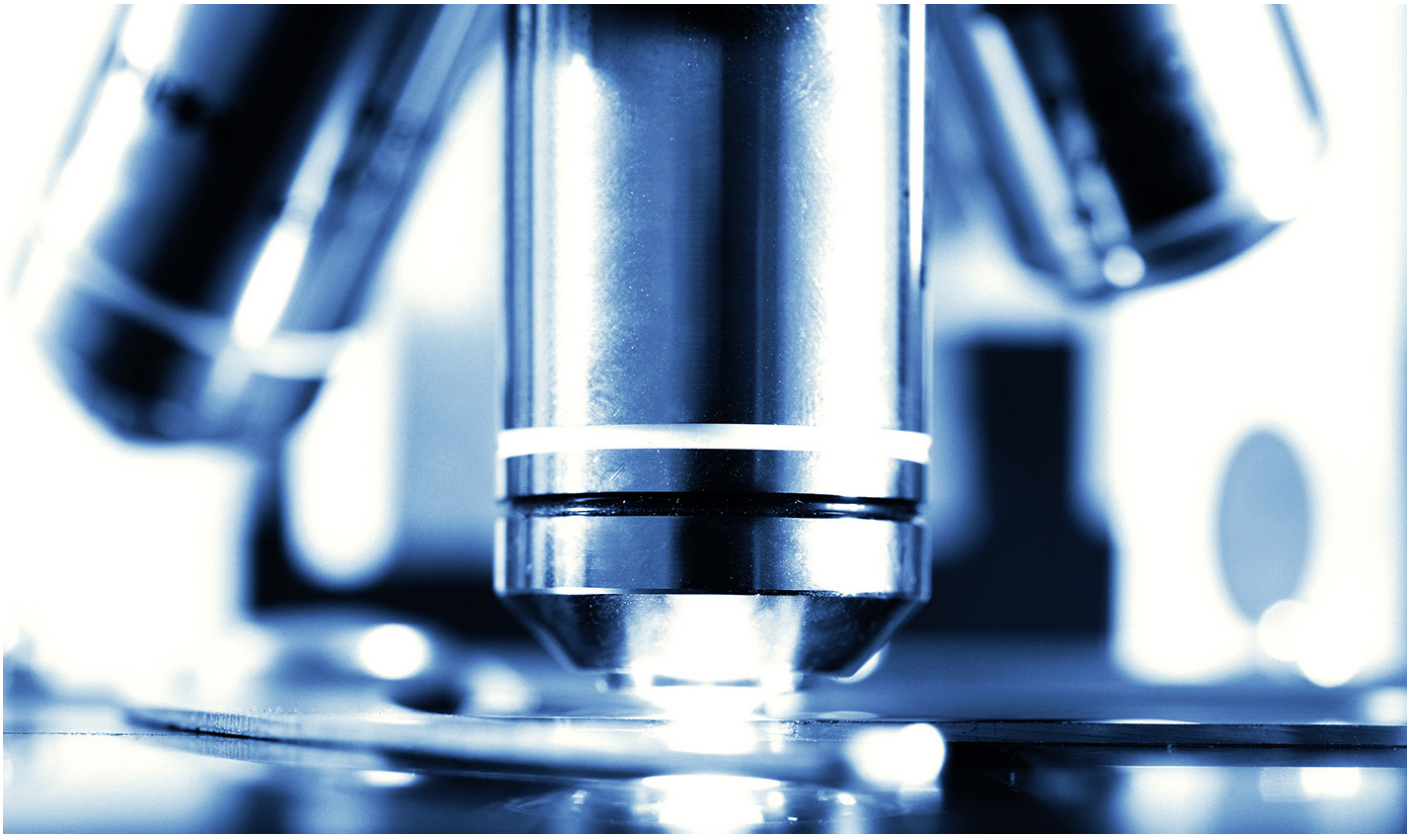

Introduction

In 2019, securities class action litigation on the whole remained at a steady high, and life sciences companies were, once again, popular targets of such lawsuits.[1] In this report, we analyze and discuss trends identified in last year's filings and decisions so that prudent life sciences companies can continue to take heed of the results.

Plaintiffs filed a total of 97 securities class action lawsuits against life sciences companies in 2019. Filings in 2019 represented a 12.8% increase from the previous year, and a 148.7% increase from 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 45.8% decrease in suits filed in the Ninth Circuit. The Third Circuit, on the other hand, saw a 122.2% increase in filings from the previous year—from 18 in 2018 to 40 in 2019. Significantly, the District of Delaware continued to see an increase in filings due, in part, to a rise in merger litigation filed in federal court; that district alone accounted for approximately 72.5% of all suits filed in the Third Circuit and about 29.9% of all securities class action lawsuits against life sciences companies generally.
- A few law firms were associated with about two-thirds of the filings against life sciences companies: RM Law, P.C. together with Rigrodsky & Long, P.A. (26 complaints), Pomerantz LLP (18 complaints) and The Rosen Law Firm (14 complaints).
- Slightly more claims were filed in the second half of 2019 than in the first half, with 46 complaints filed in the first and second quarters, and 51 complaints filed in the third and fourth quarters.

1. 2017 saw a record increase of class action securities litigation overall with 412 cases, up from the 270 securities class actions filed in 2016. In 2019, 404 securities class actions were filed.

– A growing number of lawsuits were filed against cannabis companies, with approximately 9.3% of all life sciences securities class actions filed against cannabis companies in 2019, most of which were incorporated in Canada.

– 22 cases were filed against non-U.S. issuers incorporated across eight countries. Of the 22 cases, nine were incorporated in Canada and four in Ireland.

An examination of the types of cases filed in 2019 reveals continuing trends from previous years:

– About 17.5% 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 15.5% of the claims arose from alleged misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA.

– Approximately 26.8% of the claims alleged misrepresentations regarding purported unlawful conduct in both the United States and abroad, including, but not limited to, illegal kickback schemes, anti-competitive conduct, tax issues and inadequate internal controls in financial reporting.

– About 46.4% of the claims involved alleged misrepresentations of material information made in connection with proposed mergers, sales, IPOs, offerings and other transactions.[2]

Courts throughout the country issued a large number of decisions in 2019 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, where courts were about as likely to grant motions to dismiss in full as they were to deny them, either in whole or in part.

– Claims that were independent of or arose after the development process, with which the courts were also about evenly split on outcomes.

– Claims based on the financial management of life sciences companies, which generally split between plaintiff and defendant-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 is going to slow down any time soon. The decisions this year resulted in mixed outcomes, with 24 opinions decided in favor of defendants,[3] eight[4] opinions denying motions to dismiss and 14 opinions in which only partial dismissal was achieved.[5] In addition, appellate courts also rendered opinions. In four out of the five appellate decisions we reviewed, the Court of Appeals affirmed the District Court's order, dismissing the claims. However, in one case the Court of Appeals reversed an order of dismissal and remanded for further proceedings. Accordingly, in 22 of the 46 decisions rendered in 2019 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 sued.

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2. It should be noted that six of all 2019 filings fell in more than one of these four categories.
3. Throughout this White Paper, the terms "company" or "defendants" may be used to include individual officers or directors.
4. This number includes two cases where a Magistrate Judge issued a report and recommendation denying the defendants' motions to dismiss, one of which has since been adopted by the District Court Judge. This number also includes one case in which the plaintiffs successfully filed a motion to reconsider an order granting the defendants' motion to dismiss.
5. The 46 decisions were handed down in 45 securities class action cases. The cases were compiled by filtering *Securities Class Action Clearinghouse* filings by Healthcare and cross referencing them against Westlaw searches of dispositive orders involving the Private Securities Litigation Reform Act ("PSLRA") between January 1 and December 31, 2019. 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 2019; these are not included in the tally.

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 2019 was no exception. This survey is intended to give an end-of-year overview of life sciences securities lawsuits in 2019. 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 class action decisions rendered in 2019 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.

