

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

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Introduction

Life sciences companies continued to be popular targets of securities fraud class action lawsuits filed in 2016, and prudent life sciences companies should take heed of the results of this year's decisions.

In 2016, plaintiffs filed a total of 67 class action securities lawsuits against life sciences companies, an over 70% increase from 2014. Of these cases, the following trends have emerged:

- There are more claims against small cap companies. Roughly half of the life sciences class action securities lawsuits filed in 2016 targeted companies with a market capitalization of US\$500 million or less; this figure has ranged from 50% to 63% since 2012.
- Plaintiffs filed more securities lawsuits against life sciences companies in the Second, Third and Ninth Circuits, and in particular in federal court in New York and California.
- Two plaintiffs' firms represented plaintiffs in over half of the total life sciences class action securities fraud suits in 2016: The Rosen Law Firm (18 filings) and Pomerantz LLP (17 filings).

Trends relating to the types of cases being filed in 2016 demonstrated continuing trends from previous years, with some new developments.

- Nearly 50% of all class action securities fraud cases filed against life sciences companies in 2016 complained of misrepresentations or omissions regarding product efficacy, product safety and/or the likelihood of FDA approval.
- Several cases focused on alleged misrepresentations regarding regulatory hurdles and the timing and prospects of FDA approval.
- There were also several filings arising out of conduct that was less specific to the life sciences industry.

The securities litigation bar also saw a large number of decisions rendered in 2016 involving life sciences companies, including:

- Claims that arose in the development phase before the company's product had gone to market involving issues such as failed clinical trials or adverse decisions by the FDA, with the majority of cases being decided in defendants' favor.
- Claims that arose after the company's product had already been approved by the FDA, including alleged misrepresentations regarding quality control and manufacturing processes, with courts deciding both for and against defendants.

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. Although the majority of the cases decided this last year were decided in the defendant company's favor, life sciences companies remain attractive targets for class action securities fraud claims.

Life sciences companies still popular targets for securities fraud litigation

In recent years, life sciences companies have increasingly been targeted in securities fraud lawsuits, and 2016 was no exception. This survey is intended to give a comprehensive overview of life sciences securities lawsuits in 2016. 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 2016 and how they are impacting the 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. This trend continued in 2016, with the total number of securities fraud class action lawsuits topping 270, 82 more than the 188 by the end of 2015.¹ Compared to 151 total class action securities fraud cases filed in 2012, the number of total class action securities fraud cases filed has increased almost 80%. (See **Figure 1**)

As the number of securities lawsuits has increased, so has the number of such lawsuits involving life sciences companies. A total of 67 class action securities lawsuits were filed against life sciences companies in 2016, a more than 70% increase from 2014.²

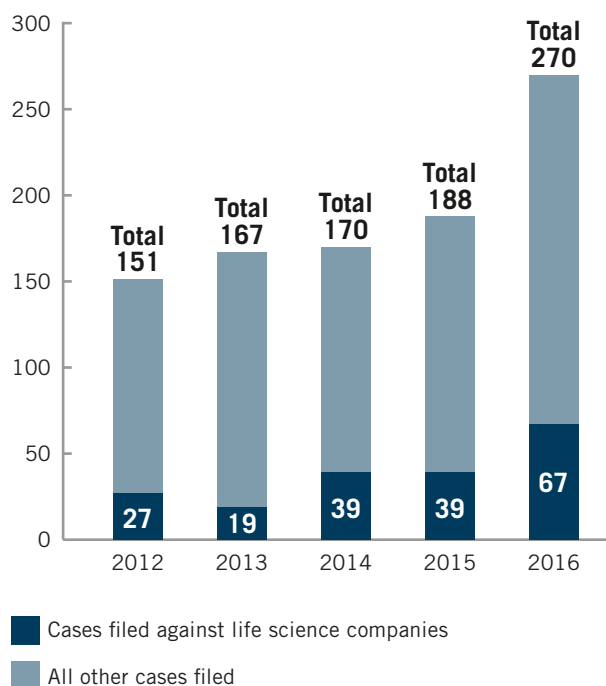
A number of factors combined to result in this rise in increased litigation. Claims arising out of an alleged price

fixing scheme, for example, were the underlying facts in six of the filings. Ultimately, however, the majority of the complaints 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 37 class action securities fraud claims against life sciences companies decided in 2016.³

