

Dechert survey: Developments in securities fraud class actions against U.S. life sciences companies

2017 Edition

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Table of contents

Introduction	4
Life sciences companies remain popular targets for securities fraud litigation	5
2017 class action securities fraud decisions in the life sciences sector	11
– Court decisions regarding alleged misrepresentation during product development	11
– Court decisions involving stock drops following failed clinical trials	11
– Court decisions arising out of overly optimistic statements regarding FDA approval	13
– Court decisions regarding alleged misrepresentations after product development	14
– Court decisions regarding alleged financial misrepresentation	15
Minimizing securities fraud litigation risks	17

Introduction

2017 was a record year for class action securities litigation, and life sciences companies continued to be popular targets of such lawsuits. Prudent life sciences companies should take heed of the results of last year's decisions and filings.

In 2017, plaintiffs filed a total of 88 class action securities lawsuits against life sciences companies, a more than 30% increase from the previous year, and a more than 225% 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 an increase in suits filed in the Third Circuit, and in New Jersey in particular.
- Three law firms were associated with more than half of the filings against life sciences companies: Levi & Korsinsky LLP (21 complaints), Pomerantz LLP (14 complaints) and The Rosen Law Firm (11 complaints).
- The vast majority of claims were filed in the first half of 2017, with 18 complaints filed in January alone.

An examination of the types of cases filed in 2017 reveals continuing trends from previous years, with some new developments.

- Nearly 33% of claims involved misrepresentations regarding product efficacy and safety, especially negative side effects of leading product candidates or the likelihood of FDA approval.
- Nearly 15% of the claims arose from misrepresentations regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA.
- Just over 20% of the claims alleged unlawful conduct in both the United States and abroad, including illegal kickback schemes and anticompetitive conduct.

The securities litigation bar also saw a large number of decisions rendered in 2017 involving life sciences companies, including:

- Claims that arose in the development phase before the company's product had gone to market, with a majority of defendants securing dismissal.
- Claims that were independent of or arose after the development process, with which plaintiffs tended to have more success in surviving dispositive motions.
- 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 filing of securities claims against life sciences companies is going to slow down any time soon. The decisions this year resulted in mixed outcomes, with 15 cases decided in favor of defendants, 13 cases denying motions to dismiss and 7 cases in which only partial dismissals were achieved. Accordingly, in 20 of the 35 decisions in 2017, the plaintiffs' claims were allowed to proceed. These numbers illustrate how life sciences companies remain attractive targets for class action securities fraud claims and should implement the best practices recommended at the end of this survey 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 targeted in securities fraud lawsuits, and 2017 was no exception. This survey is intended to give a comprehensive overview of life sciences securities lawsuits in 2017. 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 2017 and how they impact the legal landscape of these types of claims.

Increased filings

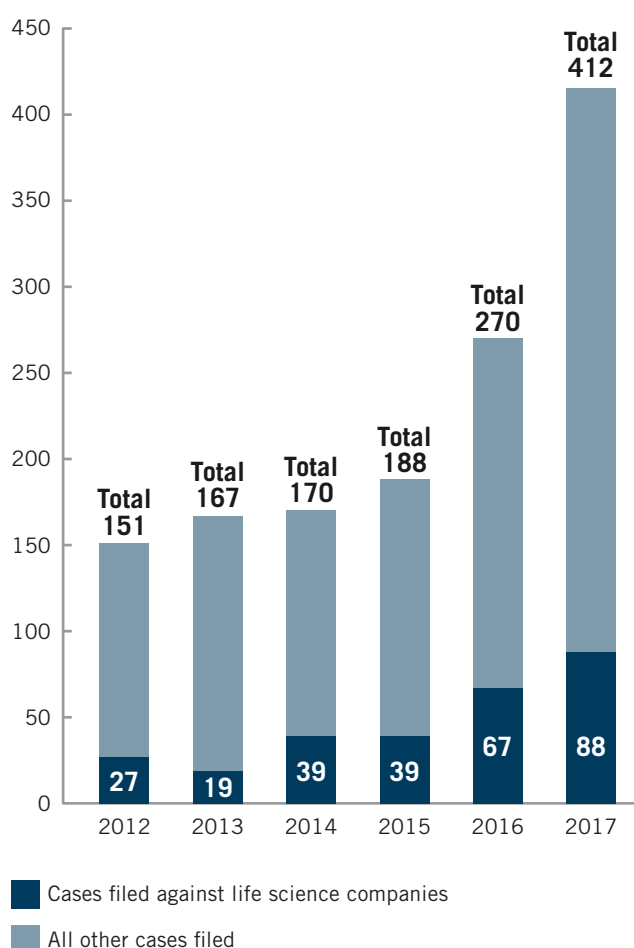
The number of securities fraud class action lawsuits in general has been increasing steadily over the last few years, but 2017 saw a dramatic spike. The total number of securities fraud class action lawsuits filed in 2017 topped 412 — 142 more than the 270 filed by the end of 2016.¹ The contrast is even starker compared to the 151 total class action securities complaints filed in 2012, a mere five years ago.²

As the number of securities lawsuits has increased, so has the number of such lawsuits involving life sciences companies. A total of 88 class action securities lawsuits were filed against life sciences companies in 2017, a more than 30% increase from 2016's 67 actions, and a more than 225% increase from 2012's 27 actions.³

A number of factors combined to result in this rise in litigation. The increase in overall class action securities litigation is largely attributable to an increase in merger objection lawsuits as well as a rise in filings by emerging law firms against small cap companies involving event-driven allegations, rather than allegations based on financial misrepresentations.⁴ These trends also impacted

Figure 1

Number of class action securities fraud cases filed from 2012–2017 (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 2016 survey on same topic. David Kistenbroker, Joni Jacobsen, David Kotler, Angela Liu, *Dechert Survey: Developments in securities fraud class actions against U.S. life sciences companies*, Dechert LLP (Feb. 1, 2017). The number of securities fraud class actions filed and decided in 2017, 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 CLEARINGHOUSE (last visited Feb. 1, 2018).

² 412 represents an increase of 172.8% from 2012's 151 filings.

³ 88 is an increase of 31.3% over 67 and an increase of 225.9% over 27.