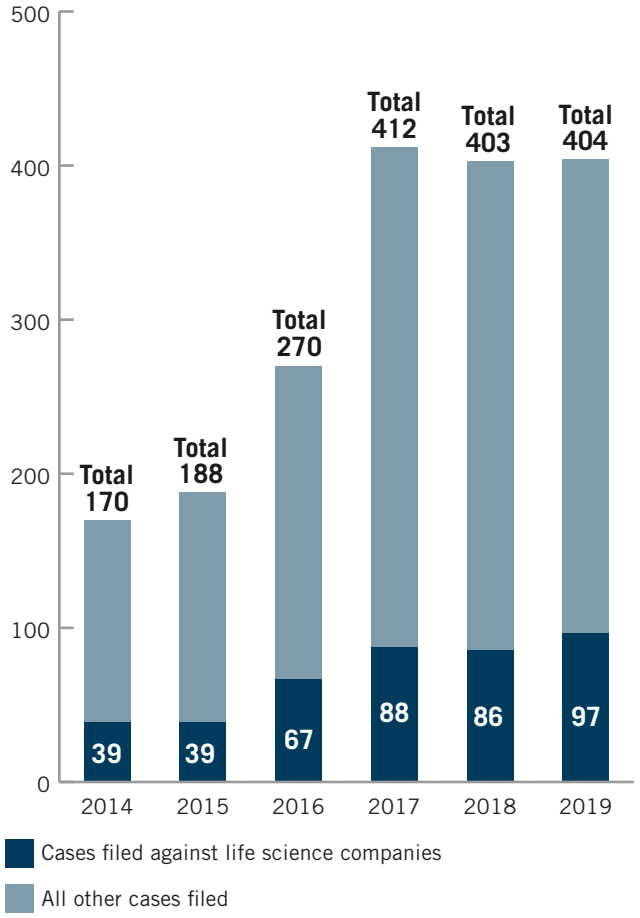
Increased Filings Involving Life Sciences Companies

The number of securities fraud class action lawsuits in general has been increasing steadily since 2012, but that number peaked in 2017, before reaching a plateau in 2018. The total number of securities fraud class action lawsuits filed in 2019 topped out at 404—just one more than the 403 securities fraud suits filed by the end of 2018, and just eight short of those filed in 2017.[6] The average number of suits filed in 2017, 2018 and 2019 remains a staggering 406.[7]

Although the overall number of securities lawsuits filed has virtually remained unchanged since last year, the proportion of such actions brought against life sciences companies increased in 2019. Indeed, a total of 97 class action securities lawsuits were filed against life sciences companies in 2019—almost one out of four of all securities fraud class action lawsuits. This represents about a 3.7% increase from 2018, when only one out of five such actions were filed against life sciences companies.

Figure 1

Number of class action securities fraud cases filed from 2014–2019 (Total cases filed compared to cases filed against life science companies)



6. Throughout this survey, data from prior years is derived from Dechert LLP's 2018 survey on the same topic. David Kistenbroker, Joni Jacobsen, Angela Liu, *Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies,* Dechert LLP (Feb. 1, 2019). The number of securities fraud class actions filed and decided in 2019, 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 Jan. 15, 2020). This survey includes litigation and cases involving drugs, devices, deal litigation and hospital management.

7. *Id.*

Filing trends

Over the past year, the number of class action securities fraud claims filed against life sciences companies increased in both numbers and proportionally when compared with the overall number of class action securities lawsuits filed over the past three years. While in 2017 and 2018 approximately one out of every five securities fraud class actions suits was brought against a life sciences company,[8] in 2019 that number increased to one in every four.[9] Yet, despite the visible increase of such filings in 2019, common patterns from previous years emerged once again, particularly in relation to when and where suits were filed, and the claims involved. Indeed, 2019 continued to bring about new and noticeable variations within these larger trends.

– **Decrease in claims against large cap companies from previous year.** In 2019, about 51% of the life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.[10] This filing trend[11] represents a decrease from 2018 filings,[12] but it is still greater than figures that emerged in 2017.[13] About 39% of the total cases filed were against life sciences companies with a market capitalization of US$1 billion or more.[14] Of these complaints, a little under half were filed against companies with a market capitalization of US$5 billion or more,[15] making up less than one fifth of the total cases filed.[16] Thus, although the number of complaints filed against companies with large market capitalizations decreased in 2019, large life science companies continue to be a popular target for class action lawsuits in 2019.

8. In 2017, 88 out of a total of 412 lawsuits were brought against a life sciences company, or 21.4%. In 2018, 86 out of a total of 403 lawsuits were brought against a life sciences company, or 21.3%.

9. 97 filings out of a total of 404 is 24%. The 97 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 Jan. 15, 2020) (these figures are based on information publicly available through January 15, 2020). 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.

10. In 2019, 97 different life sciences companies were named in class action securities fraud complaints. Of these, 96 companies had available market capitalization data as of the date of filing. Of those 96 companies, 49 had a market capitalization of US $500 million or more, or 51%. Market capitalization figures are current as of January 6, 2020, and were compiled with Yahoo! Finance and Bloomberg. Yahoo! Finance, Yahoo.com, (last visited Jan. 10, 2020); Bloomberg, Bloomberg, (last visited Jan. 10, 2020).

11. In contrast, about 71% of filings were against life sciences companies with a market capitalization of US$2 billion or less. Of these 68 companies, 31 had a market capitalization of less than US$250 million.

12. In 2018, 60% of life sciences companies named in class action securities fraud complaints had a market capitalization of US$500 million or more.

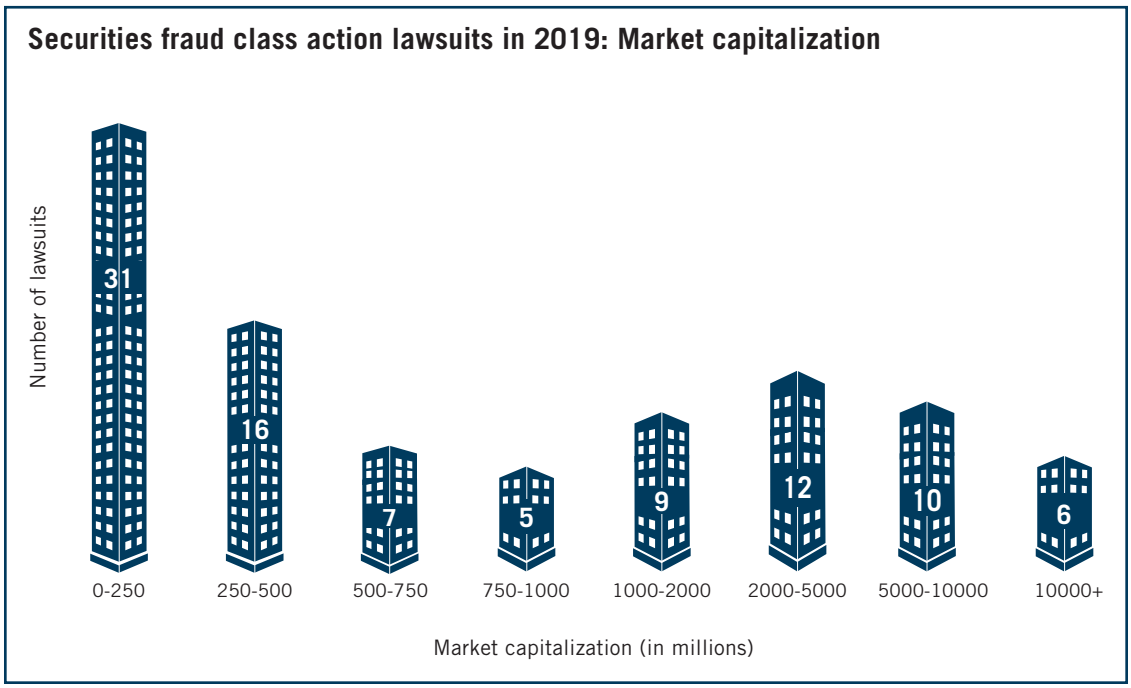
13. In 2017, 44.3% of class action securities fraud claims against life sciences companies were filed against large cap companies.

14. In 2019, 37 of 96 were filed against these companies. In 2018, this number was 37 of 77, or 48.1%. In 2017, this number was 24 out of 79, or 30.4%.