Figure 1

Number of class action securities fraud cases filed from 2012–2016 (Total cases filed compared to cases filed against life science companies)



1 The numbers of securities fraud class actions filed and decided, as well as the number of those brought against life sciences companies, are based on information reported by the *Securities Class Action Clearinghouse* in cooperation with *Cornerstone Research*, Stanford Univ., *Securities Class Action Clearinghouse: Filings Database*, SECURITIES CLASS ACTION CLEARINGHOUSE <http://securities.stanford.edu/filings.html> (last visited Jan. 17, 2017); as well as reported by The D&O Diary. Kevin LaCroix, *2016 Securities Lawsuit Filings Surge to Record Levels*, THE D&O DIARY (Jan. 2, 2017), <http://www.dandodiary.com/2017/01/articles/securities-litigation/2016-securities-lawsuit-filings-surge-record-levels/>.

2 67 is an increase of 71.8% of 39.

3 The 37 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 terminated between January 1 and December 31, 2016. Lex Machina, *Lex Machina: Cases, PTAB Trials, and ITC Investigations*, <https://law.lexmachina.com/cases/?filters=true&view=analytics&tab=summary&cols=475> (last visited Jan. 16, 2017).

Filing trends

The life sciences industry has continued to be a popular target for class action securities fraud cases. Nearly one out of every four securities fraud class action lawsuits filed in 2016 was brought against a life sciences company.⁴ With the increase in filings, trends have emerged regarding the companies that are targeted, as well as the underlying activities that give rise to these complaints:

- **More claims against small cap companies.** As in previous years, 2016 saw an increase in the number of claims filed against companies with proportionately smaller market capitalizations (see **Figure 2**). Roughly half of the life sciences class action securities lawsuits filed in 2016 targeted companies with a market capitalization of US\$500 million or less;⁵ this figure has ranged from 50% to 63% since 2012.⁶ At the other end of the spectrum, the largest proportional increase from 2014 is cases

filed against companies with \$10 billion or more in market capitalization. For example, Teva Pharmaceutical Industries (US\$34.48 billion), Illumina Incorporated (US\$23.88 billion), and Allergan (US\$81.07 billion) were just some of the higher profile companies that were targeted in 2016.⁷

- **Increase in suits filed in the Second, Third and Ninth Circuits, in particular, in New York and California.**

Of the 67 class action securities fraud suits brought against life sciences companies in 2016, the majority were brought in 3 U.S. Courts of Appeal: the Ninth Circuit with 21, the Second Circuit with 19, and the Third Circuit with 11. Among federal district courts, the largest number of filings were in the Districts of New York with 19, 18 of which were filed in the Southern District. The state with the next highest number of federal filings was California, which had 17 filings: 8 in the Central District, 3 in the Southern District, and 6 in the Northern District.



⁴ 67 filings out of a total of 270 is 24.8%.

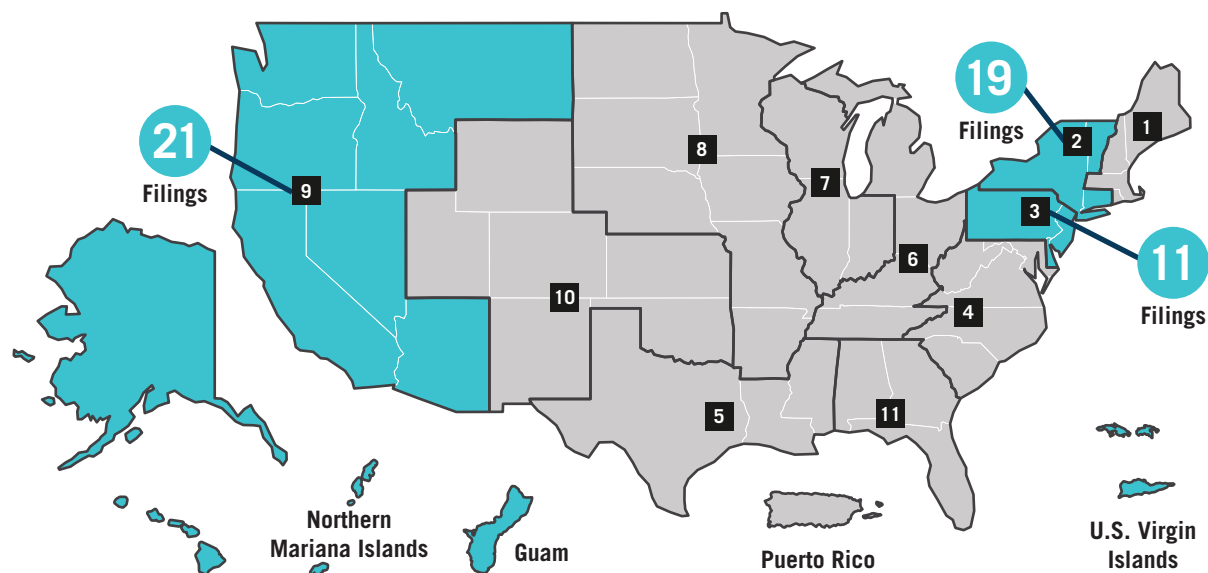
⁵ 34 out of 67, or 50.7%.