⁴ Kevin LaCroix, *Securities Suit Filings at Historically High Levels During 2017*, THE D&O DIARY (Jan. 1, 2018).

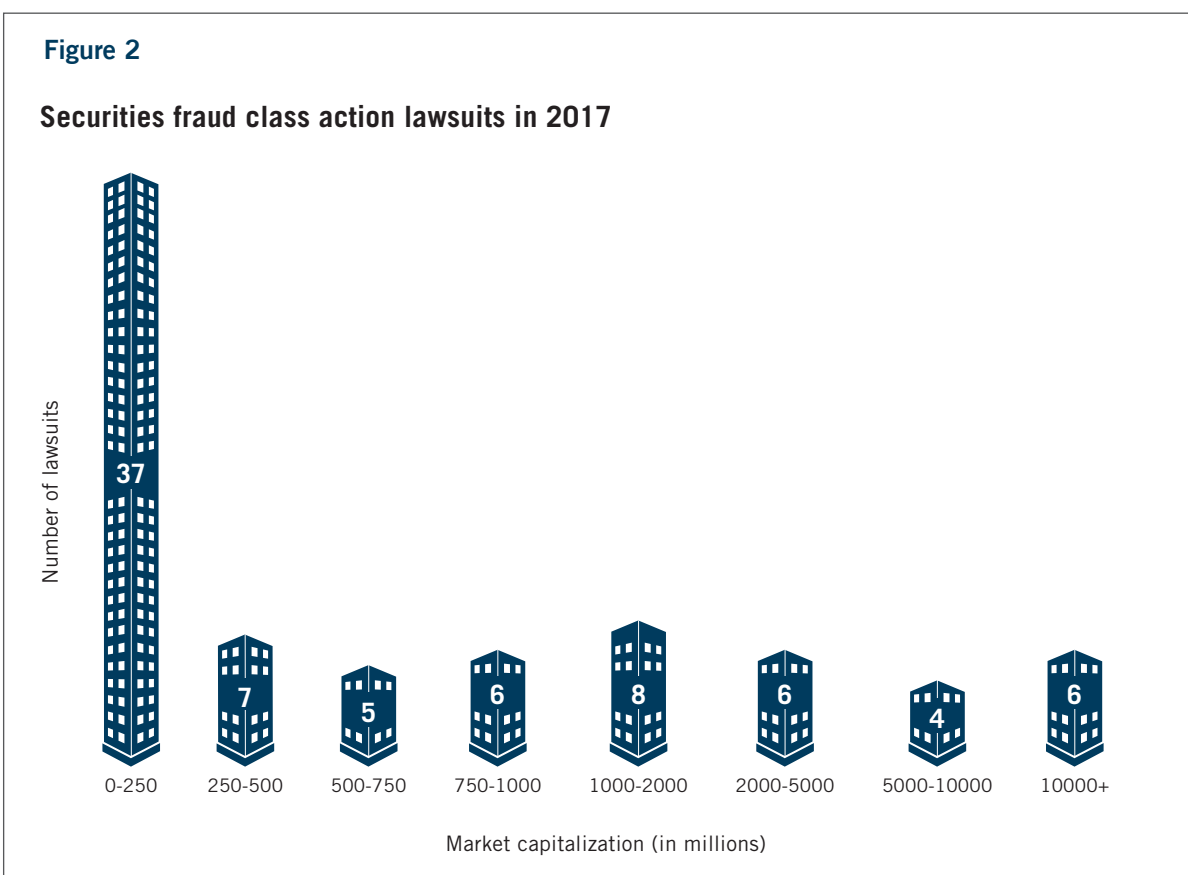
life sciences suits. More than half of the life sciences companies sued in securities fraud class actions in 2017 had a market capitalization of less than \$500 million. Life sciences companies were also subject to event-driven allegations. For example, allegations based on statements or omissions regarding unlawful activity outside the United States were present in five of the filings. Ultimately, however, the majority of the cases against life sciences companies continued to be focused on issues that pertain specifically to the life sciences industry.

The increased number of filings also corresponded with an increased number of dispositive court decisions. Based on our research, there were a total of 35 class actions securities fraud claims against life sciences companies decided in 2017.⁵

Filing trends

Over the past year, the number of class action securities fraud claims filed against life sciences companies climbed to a new height, matching the overall rise in class action securities fraud claims. In 2017, more than one out of every five securities fraud class action suits was brought against a life sciences company.⁶ While the number of filings increased in 2017, common patterns from previous years emerged once again, particularly in relation to the companies targeted and the location of filing. The past year did, however, bring about new and noticeable variations within these larger trends.

- **Rise in claims against very small cap companies.** In 2017, more than half of the life sciences companies named in class action securities fraud complaints had