15. In 2019, 16 of 37 of the complaints filed against life sciences companies with a market capitalization of at least US$1 billion were against life sciences companies with a market capitalization of US$5 billion or more, or 43.2%. In 2018, that number was 17 out of 37, or 45.9%.

16. 16 of 96 is 16.7%.

Figure 2



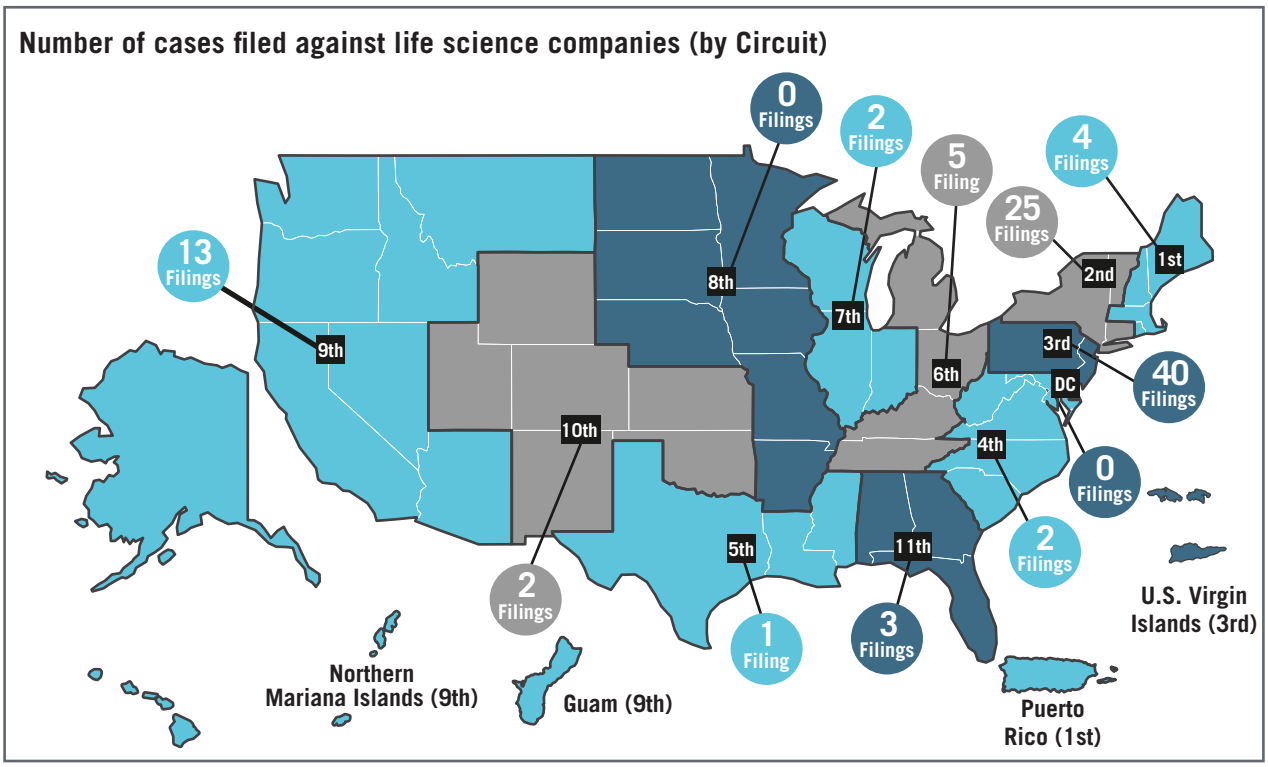
– **The Third Circuit saw the highest number of filings, displacing the Ninth Circuit, while the District of Delaware saw the highest number of filings among district courts.** Consistent with historic trends, the majority of the 97 class action securities fraud suits brought against life sciences companies were again filed in courts in three federal circuits: the Third Circuit with 40; the Second Circuit with 25 and the Ninth Circuit with 13. There was one notable shift: The Third Circuit saw a 122.2% increase in complaints filed in its district courts while the Ninth Circuit witnessed a dip in numbers, with the number of filings falling in that circuit to 13, down from 24 in 2018.[17] Within these circuits, the District of Delaware had the most filings, with 29 overall. After Delaware, district courts in New York were the second most popular with 24 total filings, 18 of which were in the Southern District of New York alone. In 2019, over half of all cases were brought in the federal district courts of two states. But unlike previous years, where federal courts in both New York and California together accounted for the largest number of filings, 2019 saw a shift in distribution of filings from California to Delaware.[18] The Third Circuit, while accounting for the most filings against life sciences companies in 2019, also saw a shift in the distribution of filings amongst its federal district courts: Delaware with 29 (or 72.5%), New Jersey with nine (22.5%) and the Eastern and Western Districts of Pennsylvania each with one (collectively, 5%).[19]

17. California recorded one of the most significant reduction of suits filed in its districts. In 2018, district courts in California had the most filings, with 21 overall and 15 in the Northern District of California alone. By contrast, only seven cases were filed in the Northern District of California in 2019, representing a 53.3% decline.

18. 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%. By contrast, 53 of 97 cases were filed in district courts in Delaware and New York in 2019, or 54.6%.

19. In 2018, eight of 18 filings brought in the Third Circuit were filed in the District of New Jersey, or 44.4%, and seven of those 18 were brought in the District of Delaware, or 38.9%. In 2017, 13 of 23 filings in the Third Circuit were filed in the District of New Jersey, or 56.5%, and two of those 23 were brought in Delaware, or 8.7%.

Figure 3



– **Three law firms were associated with about two-thirds of filings against life sciences companies.** In 2019, the two firms with the most filings of securities fraud lawsuits against life sciences companies were RM Law, P.C. together with Rigrodsky & Long, P.A. and Pomerantz LLP. These firms were listed on 26 and 18 complaints respectively, or approximately 45.4% of all cases filed, and Pomerantz LLP was selected as lead or co-lead counsel in 10 cases thus far. The Rosen Law Firm had the third most filings in 2019, accounting for 14 of the complaints filed, and serving as lead or co-lead counsel in five. The rise in lawsuits filed by RM Law, P.C. and Rigrodsky & Long, P.A., firms noticeably less visible in previous years in the context of lawsuits against life sciences companies, is attributable to the increase in merger litigation in Delaware, where those firms are particularly active.

– **Slightly more claims were filed in the second half of 2019 than in the first half.** Of the 97 complaints filed against life sciences companies in 2019, 46 were filed in the first half of the year, and 51 were filed in the second half. When broken down by quarter, 29 complaints were filed in the first quarter, 17 in the second, 26 in the third, and 25 in the fourth. This slight redistribution of the number of filings from the first half of the year to the second half of the year is consistent with 2018 figures.[20]

These figures are generally consistent with historic trends overall, but there were some notable changes in 2019. Companies with market capitalizations of over US$500 million continued to be popular targets of class action complaints filed against life sciences companies—with those against companies with market capitalizations over US$1 billion accounting for about 38.1% of the total cases filed. Three federal circuits dominated filings, in terms of the quantity, consistent with recent years, but the distribution of federal filings among the states within those circuits changed, as federal filings in California significantly decreased while Delaware saw a disproportionate increase. The increase of deal litigation in Delaware also corresponded with shifts in law firm filing trends, with RM Law and Rigrodsky & Long, the firms responsible for bringing the majority of 2019 deal litigations, accounting for the greatest number of law firm filings against life sciences companies.

20. In 2018, 42 of 86 securities fraud class action complaints filed against life sciences companies were filed in the first two quarters, or 48.8%.

Causes of Action

While there was a noticeable increase in the total number of filings brought against life sciences companies in 2019, the allegations unique to complaints against life sciences companies were consistent with those of previous years. Deal litigation also continued to be at the forefront of issues relating to life sciences companies.