⁶ As reported in our 2014 survey. David A. Kotler, Dechert Survey of Securities Fraud Class Actions Brought Against U.S. Life Sciences Companies, (Dechert LLP), March 2015, at 1.

⁷ Market capitalization figures are current as of January 16, 2017 and were compiled with Yahoo! Finance. Yahoo!, Yahoo Finance, YAHOO.COM, <https://finance.yahoo.com/> (last visited Jan. 16, 2017).

Figure 3

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



More than 50% of all the life sciences securities fraud class action suits filed in 2016 were filed in these two states.⁸ (See **Figure 3**)

- **Two plaintiffs’ firms file vast majority of securities actions against life sciences companies.** Two firms in particular represented plaintiffs in more than half of the total life sciences class action securities fraud suits in 2016: The Rosen Law Firm (18 filings) and Pomerantz LLP (17 filings).

When viewed in context, these numbers are generally in line with historic trends. This year’s distribution of filings by market capitalization has been in line with previous years.⁹ The number of class action securities fraud filings in the Second and Ninth Districts over the last few years have consistently dwarfed filings in other circuits, so this trend is consistent with the life sciences industry.¹⁰ It appears that the inherent risks involved with developing products makes these companies in the life sciences

targets for plaintiff’s firms that have found companies involved in the FDA approval process ripe for securities fraud lawsuits. There will be ample opportunity to track these trends in 2017, as there have already been a number of life sciences securities class action filings this year.¹¹

Causes of action

The types of cases filed in 2016 demonstrated continuing trends from previous years along with some new developments.

Nearly 50% of all of the class action securities fraud cases filed against life sciences companies in 2016 complained of misrepresentations or omissions regarding product efficacy, product safety, and/or the likelihood of FDA approval.¹²

⁸ 36 out of 67, or 53.7% were filed in these two states.

⁹ Kotler, *supra* note 7, at 1-2.

¹⁰ As reported in Stefan Boettrich and Svetlana Starykh, *Recent Trends in Securities Class Action Litigation: 2016 Full-Year Review*, Nera Inc., at 12, (January 25, 2016), http://www.nera.com/content/dam/nera/publications/2016/2015_Securities_Trends_Report_NERA.pdf.

¹¹ There were already four class action securities claims filed against life sciences companies in the first week and a half of 2017.

¹² 33 of the 67 complaints were reviewed and determined to have involved these issues or a combination thereof.

Seres Therapeutics,¹³ for example, was sued over information it released following interim results from its Phase 2 clinical trial. Seres had made positive representations in its IPO registration statement about the efficacy of a drug it was developing and continued to make similar statements throughout the class period.¹⁴ Prior to the start of the study, however, Seres had modified the manufacturing process and formula of its trial drug without disclosing such changes to its investors.¹⁵ After Seres disclosed the poor results and the formula changes, Seres' stock price dropped more than 70%.¹⁶ In their complaint, plaintiffs claimed that Seres' positive representations in its registration statement and subsequent statements were misleading given that at the time Seres made these statements, it was simultaneously receiving negative clinical feedback.¹⁷