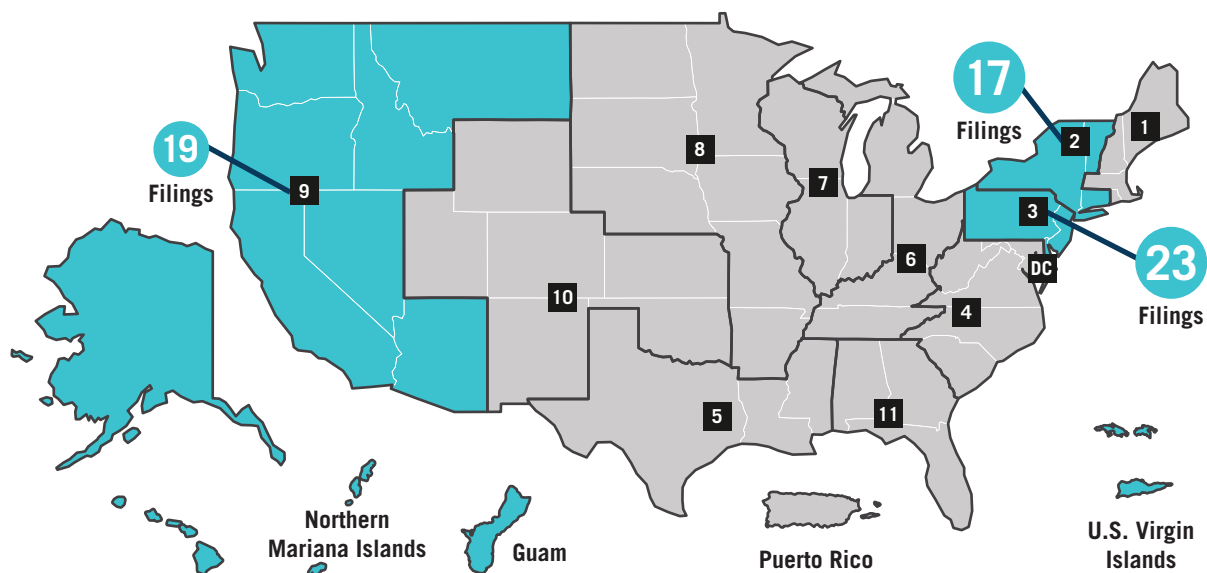


⁵ The 35 decisions were tallied by filtering all Securities Class Action Clearinghouse filings by Healthcare and comparing those numbers with a Lex Machina report of class action securities cases that involved potentially dispositive orders between January 1 and December 31, 2017. *Lex Machina, Lex Machina: Cases, PTAB Trials, and ITC Investigations*, (last visited Feb. 1, 2018). Numerous other cases concluded with settlements, voluntary dismissals and similar dispositions in 2017; these are not included in the tally.

⁶ 88 filings out of a total of 412 is 21.4%. The 88 filings were tallied by filtering all Securities Class Action Clearinghouse filings by Healthcare, then sorting them by the 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, 2018).

Figure 3

Number of cases filed against life science companies (by Circuit)



a market capitalization of US\$500 million or less.⁷ While this is consistent with filing trends in recent years, the distribution among these small cap companies changed in 2017.⁸ Most notably, almost half of the total cases filed were against life sciences companies with a market cap of US\$250 million or less — a dramatic increase of nearly 20% since 2016.⁹ Of these complaints, roughly half were filed against companies with a market cap of US\$50 million or less, making up nearly a quarter of the total cases filed.¹⁰ Thus, companies with very small market capitalization became a popular target for class action lawsuits in 2017.

- **Increase in suits filed in the Third Circuit, particularly in New Jersey.** Consistent with historic trends, the majority of the 88 class action securities fraud suits brought against life sciences companies were filed in three U.S. Courts of Appeal: the Third Circuit with 23; the Ninth Circuit with 19; and the Second Circuit with 17. District courts in California had the most filings, with 18 overall and 13 in the Northern District alone. New York was the second most popular state with 17 total filings, 15 of which were in the Southern District. While nearly 40% of all cases were brought in the district courts of these two states, this is a noticeable decrease from 2016.¹¹ Two new states saw an increase in the number of filings in 2017: New Jersey with 13 and Massachusetts with 11. The major centers of filing, then, have remained the same, but the distribution among the circuit courts markedly changed over the past year.

- **Three law firms were associated with more than half of filings against life sciences companies.** The most active firm was Levi & Korsinsky, which was listed as counsel on 21 complaints, or nearly a quarter of all

7 In 2017, 83 different life sciences companies were named in class action securities fraud complaints. Of these, 79 companies had available market capitalization data. Of those 79 companies, 44 had a market capitalization of US\$500 million or less, or 55.7%. Market capitalization figures are current as of January 23, 2018, and were compiled with Yahoo! Finance and The Street. [Yahoo! Finance](#), YAHOO.COM, (last visited Feb. 1, 2018); [THE STREET](#), (last visited Feb. 1, 2018).

8 In 2016, 50.7% of class action securities fraud claims against life sciences companies were filed against small cap companies.

9 In 2017, 37 of 79 were filed against these companies, or 46.8%. In 2016, this number was 19 out of 67, or 28.3%.

10 19 out of 79 is 24.1%.

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%.

cases filed.¹² Levi & Korsinsky was also selected as lead counsel in 13 cases. The two most prominent firms from 2016 were also associated with a large percentage of cases in 2017: Pomerantz filed 14 complaints and served as lead counsel in eight cases, while The Rosen Law Firm filed 11 complaints and also served as lead counsel in eight cases.

- **A vast majority of claims were filed in the first half of 2017.** Of the 88 complaints filed against life sciences companies in 2017, 56 were filed by the end of June. Of these, 18 were filed in January alone. This is consistent with filing trends in securities fraud class action lawsuits more broadly over the past year.¹³ It is unclear if this trend will continue in 2018, however, as only six claims were filed in the first three weeks of 2018.

These figures are generally consistent with historic trends overall, but there were some noticeable changes in 2017. While roughly half of the cases were filed against small cap companies, an even larger proportion of those were against even smaller companies. Three U.S. Courts of Appeal dominated filings, consistent with recent years, but the distribution among the circuits changed, as the Third Circuit had the most claims this year while the Second and Ninth Circuits saw a decrease proportionally. Overall, life sciences companies continue to be a popular target for class action securities fraud claims, especially related to product development and approval.

Causes of action

While the number of filings against life sciences companies increased in 2017, the allegations within these complaints were consistent with those brought in previous years. Nearly one-third of the class action securities fraud claims filed against life sciences companies in 2017 involved misrepresentations regarding product efficacy and safety, especially negative side effects of leading product candidates, or the likelihood of FDA approval.¹⁴ Stemline Therapeutics, for example, was sued for its failure to disclose a patient death in its

leading drug candidate's clinical trial.¹⁵ In prior studies, two patients died due to a negative side effect of the drug, while a third patient suffered from a life-threatening emergency.¹⁶ Stemline subsequently announced new safety and dosage protocols to prevent this side effect in the future, and the company consistently reassured investors that no patient experienced the side effect after the implementation of these measures.¹⁷ While preparing for a second public offering, Stemline filed a prospectus with the SEC touting the success of these safety measures.¹⁸ However, Stemline failed to report that a patient had died from the very same side effect just two days before the company filed the prospectus.¹⁹ When a news article revealed this omission, Stemline was forced to admit that it knew of the death at the time of filing, causing stock prices to fall 42.5%.²⁰

Nearly one-third of the class action securities fraud claims filed against life sciences companies in 2017 involved misrepresentations regarding product efficacy and safety.