Similar to previous years, one group of cases filed against life sciences companies in 2019 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.[21] For example, Apyx Medical Corporation, a medical technology company, was sued in a securities class action alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") for its failure to fully disclose the results of a clinical study that allegedly fell short of satisfying the primary efficacy endpoint for J-Plasma, a patented helium-based plasma surgical product used to reduce the appearance of wrinkles and rhytides.[22] In December 2018, Apyx announced that it had submitted a 510(k) application for regulatory clearance with the FDA for the use of J-Plasma for dermal resurfacing based on the results of the clinical study.[23] A few months later, an analyst published a report calling into question whether the clinical study on the use of J-Plasma had reached its desired primary safety endpoints.[24] After the release of the analyst's report, Apyx's stock price fell about 25%.[25] Later, in April 2019, Apyx announced that it had withdrawn its 510(k) application with the FDA for regulatory clearance, and disclosed that the study had failed to meet its primary efficacy endpoint.[26] In addition, Apyx disclosed that one of the three investigative centers involved in the study had not followed protocols. This announcement caused Apyx's stock to fall nearly 36%.[27]

Another group of complaints unique to life sciences companies arose from misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA unrelated to safety.[28] For example, investors sued Zogenix, Inc. alleging violations of Sections 10(b) and 20(a) of the Exchange Act for allegedly failing to disclose that the company had omitted critical publicly available literature from its New Drug Application ("NDA") for its lead drug candidate, ZX008, a treatment of seizures associated with Dravet syndrome, a rare disease that causes lifelong epilepsy.[29] According to the complaint, ZX008's core ingredient is fenfluramine, which is an appetite suppressant used in Pondimin and Fen-Phen.[30]

21. Such suits comprised 17 of 97 of the cases filed, or 17.5%.

22. Am. Compl., *Pritchard v. Apyx Med. Corp.,* No. 8:19-cv-00919-SCB-AEP ¶¶ 2-17 (M.D. Fla. Sept. 3, 2019).

23. *Id.* at ¶ 7.

24. *Id.* at ¶ 8.

25. *Id.* at ¶ 9.

26. *Id.* at ¶ 11.

27. *Id.* at ¶ 12; *see also, e.g.,* Compl., *Strougo v. Mallinckrodt Pub. Ltd. Co.,* No. 1:19-cv-07030 ¶¶ 3-6 (S.D.N.Y. July 26, 2019) (alleging defendants overstated the viability of H.P Acthar Gel, an injectable drug being designed to treat ALS, and failed to disclose that the drug posed significant safety concerns that rendered it a non-viable treatment for ALS); Am. Compl., *Sharma v. Amarin Corp.,* No. 3:19-cv-06601-BRM-TJB ¶¶ 5-7 (D.N.J. July 22, 2019) (alleging that Amarin made false or misleading statements or failed to disclose that the top-line results the company touted about a drug intended to treat cardiovascular disease, were not as positive as represented and that the placebo given to patients may have increased the incidence of cardiovascular events in those patients); Compl., *Feierstein v. Correvio Pharma Corp.,* No. 1:19-cv-11361-VEC ¶¶ 3-9 (S.D.N.Y. Dec. 12, 2019) (alleging that as part of a renewed application for a revoked NDA, Corrivio sought to minimize the death of a patient with no apparent heart issues who died after being administered a drug during a clinical trial). In addition, Nektar Therapeutics was again sued by investors in connection with safety issues concerning its lead immune-oncology candidate, NKTR-214, following revelations that a clinical study of NKTR-214 contained discrepancies between test batches. Compl., *Damiba v. Nektar Therapeutics*, No. 4:19-cv-05173-JSW ¶¶ 2-5 (N.D. Cal. Aug. 19, 2019). Nektar is already subject to another lawsuit filed in 2018 following the publication of a report by a hedge fund debunking statements made by Nektar that touted the efficacy of NKTR-214. Compl., *Mulquin v. Nektar Therapeutics*, No. 4:18-cv-06607-HSG ¶¶ 2-5 (N.D. Cal. Oct. 30, 2018). *See also* David Kistenbroker, Joni Jacobsen, Angela Liu, *Dechert Survey: Developments in U.S. Securities Fraud Class Actions Against Life Sciences Companies,* Dechert LLP (Feb. 1, 2019), at 6-7.

28. Such suits comprised 15 of the 97 cases filed, or 15.5%.

29. Am. Compl., *Lake v. Zogenix, Inc.*, No. 3:19-cv-01975-RS (N.D. Cal. Sept. 10, 2019) at ¶¶ 2-3, 24.

30. *Id.* at 2.

In connection with NDAs, federal law allows applicants to rely on publicly available literature in lieu of recreating costly and time-intensive studies.[31] Plaintiffs allege, however, that rather than supporting its NDA for ZX008 with publicly available literature concerning fenfluramine's use in an already approved drug, Zogenix never incorporated the publicly available data for fenfluramine in its NDA.[32] This, according to plaintiffs, caused the FDA to reject Zogenix's application "out of hand."[33] The complaint alleges that by concealing the fact that the NDA did not include the public fenfluramine literature, Zogenix falsely led investors into buying stock at artificially inflated prices.[34] Following the FDA's rejection of Zogenix's NDA, stock prices fell from US$51.85 to US$39.96 per share in one day, or 22.9%, and its overall market capitalization declined by nearly $500 million.[35]

Another group of complaints alleged other unlawful conduct, including but not limited to, illegal kickback schemes, anti-competitive conduct, tax issues and other forms of financial malfeasance.[36] There was one securities class action suit filed this year where plaintiffs made allegations of anti-competitive practices.[37] Investors sued Teva Pharmaceuticals, one of the largest generic drug manufacturers in the world and incorporated in Israel, and certain of the company's officers for violations of Sections 10(b) and 20(a) of the Exchange Act for an alleged scheme to artificially inflate the company's share price through anti-competitive practices in the generic drug industry.[38] Against the backdrop of government investigations, Teva publicly denied any involvement in anti-competitive practices, which plaintiffs alleged were false and misleading.[39] The plaintiffs alleged that these denials were purported misstatements as shown by a *Washington Post* "expose" into Teva's participation in the price-fixing scheme, and a 524-page complaint filed by 44 state attorneys general.[40] As a result of the complaint filed by the state attorneys general, the share price of Teva fell 15% in May 2019.[41]

31. *Id.* at ¶¶ 2-3.

32. *Id.* at ¶¶ 2-3, 5.

33. *Id.* at ¶¶ 2-3.

34. *Id.* at ¶ 8.

35. *Id.* at ¶ 9; *see also, e.g.,* Am. Compl., *Mo-Kan Iron Workers Pension Fund v. Teligent, Inc.,* No. 1:19-cv-03354-VM ¶¶ 2, 9-10, 130 (S.D.N.Y. Dec. 9, 2019) (alleging that defendants made a series of materially false and misleading statements that touted Teligent's ability to develop and submit NDAs in compliance with stringent FDA regulations and to secure their approval from the FDA, going as far as to falsely deny receiving letters from the FDA that listed serious compliance failures); Compl., *Wong v. Heron Therapeutics, Inc.,* No. 3:19-cv-01038-LAB-LL ¶¶ 5, 24, 28, 30-31 (S.D. Cal. June 3, 2019) (alleging that defendants made false and misleading statements and did not disclose that Heron failed to include adequate Chemistry, Manufacturing, and Controls ("CMCs") and other non-clinical information in its NDA for its leading drug candidate, resulting in the FDA refusing to approve Heron's NDA); Compl., *Huang v. CannTrust Holdings Inc.,* No. 1:19-cv-06396-JPO ¶ 2-7 (S.D.N.Y. July 10, 2019) (alleging Sections 10(b) and 20(a) Exchange Act violations due to defendants' failure to disclose to investors that CannTrust was growing cannabis while applications for regulatory approval were still pending and that CannTrust was reasonably likely to face an inventory hold by Health Canada, a government agency, until it complied with applicable regulations).

36. Such complaints comprised 26 of the 97 filings reviewed, or 26.8%. Seventeen of these 26 cases involved allegations of false or misleading statements due to material weaknesses in life sciences companies' internal controls over financial reporting.

37. This is three less than in 2018, when four such cases were filed.

38. Compl., *Employees' Ret. Sys. of the City of St. Petersburg, Fla. v. Teva Pharm. Indus. Ltd.,* No. 2:19-cv-02711-CMR ¶¶ 1-3 (E.D. Pa. June 21, 2019).

39. *Id.* at ¶ 7-8, 28.

40. *Id.* at ¶ 10-11, 37-38.

41. *Id.* at ¶ 12, 39.

Notably, nearly half of the class action securities fraud claims filed against life sciences companies in 2019 alleged misrepresentations and omissions related to proposed mergers, sales, IPOs, offerings and other transactions.[42] The allegations found in such complaints are similar to other complaints relating to other industries. For example, investors sued Genomic Health, Inc. and members of its board of directors, for breaches of fiduciary duty and for violations of Section 14(a) of the Exchange Act. Specifically, the complaint alleged that the defendants made material misrepresentations and omissions in the registration statement soliciting stockholders to vote in favor of a merger between Genomic Health, its parent Exact Sciences Corporation and Spring Acquisition Corp., a wholly owned subsidiary of Exact Sciences Corporation.[43] The plaintiffs alleged that defendants breached their fiduciary duties by failing to maximize the value stockholders received in exchange for their shares and by agreeing to unreasonable deal-protection provisions in the merger agreement that impeded other potential bidders from submitting a superior offer to acquire Genomic Health after the merger agreement was signed.[44] In addition, investors alleged the defendants made material omissions and misrepresentations in the registration statement that purportedly prevented them from making an informed decision whether to vote their shares in favor of the merger.[45] The alleged misrepresentations related to Genomic Health's financial projections provided to its financial advisor, Goldman Sachs, the sales process and certain conflicts of interest of management and the data and inputs underlying the financial valuation analyses used to support the fairness opinions provided by Genomic Health's financial advisor.[46]

Finally, another noteworthy trend has been the number of life sciences companies that are incorporated abroad but have still been subject to suit in the United States, which is in line with general securities litigation trends across all industries.[47] While some of these companies were seeking FDA approval,[48] others involved allegations that were not U.S. specific. For example, Canopy Growth, together with its subsidiaries, engaged in production, distribution and sale of cannabis in Canada.[49] Canopy is incorporated in Canada

42. Such suits comprised 45 of 97 of the cases filed, or 46.4%. *See also, e.g.,* Compl., *Wheby, Jr. v. BioScrip, Inc.,* No. 1:19-cv-01106-UNA (D. Del. June 14, 2019) ¶¶ 38-63 (alleging Section 14(a) and 20(a) Exchange Act violations relating to purported omissions and misrepresentations in BioScrip's proxy statement to approve merger, which included financial projections, analyses performed by financial advisor, the nature of the financial advisor's various relationships with companies involved in the merger, potential conflicts, the timing and nature of communications regarding future employment of officers and directors, and manner in which members of the transition committee had been selected); Compl., *Rosenblatt v. Achillion Pharms, Inc.,* No. 1:19-cv-02112-UNA ¶¶ 37-50 (D. Del. Nov. 8, 2019) (alleging that proxy statement asking stockholders to approve merger was false and misleading because it failed to disclose company's financial projections and analyses performed by company's financial advisor); Compl., *Kent v. The Medicines Co.,* No. 1:19-cv-02248-UNA ¶¶ 37-47 (D. Del. Dec. 10, 2019) (alleging that solicitation statement asking stockholders to approve merger was false and misleading and made omissions concerning Medicines Company's financial projections and analyses performed by its financial advisors).

43. Compl., *Seligman v. Genomic Health, Inc.,* No. 3:19-cv-05710-VC ¶¶ 1, 12 (N.D. Cal. Sept. 11, 2019).

44. *Id.* at ¶¶ 4-6.

45. *Id.* at ¶ 12.

46. *Id.*

47. Approximately 22.7%, or 22 of 97 cases, filed in 2019 were against non-U.S. issuers incorporated across eight countries. In comparison, only six of 86 such cases were filed in 2018, or 6.9%. *See, e.g.*, David H. Kistenbroker, Joni S. Jacobsen, Angela M. Liu, *Non-U.S. Issuers Targeted in Securities Class Actions Filed in the U.S.* (2019).

48. *See also, e.g.,* Compl., *Feierstein v. Correvio Pharma Corp.,* No. 1:19-cv-11361-VEC ¶¶ 3-9 (S.D.N.Y. Dec. 12, 2019) (Correvio, incorporated in Canada and headquartered in Vancouver, was seeking FDA approval).

49. *Ortiz v. Canopy Growth Corp.,* No. 2:19-cv-20543-KM-ESK (D.N.J. Nov. 20, 2019).

with principal executive offices in Ontario, but trades on the New York Stock Exchange. Investors sued Canopy under Sections 10(b) and 20(a) of the Exchange Act relating to purported failure to disclose the company was experiencing weak demand for its softgel and oil product, and as a result, the company would be forced to take a CA$32.7 million restructuring charge. Upon this news, the stock purportedly dropped by approximately 14.4%.[50]

Similar to past years, the common themes of these complaints show the unique challenges life sciences companies face as issuers, but also 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. Moreover, the filings show life sciences companies also face challenges similar to those faced by other non-life sciences issuers, particularly challenges relating to disclosures in the sale or merger of life sciences companies. In addition, similar to other non-U.S. issuers, those life sciences companies with headquarters located outside of the U.S. may still be targets of securities class actions in the U.S. 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 from more common forms of securities fraud claims as well.

50. *See also, e.g., Wilson v. Aurora Cannabis Inc.,* 2:19-cv-20588-JMV-JBC (D.N.J. Nov. 21, 2019) (involving allegations of misrepresentations regarding revenue decline and CA$190 million in capital expenditures, along with the halting of construction in Denmark and Alberta regarding Canadian corporation, headquartered in Canada and trading on the NYSE).

2019 Class Action Securities Fraud Decisions in the Life Sciences Sector

During 2019, courts continued the trend of issuing a large number of securities fraud decisions involving life sciences companies. Dechert identified 51 such decisions analyzed under the PSLRA in 2019, falling into three broad categories:[51] (i) cases involving claims that arose in the development phase, such as cases involving a drop in stock price after the failure of a clinical trial, and cases involving overly optimistic statements regarding the FDA approval of a drug or device; (ii) cases involving claims that arose independent of or after the development process; and (iii) cases involving financial management of life sciences companies. As in 2018, 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

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 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 2019, courts issued opinions in dozens of securities fraud class actions relating to life sciences companies. Of the 51 opinions we analyzed under the PSLRA from 2019, 12 related to alleged misrepresentations that companies made while a drug or device 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.

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 around the country 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. In 2019, courts were almost as likely to deny defendants' motions to dismiss relating to alleged misrepresentations during product development, in whole or in part, as they were to grant them. Five of the cases we identified as falling into this category resulted in motions to dismiss being either denied in their entirety[52] or denied in part. In contrast, Dechert identified six district court decisions from 2019 where motions to dismiss claims relating to product development were granted in their entirety, and one appellate opinion where a dismissal was affirmed.[53]

51. *Supra* note 4.

52. *Bailey v. Esperion Therapeutics, Inc.,* No. 18-11438, 2019 WL 3296235, (E.D. Mich. Feb. 19, 2019) (granting motion to dismiss for failure to plead scienter despite allegations that the company "trumpeted" bempedoic acid's safety and tolerability despite several red flags and the revelation of alarming safety results from the Phase 3 clinical trial); *Nguyen v. New Link Genetics Corp.,* No. 16-CV-3545, 2019 WL 591556 (S.D.N.Y. Feb. 13, 2019) (granting motion to dismiss despite allegations that the company made a series of misrepresentations through Phase 2 and Phase 3 clinical trials about the drug's efficacy); *In re Regulus Therapeutics Inc. Sec. Litig.,* 406 F. Supp. 3d 845 (S.D. Cal. 2019) (granting motion to dismiss despite allegations the company overstated RG-101's approval prospects because patients treated with RG-101 were at increased risk of treating jaundice); *In re Ocular Therapeutix, Inc. Sec. Litig.,* No. CV 17-12146-GAO, 2019 WL 1950399 (D. Mass. Apr. 30, 2019) (granting motion to dismiss despite allegations that after submitting an NDA to the FDA, the company misled investors about the problems its manufacturing operations faced and the impact those problems would have on FDA approval), *appeal filed* (1st Cir. 2019).