A second group of cases filed against life sciences companies in 2017 arose from misrepresentations

15 Am. Compl., *In re Stemline Therapeutics, Inc. Sec. Litig.*, No. 1:17-CV-00832 (PAC) ¶¶ 2-5 (S.D.N.Y. Feb. 2, 2017).

16 *Id.* at ¶¶ 36-40.

17 *Id.* at ¶¶ 50-66 (describing Stemline's misleading statements during the class period).

18 *Id.* at ¶¶ 52-53.

19 *Id.*

20 *Id.* ¶¶ 67-69. See also Consol. 2d Am. Compl., *Patel v. Seattle Genetics, Inc.*, No. 2:17-CV-00041-RSM ¶¶ 2-11 (W.D. Wash. Nov. 11, 2017) (alleging that defendants made false or misleading statements regarding liver toxicity in a clinical trial of a new drug, causing stock to drop when the FDA placed a hold on drug trials following patient deaths); Am. Compl., *In re Neurotrope, Inc. Sec. Litig.*, No. 1:17-CV-03718-LGS ¶¶ 3-12 (S.D.N.Y. Oct. 9, 2017) (alleging that defendants "blatantly misled investors" by inflating expectations about the efficacy of leading drug candidate, causing stock prices to drop when Phase 2 data failed to demonstrate statistical significance); Compl., *DeSmet v. Intercept Pharma., Inc.*, No. 1:17-CV-07371-LAK, 2017 WL 4296085 ¶¶ 2-10 (S.D.N.Y. Sep. 27, 2017) (alleging that defendants issued misleading statements about deaths in clinical trials of new drug being unrelated to the treatment, causing stock to drop after the FDA issued a safety announcement about the drug's side effects).

12 21 of 88 is 23.9%.

13 LaCroix, *supra* note 4.

14 Such suits comprised 27 of 88 of the cases filed, or 30.7%.

regarding regulatory hurdles, the timing of FDA approval or the sufficiency of applications submitted to the FDA.²¹ For example, investors sued Innocoll Holdings for overstating the prospects of FDA approval of its leading product.²² Innocoll's leading product candidate was a drug/device combination consisting of a collagen sponge inserted near a surgical site to treat post-operative pain.²³ For this type of product, companies must obtain FDA approval of both the drug and the device components.²⁴ Plaintiffs alleged that Innocoll misled them by stating that it was working closely with the FDA for product approval, which was near certain by the end of the year.²⁵ In reality, the FDA was not up to date on Innocoll's progress, and Innocoll had only conducted studies on the drug portion of the product, not the device element as required.²⁶ As a result, the FDA issued a "Refusal to File" letter, declaring Innocoll's application so deficient that it would not even conduct a substantive review, leading stock prices to fall more than 60%.²⁷

Another group of complaints alleged other unlawful conduct both in the United States and abroad, including illegal kickback schemes and anticompetitive conduct.²⁸

Three of these complaints alleged that a life sciences company was involved in an illegal kickback scheme or encouraged physicians to write off-label prescriptions,²⁹ while two other complaints alleged unlawful monopolistic activities by the company.³⁰ Two complaints were brought against the same CEO while he served at two separate companies, alleging that he hired the same stock promotion company to flood the market with positive (but false) articles about the company's leading product, while forbidding the authors to disclose their compensation.³¹ Five other cases involved false or misleading statements or omissions about unlawful activities outside the United States.³²

21 Such suits comprised 13 of the 88 cases filed, or 14.8%.

22 Am. Compl., *In re Innocoll Holdings Public Ltd. Co. Sec. Litig.*, No. 17-CV-00341 (E.D. Pa. May 25, 2017).

23 *Id.* at ¶ 33.

24 *Id.* at ¶¶ 34-46.

25 *Id.* at ¶¶ 63-115 (describing the false and misleading statements made during the class period).

26 *Id.* at ¶¶ 116-119.

27 *Id.* at ¶¶ 116-17. See also Am. Compl., *In re Egalet Corp. Sec. Litig.*, No. 2:17-CV-00617 (MMB) (E.D. Pa. July 3, 2017) (alleging that defendants misled investors by overstating prospects that the FDA would approve abuse-deterrent labeling for its lead product candidate, providing a competitive advantage, when the FDA had already granted three year exclusivity to another product); Compl., *Paoli v. TherapeuticsMD, Inc.*, No. 9:17-CV-80473-RLR, 2017 WL 1382301 ¶¶ 25-40 (S.D. Fla. Apr. 4, 2017) (alleging that defendants made false or misleading statements about Phase 3 clinical trial, causing stock to drop after the FDA found both the clinical program and the NDA deficient); 2d Am. Compl., *Nguyen v. Endologix, Inc.*, No. 2:17-CV-00017 ¶¶ 2-30 (C.D. Cal. Jan. 9, 2018) (alleging that defendants repeatedly made false statements about prospects for FDA approval, despite knowing their medical device had serious side effects, causing the FDA to delay premarket approval for years).

28 Such complaints comprised 19 of the 88 filings reviewed, or 21.6%. Additionally, 29 of the 88 cases reviewed involved allegations of false or misleading statements or omissions of financial information filed with the SEC in preparation for a merger, sale or similar event.

29 2d Am. Compl., *In re INSYS Therapeutics, Inc. Sec. Litig.*, No. 1:17-CV-01954-PAC ¶ 2 (S.D.N.Y. Oct. 27, 2017) (alleging that defendants failed to disclose that growth was due to off-label marketing and kickback schemes, concealing this activity by prematurely recording revenue and understating sales allowances); Consol. Compl., *Miller v. Galena Biopharma, Inc.*, No. 2:17-CV-00929-KM-JBC ¶ 26 (D.N.J. Oct. 6, 2017) (alleging defendants paid illegal kickbacks to physicians who wrote off-label prescriptions); Consol. Am. Compl., *In re Novo Nordisk Sec. Litig.*, No. 3:17-CV-00209-BRM-LHG ¶ 4 (D.N.J. Aug. 4, 2017) (alleging that defendants failed to disclose that growth in insulin market was due to illegal kickback schemes with pharmacy benefit managers, not superior production as defendants claimed).