53. *In re Arrowhead Pharm., Inc. Sec. Litig.,* 782 Fed. App'x 572 (9th Cir. 2019) (affirming dismissal of allegations that the defendants made misleading statements to investors regarding ARC-520's general safety and toxicity risks, the FDA's partial clinical hold on ARC-520's multiple-dose study, as well as non-human primate deaths in toxicology studies).

Defendants frequently defeat securities class action claims by arguing that no misrepresentation was made and that they did not act with scienter. For example, the Court of Appeals for the Ninth Circuit affirmed a dismissal in *In re Arrowhead Pharmaceuticals, Inc. Securities Litigation*.[54] In this case, the plaintiffs argued that Arrowhead Pharmaceuticals, Inc. made misleading statements to investors regarding ARC-520's general safety and toxicity risks, the FDA's partial clinical hold on ARC-520's multiple-dose study, as well as non-human primate deaths in toxicology studies.[55] Because the plaintiffs pointed only to a former Arrowhead employee's single statement to establish dose accumulation toxicity risks and provided no corroborating details nor other facts, the court found that the plaintiffs failed to plead falsity.[56] In addition, the court also found that the plaintiffs failed to allege scienter because the plaintiffs failed to specifically allege who at Arrowhead knew about the deaths.[57] As a result, the Ninth Circuit affirmed the District Court's dismissal for failure to plead falsity and scienter.[58]

Courts also granted motions to dismiss based on alleged misrepresentations that were nonactionable statements of opinion. For example, in *Lehman v. Ohr Pharm. Inc.,*[59] shareholders brought a securities class action complaint against Ohr Pharmaceutical, Inc., a clinical stage pharmaceutical company developing therapies for ophthalmic diseases.[60] Ohr's leading drug candidate, Squalamine, is a novel drug aimed at providing therapy to vision.[61] The plaintiffs challenged public statements relating to its Phase II results.[62] Later, when the company announced the results from its MAKO study, it announced that it did not meet its primary efficacy endpoint.[63] As the plaintiffs characterize it, the results were an "utter disaster as patients in the [treatment arm] performed worse than the [control arm.]"[64] After the stock subsequently dropped 81.2%, the plaintiffs asserted claims of securities fraud under Section 10(b) and 20(a) of the Exchange Act.[65] The court granted the defendants' motion to dismiss, explaining that the statements at issue were opinion statements. Indeed, the court, relying on the U.S. Supreme Court decision in *Omnicare* and its progeny, agreed that the interpretation of the interim and final Phase II trial results were not misleading, further emphasizing that the court would not adopt a rule that "discourages free scientific inquiry in the name of shielding investors from risks of failure."[66] With regard to scienter, the court rejected allegations of knowledge of omitted facts and information, namely that the defendants knew about other trial data that would have put their statements in proper context.[67] The court stated "[h]ad the MAKO [Phase III] trial succeeded, which [p]laintiffs do not allege was out of the realm of possibility as envisioned by [d]efendants, then there clearly would have been no scienter. It cannot be the case that *ex ante* intent is based on *ex post* results."[68] The motion to dismiss was granted, and the case has been appealed to the Second Circuit.

Courts also granted motions to dismiss based on loss causation.[69] In *Nguyen v. New Link Genetics Corporation*, the plaintiffs filed a Second Amended Class Action Complaint, and the defendants cabined their motion to dismiss to falsity and loss causation. The plaintiffs claimed that NewLink made a series of misrepresentations regarding the development of its flagship pancreatic cancer drug. Through both the Phase 2 and Phase 3 clinical trials, NewLink and its officers allegedly misrepresented the drug's efficacy and misled the market into believing that the company would obtain FDA approval to market the drug.[70] However, the drug failed to achieve the requisite markers in its clinical trial, foreclosing its chances for FDA approval.[71] As for loss causation, the plaintiffs alleged that three partial or corrective disclosures revealed the truth

54. *Id.*
55. *Id.* at 574.
56. *Id.* at 574-75.
57. *Id.*
58. *Id.*
59. *Lehmann v. Ohr Pharm. Inc.,* No. 18 CIV. 1284 (LAP), 2019 WL 4572765 (S.D.N.Y. Sept. 20, 2019).
60. *Id.* at *1.
61. *Id.*
62. *Id.* at *1-2.
63. *Id.* at *2.
64. *Id.*
65. *Id.*
66. *Id.* at *5.
67. *Id.* at *6.
68. *Id.*
69. *Nguyen v. New Link Genetics Corp.,* No. 16cv3545, 2019 WL 591556, at *1 (S.D.N.Y. Feb. 13, 2019).
70. *Id.*
71. *Id.*

behind NewLink's alleged misrepresentations, in addition to the final disclosure that Phase 3 had failed, which all caused the stock to drop.[72] NewLink countered that these disclosures were simply bad news that triggered dips in its stock price.[73] The court agreed. As for the three partial disclosures, two were irrelevant (announcements of interim trial results), and the third had nothing to do with the defendants' statements about patient enrollment.[74] Finally, other allegations were insufficient to allege loss causation because they merely showed that the market reacted to bad news.[75] The case was dismissed with prejudice.

In addition to potential litigation surrounding the success of a clinical trial, courts also focused on plaintiffs' allegations that life sciences companies made misrepresentations relating to the likelihood that the drug or device will ultimately be approved or that they mischaracterized communications with the FDA. For example, *Smith v. Antares Pharma, Inc.,*[76] is another example of a case involving FDA approval allegations. In *Antares,* the plaintiffs alleged that Antares Pharma and its board of directors made materially false and misleading statements about the likelihood of obtaining FDA approval of its drug, XYOSTED[77]. Indeed, the gravamen of the complaint was that Antares made "materially false and misleading statements regarding the company's business, operational and compliance policies[,] as related to the [FDA] approval process of XYOSTED." Plaintiffs asserted a claim under Section 10(b) of the Exchange Act and a claim against the officer defendants for violation of Section 20(a) of the Exchange Act. Despite the plaintiffs' arguments to the contrary, the court agreed with the defendants that the allegations[78] attributed to the confidential witness must be "steeply discount[ed]" because they were vague and utterly unsupported by any corroborating allegations. The court then held that the plaintiffs' remaining allegations were not pleaded with particularity, as required by the heightened pleading standards of the PSLRA and thus dismissed the action with leave to amend.

Similarly, in *In re Regulus Therapeutics Inc. Securities Litigation,*[79] Regulus, a biopharmaceutical company that was developing a drug to treat the hepatitis C virus, sought approval from the FDA to market and sell the drug to the public. Regulus was required to submit an Investigational New Drug ("IND") application to obtain approval to test it on human subjects. The complaint alleged that the defendants made false or misleading statements and/or failed to disclose that patients treated with this drug were at increased risk of contracting jaundice, and that the company misrepresented its approval prospects.[80] The company then announced that it received a verbal notice from the FDA and that the FDA placed a hold after a second serious adverse event of jaundice was reported in a patient treated with the drug.[81] Later, the company issued a press release announcing that after "[c]omprehensive pre-clinical investigation and thorough evaluation of the clinical data from RG 101," the company was discontinuing the development of its drug. The stock price subsequently declined.[82] The court in Regulus found that the proposed class action offered only "vague and impressionistic" allegations that Regulus tried to downplay issues as it went through clinical trials.[83] Although Regulus continued to make rosy statements about the drug, the court stated that the defendants did disclose the existence of the investigator's conclusions that the drug was "possibly" the cause of one of the SAEs and so investors were given the same information that the defendants possessed.[84] The court ultimately granted the motion to dismiss with leave to amend.[85] After a subsequent amended complaint was filed, the plaintiffs' moved for preliminary approval of a $900,000 settlement, which was denied without prejudice due to the settlement claim release provision being "convoluted."[86] The case is currently still pending.

72. *Id.*

73. *Id.*

74. *Id.* at *7-8.

75. *Id.* at *8.

76. *Smith v. Antares Pharma, Inc.,* No. 17-8945, 2019 WL 2785600 (D.N.J. July 2, 2019).

77. *Id.* at *1.

78. *Id.* at *9.

79. *In re Regulus Therapeutics Inc. Sec. Litig.,* 406 F. Supp. 3d 845 (S.D. Cal. 2019).