30 Compl., *Pelletier v. Endo Int'l PLC*, No. 2:17-CV-05114 (JP), 2017 WL 5490856 ¶¶ 6-11 (E.D. Pa. Nov. 14, 2017) (alleging that defendants misled investors about benefits of acquisition, as competitive advantages were due to collusion to fix generic drug prices); Compl., *Shenk v. Mallinckrodt PLC*, No. 1:17-CV-00145 (EGS), 2017 WL 370192 ¶¶ 9-10 (D.D.C. Jan. 23, 2017) (alleging that defendants failed to disclose illegal anticompetitive conduct to prevent a synthetic version of drug from reaching the market, thereby maintaining the company's monopoly).

31 Am. Compl., *Rabkin v. Lion Biotech, Inc.*, No. 3:17-CV-02086 (SI) ¶¶ 7-9 (N.D. Cal. Sept. 8, 2017) (alleging that defendants hired Lidingo Holdings to publish at least 14 misleading articles to artificially inflate stock prices, thereby allowing the CEO to receive financial incentives); Consol. Am. Compl., *Arthur Kaye IRA FCC as Custodian DTD 6-8-00 v. ImmunoCellular Therapeutics, Ltd.*, No. 2:17-CV-03250-FMO (SKx) (C.D. Cal. Aug. 24, 2017) (alleging that defendants hired Lidingo Holdings to issue false and misleading articles to artificially inflate stock prices, while Phase 1 and Phase 2 trials of leading vaccine candidate did not show statistically significant effectiveness).

32 Consol. Am. Compl., *Rumbaugh v. USANA Health Scis.*, No. 2:17-CV-00106 (DB) ¶ 20 (D. Utah Aug. 4, 2017) (alleging that defendants engaged in sales practices violating Chinese multi-level marketing, or pyramid selling, laws, leading the government to freeze company assets and made over a dozen arrests); Am. Compl., *Costabile v. Natus Med. Inc.*, No. 4:17-CV-00458-JSW ¶¶ 13-15 (N.D. Cal. July 14, 2017) (alleging defendants misled investors

The common themes of these complaints show the unique challenges life sciences companies face when selling securities. First, the past year's filings demonstrate that negative side effects in clinical trials can create a claim for securities fraud when management attempts to conceal these effects, subsequently overstating the trial's results and the prospects of FDA approval. Second, these filings indicate that companies cannot inflate investors' expectations of FDA approval when their applications contain fatal deficiencies or inadequate clinical data that will delay or prevent approval altogether. While these filings do 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, like those involving inaccurate or incomplete financial information.

about supply contract with the Venezuelan Ministry of Health, failing to disclose that the government already failed to make millions of dollars in prepayments and that the contract was apparently never executed); Compl., *Luo v. Sinovac Biotech Ltd.*, No. 2:17-CV-04883-JMV-MF, 2017 WL 2861576 ¶ 25 (D.N.J. July 3, 2017) (alleging that CEO bribed a member of the Chinese Food and Drug Administration to assist vaccine clinical trial in violation of the Foreign Corrupt Practices Act); Compl., *Bergeron v. Mazor Robotics Ltd.*, No. 1:17-CV-04387, 2017 WL 2589423 ¶¶ 21-23 (S.D.N.Y. June 9, 2017) (alleging that defendants failed to disclose the Israeli Securities Authority conducted a search at offices); Am. Compl., *In re Psychomedics Corp. Sec. Litig.*, No. 1:17-CV-10186-RGS ¶ 2 (D. Mass. June 2, 2017) (alleging defendants participated in and concealed from investors an illegal scheme to monopolize the Brazilian hair drug test market).



2017 class action securities fraud decisions in the life sciences sector

With securities fraud filings on the rise, last year also saw the courts continue to hand down a large number of decisions involving life sciences companies. Dechert identified 35 decisions in such cases in 2017, falling into three broad categories: (i) cases involving claims that arose in the development phase before the company's product had gone to market; (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 2016, a majority of these decisions addressed claims centering on Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

Court decisions regarding alleged misrepresentation during product development

Life sciences companies can face both great potential and great risk during development of a drug, device or product. On one hand, effective development is the root of success in the life sciences industry, as individual drugs or products can turn an upstart company into a competitor in the field. On the other hand, the temptation to attract and appease investors can lead drug manufacturers to mischaracterize or exaggerate trial results, opening themselves up to liability under U.S. securities laws.

In 2017, courts addressed a variety of securities fraud claims centering on alleged misrepresentations pertaining to drug, product and device development. Of the 35 decisions we analyzed from last year, 15 involved assertions that companies made misrepresentations during the development stage. In many instances, announcements of poor trial performance were followed by claims that the company had misreported or exaggerated test results to boost stock prices. In other cases, companies disclosing bad news from the FDA then encountered plaintiffs who claimed that the company had misled investors with respect to FDA approval.

Court decisions involving stock drops following failed clinical trials

Medical product development carries certain inherent risk due to the relatively low odds that any one candidate will succeed during trials and enter the market. When products run up against poor clinical trial results, investors are increasingly turning to securities fraud class action claims supported by assertions that product developers somehow misled them. The courts tended to favor defendants in such cases last year, with eight of the 15 such cases resulting in dismissal.

In such cases, plaintiffs sometimes met challenges in proving both that defendants had made false statements and that defendants had done so with scienter. The plaintiff in *In re Arrowhead Pharmaceuticals, Inc. Securities Litigation.*, for example, charged that the defendants downplayed certain toxicity risks in the development of a drug candidate.³³ According to the plaintiff, Arrowhead said during trials that the drug and its delivery mechanism did not present any dose-limiting toxicities, which would undermine the drug's viability on the market.³⁴ Eventually, though, the FDA halted Arrowhead's proposed trials because of the existence of such toxicities.³⁵ Despite the plaintiffs' assertions regarding FDA intervention, the court dismissed their claim, concluding that the allegations did not point to particularized facts showing that the defendants had actual knowledge that their statements regarding the drug's trial performance were false at the time they were made.³⁶ Defendants achieved similar results in four other cases involving assertions of misrepresented trial results.³⁷

³³ *In re Arrowhead Pharma., Inc. Sec. Litig.*, CV 16-08505 PSG-PJW, 2 (C.D. Cal. Dec. 21, 2017).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.* at 9.