80. *Id.* at 856.

81. *Id.* at 852.

82. *Id.* at 854.

83. *Id.* at 857.

84. *Id.* at 859.

85. Id. at 864.

86. Order, *In re Regulus Therapeutics Inc. Sec. Litig.,* No. 3:17-cv-00182, ECF No. 39, at 2 (S.D. Cal. Dec. 20, 2019).

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 2019, courts issued decisions in at least 16 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,[87] or inspection of facilities by the FDA followed by various communications and warning letters,[88] among other issues.

Once a product reaches the market, post-market issues may arise. In *Forman v. Meridian Bioscience, Inc.,*[89] for example, the plaintiffs alleged that Meridian Bioscience made misstatements about several issues, including the efficacy of its LeadCare products, its performance expectations for an acquired company, Magellan, the purported fact that Magellan was "a leading manufacturer of FDA-cleared products for the testing of blood to diagnose lead poisoning," and the effectiveness of its internal controls."[90] The court held that the only actionable misstatement was Meridian's statement in a Form 10-K that diagnostic products marketed in the U.S. had been cleared by the FDA pursuant to the 510(k) clearance process because the plaintiffs alleged that the LeadCare systems were not FDA-cleared.[91] Turning to scienter, the court also examined the plaintiffs' overarching theory of liability, but found that it was not as credible as Meridian's non-culpable explanation for the alleged misstatements, thereby granting the defendants' motion to dismiss.[92] However, upon reconsideration, the court found that it had misapplied the scienter standard, focusing too much on the company's non-culpable explanation for its decision to purchase Magellan. The court reasoned this argument was not directly responsive to the more specific issue of whether Meridian acted recklessly eight months after it acquired Magellan when it made its statements in the Form 10-K that all the products were FDA cleared. The court also found that it had previously conflated two separate issues in the scienter analysis, and granted the motion for reconsideration.[93] The court has preliminarily approved a settlement of this case.[94]

Inchen Huang v. Higgins, et al.,[95] is an example of a securities class action relating to off-label marketing. Assertio Therapeutics is a "specialty pharmaceutical company" that "engages in the development, sale, and licensing of products, including opioids, for pain and other central nervous system conditions."[96] The plaintiffs alleged numerous false or misleading statements that described recent marketing achievements as successes while they "did not disclose that these supposed successes were obtained in part through an illicit off-label marketing campaign."[97]

87. *See, e.g., In re Restoration Robotics, Inc. Sec. Litig.,* No. 5:18-cv-03712-EJD, 2019 WL 5295059, at *17 (N.D. Cal., Oct. 18, 2019) (granting in part and denying in part motion to dismiss where the plaintiffs alleged that the defendants made misrepresentations regarding the efficacy of their hair restoration system); *Biondolillo v. Roche Holding AG,* No. CV 17-4056, 2019 WL 1468140, at *4 (D.N.J. Apr. 3, 2019) (granting motion to dismiss).

88. *See, e.g., In re Dr. Reddy's Lab. Ltd. Sec. Litig.,* No. 317CV6436PGSDEA, 2019 WL 1299673, at *15-16 (D.N.J. Mar. 21, 2019) (granting in part and denying in part motion to dismiss where plaintiffs alleged that the defendants downplayed FDA "observations" of potential violations at one of the defendants' largest manufacturing facilities); *Forman v. Meridian Bioscience, Inc.,* 367 F. Supp. 3d 674, 685 (S.D. Ohio 2019) (granting plaintiffs' motion for reconsideration of the order dismissing the case where the company's stock price fell after FDA inspected facility of a company that the defendants acquired and issued a press release warning that certain blood tests, made by the acquired company, provided inaccurate results in some instances).

89. *Forman v. Meridian Bioscience, Inc.,* 387 F. Supp. 3d 791 (S.D. Ohio 2019).

90. *Id.* at 794.

91. *Id.*

92. *Id.* at 795.

93. *Id.* at 798.

94. Preliminary Approval, Case No. 1:17-cv-00774 (Oct. 9, 2019) (Dkt. 58).

95. *Inchen Huang v. Higgins, et al.,* No. 17-CV-04830, 2019 WL 1245136 (N.D. Cal. Mar. 18, 2019).

96. *Id.* at *1.

97. *Id.* at *5.

In addition, the plaintiffs contended that certain risk statements were misleading because they did not provide the necessary context that the company had "already been deliberately engaged in off-label marketing."[98] The court disagreed. First, it explained that the alleged conduct of a different company three years prior provides an insufficient basis to infer that the company engaged in those practices.[99] While the plaintiffs attempted to plead facts from confidential witnesses, the court concluded that taken collectively, the former employee statements suggested little direct evidence of any off-label marketing, particularly because the same former employees did not work at the company during the entire class period.[100] In addition, allegations relating to an investigation and subpoenas were directed at the marketing practices of five opioid manufacturers generally, rather than detailing specific instances of off-label marketing by Assertio personnel.[101] The court also found that because the plaintiffs did not adequately plead a widespread off-label marketing scheme, the company did not materially misstate the likelihood or the extent of regulatory risks.[102] Regarding scienter, the court found that the allegations revealed only isolated instances of off-label marketing, rather than widespread deception.[103] The defendants' motion to dismiss was granted without prejudice, and the case is still pending.[104]

This year, courts again grappled with inspection and quality control at manufacturing facilities around the world. For example, *In re Dr. Reddy's Laboratory Limited Securities Litigation,*[105] involved Dr. Reddy's, an Indian pharmaceutical manufacturing company with U.S. headquarters in New Jersey.[106] Dr. Reddy's allegedly misrepresented that it met mandatory manufacturing quality standards when it did not. The plaintiffs asserted that the defendants were subject to current good manufacturing practices which set minimum standards for safely manufacturing drugs.[107] But Dr. Reddy's compliance with those standards came into question after investors learned that the FDA observed nine potential violations at one of Dr. Reddy's largest facilities, which was purportedly downplayed to the market.[108] The FDA issued a Warning Letter that described three manufacturing facilities that suffered from "recurrent" and "longstanding failures." While the defendants claimed to the public they had completed their commitments to the FDA, the plaintiffs alleged that the defendants knew they had not.[109] After a German regulator would not renew a compliance certificate for a manufacturing facility and Dr. Reddy's disclosed that the company had been advised of new FDA observations of a potential no-compliance at a United Kingdom facility, Dr. Reddy's ADSs fell almost 6%.[110] In granting the motion to dismiss in part and denying in part, the *Dr. Reddy's* court first addressed the defendants' standing argument. The court explained that because some alleged misstatements were corrected months before the plaintiffs' first stock purchase, and other statements were made after the plaintiffs' last stock purchase, the plaintiffs could not establish standing for those statements.[111] As for the remaining statements, the court held that the plaintiffs had sufficiently alleged scienter. The court explained that the totality of the direct contradictions of the truth, statements about core operations, information provided by a confidential witness and additional allegations supported a strong inference of scienter.[112]

98. *Id.*
99. *Id.* at *6.
100. *Id.* at *7.
101. *Id.*
102. *Id.* at *10.
103. *Id.* at *15.
104. *Id.* at *18.
105. *In re Dr. Reddy's Lab. Ltd. Sec. Litig.,* No. 317cv6436PGSDEA, 2019 WL 1299673 (D.N.J. Mar. 21, 2019).
106. *Id.* at *1.
107. *Id.*
108. *Id.*
109. *Id.* at *4-6.
110. *Id.*
111. *Id.* at *11-14.
112. *Id.* at *17.

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 2019, 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 11 such cases (with or without leave to amend), but allowed 13[113] others to proceed past the motion to dismiss phase.