³⁷ See *Markette v. XOMA Corp.*, Case No. 15-cv-03425-HSG, 2017 WL



Even if plaintiffs pleaded an actionable misstatement, they must still face difficulty in meeting the courts' standards for pleading scienter. The plaintiff in *Patel v. Seattle Genetics, Inc., et al.*, asserted that executives at Seattle, a biopharmaceutical company developing a cancer treatment, repeatedly characterized their drug candidate as having a superior design and taking advantage of more advanced technology than an older drug.³⁸ Stock prices dropped, though, when the manufacturer revealed trial data indicating that the drug caused toxic side effects and liver disease.³⁹ After the plaintiff brought suit, the defendant company moved to dismiss, and the court ultimately concluded that while

the plaintiff had adequately pleaded misrepresentation, there was insufficient indication that the individual defendants were aware of the data suggesting liver toxicity.⁴⁰ Courts found plaintiffs' pleadings similarly deficient with respect to scienter in two other decisions involving allegedly false trial reporting.⁴¹

In certain instances, though, plaintiffs were able to adequately demonstrate that defendants had made false or misleading statements of material facts with respect to medical product development and that defendants acted with scienter. In *Medina v. Clovis Oncology, Inc.*, for example, the plaintiff brought suit based on alleged misrepresentations related to Clovis's development of a lung cancer drug candidate.⁴² Clovis executives told investors that their drug had exhibited an "impressive" and "very compelling" safety and efficacy profile during trials.⁴³ Stock prices tripled after the defendants reported that the drug was performing well against a rival drug, but the company ultimately revealed that its pronouncements

4310759, at *5-10 (N.D. Cal. Sept. 28, 2017) (granting dismissal of allegations that eye disease treatment developer knowingly mischaracterized trial performance metrics on investor conference calls); *In re PTC Therapeutics, Inc. Sec. Litig.*, Civ. No. 16-1124 (KM) (MAH), 2017 WL 3705801, at *11-14 (D.N.J. Aug. 28, 2017) (granting partial dismissal of claims that muscular dystrophy drug developer manipulated trial data and reported only the most positive results); *Harrington v. Tetraphase Pharma. Inc.*, Civil No. 16-10133-LTS, 2017 WL 1946305, at *11-12 (D. Mass. May 9, 2017) (granting dismissal of claims that defendant drug company hid poor trial results while making claims about a drug candidate's likely efficacy); *Lerner v. N.W. Biotherapeutics*, Case No. GJH-15-2532, 2017 WL 1229710, at *8-10 (D. Md. Mar. 31, 2017) (granting dismissal of claims asserting that cancer treatment manufacturer exaggerated a drug candidate's trial performance and engaged in a fictitious social media campaign to boost stock prices).

38 *Patel v. Seattle Genetics, Inc.*, Case No. C17-41RSM, 2017 WL 4681380, at *1 (W.D. Wash. Oct. 18, 2017).

39 *Id.* at *2.

40 *Id.* at *6.

41 See *Harrington*, 2017 WL 1946305, at *7 (dismissing fraud claim in part because "allegations [fell] far short of the strong inference of scienter necessary to support" it); *Lerner*, 2017 WL 1229710, at *14-15 (concluding that neither defendants' position within a company nor financial motives, without more, could support a finding of scienter).

42 *Medina v. Clovis Oncology, Inc.*, 215 F.Supp.3d 1094 (D. Colo. 2017).

43 *Id.* at 1122-23.

had been based on unconfirmed data.⁴⁴ When the trial results were finalized, they showed far worse performance, and the FDA followed that revelation with a report stating that the drug was not safe.⁴⁵ The plaintiffs' claims survived a motion to dismiss, as the court concluded that the defendants' statements were both false and material.⁴⁶ In addition, their explicit pronouncements that they had had access to the underlying data served to demonstrate the defendants' scienter in making such misrepresentations.⁴⁷ The parties ultimately settled for US\$142 million, the second-largest settlement among life sciences securities class action suits in 2017.⁴⁸ Plaintiffs also survived motions to dismiss — though perhaps not resulting in settlements of such magnitude — in six other instances in 2017.⁴⁹

44 See Am. Compl., *Medina v. Clovis Oncology, Inc.*, No. 1:15-cv-02546-RM-MEH ¶ 12 (D. Colo. Feb. 22, 2017); *Medina*, 215 F. Supp.3d at 1108.

45 *Id.* at 1109.

46 *Id.* at 1111-24.

47 *Id.* at 1125.

48 See Judgment Approving Class Action Settlement, *Medina v. Clovis Oncology, Inc.*, No. 1:15-cv-02546-RM-MEH (D. Colo. Oct. 26, 2017). The largest settlement of any life sciences securities class action in 2017 came in *In re Salix Pharmaceuticals, Ltd.*, which the parties resolved for \$210 million. See Judgment Approving Class Action Settlement, *In re Salix Pharmaceuticals, Ltd.*, No. 14 Civ. 8925 (KMW) (S.D.N.Y. Aug. 18, 2017).

49 See *Cooper v. Thoratec Corp.*, 698 Fed. Appx. 516, 516 (9th Cir. 2017) (reversing lower court's dismissal on grounds that plaintiff alleged with sufficient particularity that defendant had made misleading statements about a drug candidate's side effects); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *11-14 (dismissing claims regarding speculation of a drug candidate's development timeline but upholding others directed at specific misstatements of drug trial results); *In re CytRx Corp. Sec. Litig.*, CV 16-05519 SJO, 10-12 (SKx) (C.D. Cal. Aug. 14, 2017) (denying in part defendants' dismissal motion and concluding that plaintiff adequately pleaded that defendant had falsely characterized drug trials in light of an FDA Special Protocol Assessment); *Hsu v. Puma Biotech, Inc.*, SACV 15-00865 AG (JCGx), 6 (C.D. Cal. July 25, 2017) (finding that defendants had contradicted data available to them in mischaracterizing a drug candidate's safety profile); *In re Juno Therapeutics, Inc.*, Case No. C16-1069RSM, 2017 WL 2574009, at *5 (June 14, 2017) (denying defendants' motion to dismiss where plaintiffs adequately alleged improper concealment of drug candidate's toxicity during trials); *Schueneman v. Arena Pharma, Inc.*, Case No. 3:10-CV-1959-CAB-BLM, 2-3 (S.D. Cal. Apr. 28, 2017) (finding adequate pleading of false opinion statements, assessed under the *Omnicare* framework, regarding a drug candidate's performance in trials).

The courts have historically applied a close lens to plaintiffs' claims of misrepresentations pertaining to medical product development. Plaintiffs seeking redress for alleged securities fraud are frequently tasked with addressing specifically the question of when defendants have access to particular trial results, the knowledge of which may be an important foundation for scienter.⁵⁰ Courts have tended to expect a similar level of specificity in pleadings relating to FDA guidance on trials; where plaintiffs base charges on FDA communications, they must point to particular inconsistencies in defendants' statements rather than highlighting a generally negative FDA opinion.⁵¹

Court decisions arising out of overly optimistic statements regarding FDA approval

While discussion of drug performance during trials marks one potential stumbling block for life sciences companies, such firms also face risk stemming from comments on the likelihood of FDA approval. Drug manufacturers must communicate with the FDA throughout the development process, and, in certain instances, the FDA may provide feedback suggesting that a drug candidate is unlikely to secure approval or that development will require significantly more funding. When companies announce negative feedback from the FDA, investors sometimes scrutinize their prior characterizations of the feedback that the FDA provided during earlier stages of the development process. Securities claims may follow, with plaintiffs asserting that the company misled investors by hiding adverse commentary by the FDA.

In 2017, courts sided with two companies, TransEnterix and Eagle Pharmaceuticals, who were each charged with

50 *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *4-5 (finding scienter where defendants had completed a previous round of trials and encountered similarly negative results); *Harrington*, 2017 WL 1946305 (finding a lack of scienter where plaintiffs did not adequately allege that defendants possessed trial results in question).

51 See *In re Arrowhead Pharm., Inc. Sec. Litig.*, CV 16-08505 PSG-PJW, 9 (C.D. Cal. Dec. 21, 2017) (concluding that plaintiff did not adequately specify contradictions between defendant statements and FDA guidance on a drug candidate).

false characterization of FDA guidance. In both *TransEnterix and Bauer v. Eagle Pharmaceuticals, Inc.*, the court also dismissed the plaintiffs' claims in part because the defendants' optimistic statements regarding FDA approval were forward-looking and thus qualified for the Private Securities Litigation Act safe harbor.⁵² In those instances, the companies provided sufficient cautionary language to justify protection under the safe harbor provision. In each instance, the court also found that the plaintiffs had not adequately alleged falsity. In *TransEnterix Investor Group v. TransEnterix, Inc.*, for example, the plaintiffs brought suit alleging that TransEnterix had duped investors through excessively optimistic statements regarding the company's chances to bring a robotic surgical product to market.⁵³ They asserted that the company hid from investors the news that the FDA had, in fact, denied TransEnterix's application, leading the company to shelve the product — a development that, when eventually disclosed, caused a 50% drop in TransEnterix's stock price.⁵⁴ The court discussed the import of *Omnicare*, searching for (and failing to find) allegations of material facts that would conflict with a reasonable investor's conclusions from TransEnterix's statements, despite their unrealized optimism.⁵⁵ Without determining whether *Omnicare* would govern, though, the court determined that dismissal would be appropriate regardless.⁵⁶

Court decisions regarding alleged misrepresentations after product development

Completing the development phase, of course, does not shield life sciences companies from the risk of liability moving forward. In 2017, courts issued rulings in at least

seven cases involving post-development fraud claims, six of which turned in favor of the plaintiffs (at least in part).⁵⁷ Whereas pitfalls followed a consistent pattern in cases focusing on the development stage, disputes arising after products went to market were more diverse in character, ranging from manufacturing issues to ongoing integrity of statements regarding FDA approval.

In 2017, courts issued rulings in at least seven cases involving post-development fraud claims, six of which turned in favor of the plaintiffs.

The court in *In re Atossa Genetics Inc. Securities Litigation* underscored the risks that life sciences companies face when they attempt to recast existing products for other uses.⁵⁸ There, the plaintiffs asserted that Atossa had made improper statements regarding the viability of two products — one already on the market and one still in need of FDA approval.⁵⁹ In advance of an initial public offering, Atossa marketed a previously approved device as part of a combination with another device, which had not been approved either alone or in combination.⁶⁰ The FDA responded with a warning letter,

⁵² *TransEnterix Investor Grp. v. TransEnterix, Inc.*, No. 5:16-CV-313-D, 2017 WL 4246780, at *15 (E.D.N.C. Sept. 22, 2017); *Bauer v. Eagle Pharma., Inc.*, No. 16-3091 (JLL), 2017 WL 2213147, at *9-10 (D.N.J. May 19, 2017) (finding that defendants' statements on the likelihood of FDA approval of a drug candidate were forward looking and adequately accompanied by cautionary language).

⁵³ *TransEnterix Investor Grp. v. TransEnterix, Inc.*, No. 5:16-CV-313-D, 2017 WL 4246780, at *5.

⁵⁴ *Id.* at *4-7.

⁵⁵ *Id.* at *14.

⁵⁶ *Id.*

⁵⁷ See *In re Atossa Genetics Inc. Sec. Litig.*, 868 F.3d 784, 803 (9th Cir. 2017) (reversing lower court's dismissal where plaintiffs adequately pleaded falsity of defendants' assertions regarding FDA approval of two medical devices); *Meyer v. Concordia Int'l Corp.*, 16 Civ. 6467 (RMB), 7-9 (S.D.N.Y. July 28, 2017) (denying in part defendants' motion to dismiss and finding that plaintiff sufficiently alleged defendants' failure to disclose material facts regarding key drug's sales trends); Order, *City of Cape Coral Municipal Firefighters' Ret. Plan v. Emergent Biosols., Inc.*, HQ, No. RWT 16-2625 (D. Md. July 7, 2017) (denying defendants' motion to dismiss where plaintiff claimed that defendant had exaggerated demand for its sole drug and the size of a forthcoming government contract); Order, *Ark. Teacher Ret. Sys. v. Insulet Corp.*, No. 1:15-cv-12345-MLW (D. Mass. Mar. 17, 2017) (denying defendants' motion to dismiss where plaintiff had asserted defendants' omission of medical device manufacturing and quality problems); see *In re Psychomedics Corp. Sec. Litig.*, No. 17-10186-RGS, 2017 WL 5159212, at *4-7 (D. Mass. Nov. 7, 2017) (granting dismissal of claims that defendants had engaged in a foreign cartel scheme and concluding that plaintiffs did not sufficiently demonstrate defendants' knowledge of the scheme).