Several of the cases involved allegations of price fixing. For instance, in *New York Hotel Trades Council & Hotel Ass'n of New York City, Inc. Pension Fund v. Impax Labs. Inc,*[114] the plaintiffs alleged that the defendants were involved in a price fixing and price erosion scheme.[115] The court dismissed plaintiffs' price fixing claims because it found that the plaintiffs failed to plead loss causation.[116] In its reasoning, the court divided the plaintiffs' loss causation shortcomings into two buckets—either: (1) the plaintiff tried to "tie a purported misstatement to stock price decreases, which misunderstands that loss causation is about linking corrective disclosures to stock price changes," or (2) "they characterize[d] disclosures of investigations as corrective disclosures[], which in and of itself fails to prove loss causation under Ninth Circuit law[.]"[117] With respect to the plaintiffs' price erosion claims, the plaintiffs alleged false statements made by the defendants regarding two of their products, Diclofenac and Budeonside.[118] The court found that plaintiffs failed to sufficiently plead the falsity of defendants' statements about Diclofenac, which the court found to consist of non-actionable puffery, accurate statements of past performance, non-actionable opinion statements, or forward-looking statements that were not made with knowledge that they were false at the time.[119] The court also rejected plaintiffs' claims that defendant willfully overvalued the acquisition of their product Budeonside at $251 million because the court found it was far more reasonable that the defendant company had simply, and non-culpably, mistakenly overvalued the acquisition.[120]

Unlike *Impax Labs,* Inc. the defendants in *In re Mylan N.V. Securities Litigation* were only partially successful in their motion to dismiss claims pertaining to an alleged price fixing scheme and antitrust conduct in relation to their product, EpiPen.[121] The plaintiffs alleged that defendants both misclassified EpiPen as a generic drug in order to take advantage of the Medicaid Drug Rebate Program ("MDRP") and also committed antitrust violations intended to block competitors from the market and inflate prices of various drugs including the drug EpiPen.[122] Thus, plaintiffs

113. This number includes two cases where a Magistrate Judge issued a report and recommendation denying the defendants' motion to dismiss, one of which has since been adopted by the District Court Judge. This number also includes one case in which the plaintiffs successfully filed a motion to reconsider an order granting the defendants'motion to dismiss.

114. *N.Y. Hotel Trades Council & Hotel Ass'n of N.Y.C., Inc. Pension Fund v. Impax Labs. Inc.,* No. 16-CV-06557-HSG, 2019 WL 3779262, at *2 (N.D. Cal. Aug. 12, 2019). Impax was the subject of a lawsuit that was decided in 2018 that involved anti-competitive conduct that also ended in a successful motion to dismiss. *See Fleming v. Impax Labs. Inc.,* No. 16-CV-06557-HSG, 2018 WL 4616291 (N.D. Cal. Sept. 7, 2018) (holding that the plaintiffs failed to adequately plead scienter when they made no showing that the defendants acted recklessly or willingly when they were involved in an alleged price fixing scheme).

115. *N.Y. Hotel Trades Council & Hotel Ass'n of N.Y.C., Inc. Pension Fund,* 2019 WL 3779262, at *2.

116. *Id.*

117. *Id.* at *3 (citing *Loos v. Immersion Corp.,* 762 F.3d 880, 890 & n.3 (9th Cir. 2014)).

118. *Id.*

119. *Id.* at *4-5.

120. *Id.* at *6

121. *In re Mylan N.V. Sec. Litig.,* 379 F. Supp. 3d 198 (S.D.N.Y. 2019).

122. *Id.* at 203.

claimed that defendants' statements of historical income and statements respecting future regulatory scrutiny were misleading given defendants' underlying anti-competitive conduct.[123] Although the court found that simply failing to disclose regulatory risk did not render the historical income statements misleading, the court still found that the defendants' statements "explaining income" were actionable because defendants "'put [the company's] sources of income at issue,' and the statements were misleading for failing to disclose the extent to which [the company's] income was inflated by its misclassification of the EpiPen and its other alleged anti-competitive activities."[124] The court also found that the plaintiffs adequately pled that the anti-competitive nature of the Medicaid rebate scheme blocked competitors from the market and caused the price of EpiPen to increase—the disclosure of which the plaintiffs alleged caused a drop in stock price.[125] However, the court dismissed the plaintiffs' claims related to the alleged price fixing agreement.[126] In addition, the court found that the plaintiffs relied on circumstantial evidence regarding the alleged price fixing scheme of generic drugs rather than direct evidence, and the conclusory assertions of the plaintiffs were unable to adequately plead the existence of the unlawful agreements.[127]

In 2019, courts once again decided cases involving instances of fraud related to Medicare. This can be seen in *Alaska Elec. Pension Fund v. Asar.*[128] In this case, the Court of Appeals for the Fifth Circuit affirmed an order from the Western District of Texas, granting the defendants' motion to dismiss when they found that the plaintiffs failed to adequately plead scienter.[129] Here, the plaintiffs alleged that the defendants made material misrepresentations concerning the internal controls of the company, which purportedly led to an increase in failure of Medicare audits.[130] The plaintiffs alleged that the defendants made misrepresentations that they had sufficient internal controls over their Medicare audit process and failed to increase its reserve for disallowed Medicare sales.[131] The defendants began disclosing failures within their Medicare audit process that eventually led to the defendants restating their financial statements from 2012 through 2014 and admitting that they overstated their pre-tax income by US$87 million.[132] The plaintiff alleged that a number of factors create a strong inference of scienter including: (1) the magnitude of the restatement, (2) the stock transactions of the individual defendants, (3) the findings of the Audit Committee and (4) certifications of SEC filings under the Sarbanes-Oxley Act of 2002 in spite of red flags that they ignored around the Medicare audit process.[133] However, the court found that, when looking at all of these facts holistically, they did not create a strong inference of scienter, and affirmed the lower court's decision.[134]

123. *Id.* at 205-206.

124. *Id.* at 206.

125. *Id.* at 208-210.

126. *Id.* at 209.

127. *Id.* at 210.

128. *Alaska Elec. Pension Fund v. Asar,* 768 F. App'x 175 (5th Cir. 2019).

129. *Id.*

130. *Id.* at 177.

131. *Id.*

132. *Id.* at 178.

133. *Id.* at 180.

134. *Id.* at 189.

Minimizing Securities Fraud Litigation Risks

Life sciences companies continue to be a popular target for class action securities fraud claims. While many of the companies discussed above were successful in defending against these claims, being prepared to reduce the risk of being targeted in a class action securities fraud claim is preferable. Below is a list of practices that life sciences companies should consider:

- Life sciences companies in particular deal with regulatory setbacks, negative side effects in clinical trials, clinical trial failures, etc. which when disclosed may trigger a stock drop. Be particularly cognizant when making disclosures or statements to disclose both positive and negative results, including after preliminary results are issued. Ensure that a disclosure regimen and processes are well documented and consistently followed.
- In addition to large cap companies, smaller life sciences companies are also susceptible to securities class actions and should work with counsel to ensure that they adopt a disclosure plan. Disclosure plans should not only cover written disclosures made in press releases or SEC filings, but also any statements made by executives during analyst calls. Websites should also be continually updated.
- Life sciences companies are not immune to issues that may cut across all industries and should be prepared to make appropriate disclosures relating to transactions, consolidated financials, internal controls, conflicts of interest, anti-competitive conduct, quality control, etc.
- Because deal litigation has been at the forefront in filings against life sciences companies, materials to investors relating to the transaction should contain detailed explanations about the history of the transaction, alternatives to the transaction, reasons for recommendation, the terms of the transaction, fairness opinions and conflicts of interest among other issues.
- Even if incorporated abroad, life sciences companies that are also non-U.S. issuers may be targeted in the U.S. despite events occurring that may not be U.S. specific.
- Regarding statements made in public filings, courts continue to weigh in on opinion statements and the law is continuing to evolve. Be aware that opinion statements should not conflict with information that would render the statements misleading.
- Forward-looking information about a drug or device should be clearly identified as such and distinguished from historical fact. Analyst calls and webcasts should also identify disclosures as forward-looking statements.
- Risk disclosures that are current, relevant and upfront help to ward off securities class actions. Ensure that public statements and filings contain not only general disclaimers relating to forward-looking statements, but also 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 commercialization.
- Be aware that former employees in all departments, not just those relating to clinical trials, may become confidential witnesses. Educate employees about not sharing confidential information with others and limiting social media about the company.
- Develop and publish an insider trading policy to minimize the risk of inside trades, including 10b5-1 trading plans and trading windows. 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.
- Work with insurers to hire experienced counsel who specialize in and defend securities class action litigation on a full-time basis.

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