⁵⁸ *In re Atossa Genetics*, 868 F.3d 784.

⁵⁹ *Id.* at 790-91.

⁶⁰ *Id.* at 791.

which the company then disclosed without mentioning the approval issues facing its devices.⁶¹ Ultimately, the FDA ordered a recall of both products for improper marketing, and Atossa stock dropped by 46%.⁶² After the district court dismissed the plaintiffs' claims, the Ninth Circuit reversed, finding that company executives falsely characterized the previously approved device even after the FDA issued its warning letter.⁶³

Quality control also marks an area of risk for life sciences companies who have advanced beyond the development stage. In *Arkansas Teacher Retirement System v. Insulet Corp., et al.*, the plaintiff brought claims pertaining to a new diabetes pump marketed by Insulet.⁶⁴ The company touted the product as drawing positive feedback from users and told investors that sales were surging.⁶⁵ The plaintiffs, though, alleged that the company had encountered significant manufacturing and quality issues, such as defective needle and alarm mechanisms, that eroded patients' faith in the product.⁶⁶ The company ultimately disclosed that patients and revenues were trending downward, leading to significant drops in stock

prices.⁶⁷ The plaintiff's claims survived a motion to dismiss in 2017, and the case is ongoing.⁶⁸

Court decisions regarding alleged financial misrepresentation

While life sciences companies must navigate distinct sources of risk when communicating with investors, they also face a range of issues common to companies of all types. In 2017, courts issued 13 decisions in cases involving allegations of financial misstatements, including bribery issues, improper accounting and insider trading, among other claims. The results were mixed for life sciences companies facing such allegations, as the courts dismissed six such cases but allowed seven others to proceed past a motion to dismiss.

Plaintiffs challenging life sciences companies for financial statements encountered similar issues of proving falsity and scienter. In *In re Tenet Healthcare Corp. Securities Litigation*, the court addressed claims that Tenet, a hospital chain, had engaged in a substantial kickback



61 *Id.* at 791-93.

62 *Id.* at 793.

63 *Id.* at 798.

64 See Am. Compl., *Ark. Teacher Ret. Sys. v. Insulet Corp.*, No. 1:15-cv-12345-MLW ¶ 2 (D. Mass. June 1, 2016).

65 *Id.* at ¶ 3.

66 *Id.* at ¶ 4, 6.

scheme that enabled it to claim millions of dollars in

67 *Id.* at ¶¶ 6-7, 14, 16.

68 See Order, *Ark. Teacher Ret. Sys. v. Insulet Corp.*, No. 1:15-cv-12345-MLW (D. Mass. Mar. 17, 2017).

Medicare and Medicaid reimbursements.⁶⁹ The plaintiffs alleged that instead of disclosing government investigations into the scheme, Tenet reaffirmed the strength of its compliance policies.⁷⁰ In dismissing the case, the court ruled that Tenet's statements on compliance were neither sufficiently specific nor sufficiently concrete to convey an image of *complete* compliance within the company.⁷¹ In addition, the court found a lack of "intentional or severely reckless fraud" on the part of the defendants, thereby undermining the plaintiffs' assertions of scienter.⁷²

There, the court found scienter in part because three separate independent auditing firms had raised the auditing errors to management, who had opted not to disclose the issues.⁷⁷

In 2017, courts issued 13 decisions in cases involving allegations of financial misstatements, including bribery issues, improper accounting and insider trading.

The pharmaceutical company Akorn found less success in attempting to secure dismissal of a securities fraud case targeting the company's alleged financial misrepresentations. In *In re Akorn, Inc. Securities Litigation*, the plaintiffs claimed that Akorn had engaged in accounting violations related to understatements of rebates, chargebacks and contractual allowances.⁷³ In addition to these errors, the company was alleged to have failed to implement and enforce adequate internal financial reporting controls.⁷⁴ The court concluded that the company's statements regarding its financial performance were both false and material, finding support in part from the 22% drop in stock price that followed one corrective filing.⁷⁵ The court also assessed a statement that the company was "on track" with the integration of a new subsidiary (eventually revealed to be false), finding that it was not forward-looking and instead conveyed "the current state of the integration efforts."⁷⁶

⁶⁹ *In re Tenet Healthcare Corp. Sec. Litig.*, No. 3:16-cv-02848-C, 1-2 (N.D. Tex. Dec. 20, 2017).

⁷⁰ *Id.* at 6-8.

⁷¹ *Id.* at 8.

⁷² *Id.* at 15.

⁷³ *In re Akorn, Inc. Sec. Litig.*, 240 F.Supp.3d 802, 807-13 (N.D. Ill. 2017).

⁷⁴ *Id.* at 805-07.

⁷⁵ *Id.* at 811.

⁷⁶ *Id.* at 816-18.

⁷⁷ *Id.* at 820.

Minimizing securities fraud litigation risks

Life sciences companies are 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.
- ✓ 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.
- ✓ Ensure that the sometimes fine line between puffery and statements of fact is not crossed in public statements or filings, or even in extemporaneous statements during conference calls or media commentary. A common source of class action claims in 2017 arose from conference calls with investors and/or analysts in which company management made overzealous statements about FDA approval when the company’s application contained glaring deficiencies or statements allaying investors’ concerns about negative trial data. Although mere puffery that projects a positive image about a company is not misleading under securities laws, class action lawyers will seize upon hard statements of fact — with the benefit of 20/20 hindsight — to concoct a lawsuit.
- ✓ Be aware that while incomplete statements do not create liability, such omissions must not make the actual statements misleading.
- ✓ Be aware that opinion statements will be reviewed under the *Omnicare* standard and 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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