Several cases focused on alleged misrepresentations regarding regulatory hurdles and the timing and prospects of FDA approval.¹⁸

In *CytRx*, for instance, the FDA had placed a hold on CytRx's Phase 3 clinical trial in November 2014.¹⁹ Despite the hold, CytRx purportedly assured investors that the hold would be removed and that CytRx would

have Phase 3 results by June 2016.²⁰ The hold on the trial, however, caused two-thirds of the enrolled patients to have insufficient time for follow-up, resulting in an exclusion of their results. Ultimately, these issues required CytRx to conduct a second trial.²¹ Plaintiffs claimed that CytRx hid from investors the likelihood that the FDA hold would cause issues with the first trial, require a second trial and that due to these issues, FDA approval would ultimately be delayed.²²

A third group of cases arose from allegations not specifically related to the life sciences field.

There were also several filings arising out of conduct that was less specific to the life sciences industry. In six of the cases, for instance, plaintiffs alleged that companies had engaged in a scheme of generic drug price fixing stemming from an ongoing Justice Department investigation that began in 2014.²³ These complaints claim that the defendant companies led the investors to believe that the companies' internal controls and financial reporting were accurate, and that they were in compliance with the necessary laws and regulations,

13 Complaint, *Mazurek v. Seres Therapeutics, Inc.*, No. 1:16-CV-11943 (DJC), 2016 WL 5650505 (D.Mass. Sep. 28, 2016).

14 *Id.* ¶¶ 26-32.

15 *Id.* ¶¶ 33-26.

16 *Id.* ¶ 36.

17 *Id.* ¶ 33; see also Complaint, *Reilly et al. v. Abeona Therapeutics, Inc. et al.*, No. 1:16-CV-09730, 2016 WL 7366010 (S.D.N.Y. Dec. 16, 2016) (plaintiffs claimed defendants' statements about their trial drug overstated the drug's potential viability, causing the stock to drop when an analyst firm published an article questioning the science behind the drug therapy); Complaint, *Ayeni, v. Spectrum Pharm., Inc.*, 2:16-CV-07074, 2016 WL 5219492 (C.D. Cal. Sep. 21, 2016) (alleging defendants' statements about drug's likelihood of FDA approval were misleading, causing the stock to drop after the drug's NDA was rejected and news revealed that the FDA questioned the company's study data and discouraged the company from submitting an NDA).

18 14 of the filings reviewed involved claims arising out of approval timing issues.

19 Complaint ¶ 3, *Crihfield v. CytRx Corp. et al.*, No. 2:16-CV-05519, 2016 WL 4009812 (C.D. Cal. July 25, 2016).

20 *Id.* ¶ 34.

21 *Id.* ¶ 36.

22 *Id.* ¶ 35; see also Complaint, *Soontjens v. Dynavax Tech. Corp. et al.*, No. 3:16-CV-06690 (HSG), 2016 WL 6871996 (N.D. Cal. Nov. 18, 2016) (plaintiffs alleged defendants omitted details of an FDA review of safety data causing the stock to decline after the FDA issued a letter informing defendants it had not completed its review, delaying approval); Complaint, *Bauer v. Eagle Pharm., Inc. et al.*, No. 2:16-CV-03091-JLL-JAD, 2016 WL 3068007 (D.N.J. May 31, 2016) (plaintiffs alleged defendants issued misleading statements about the likely timing of the FDA's approval of their drug, and stock dropped following news that the approval would be delayed due to additional requests by the FDA).

23 Complaint, *Nunez, Jr. v. Impax Lab., Inc. et al.*, No. 3:16-CV-08420 (MAS) (TJB) (D. N.J. Nov. 10, 2016); Complaint, *Utesch, v. Lannett Co., Inc.*, No. 2:16-CV-05932 (WB), 2016 WL 6803195 (E.D. Pa. Nov. 16, 2016); Complaint, *Shasha, v. Endo Intl. PLC et al.*, No. 1:16-CV-08645, 2016 WL 6607271 (S.D.N.Y. Nov. 7, 2016) dismissed (S.D.N.Y. Dec. 12, 2016); Complaint, *Galmi v. Teva Pharm. Indus. Ltd, et al.*, No. 2:16-CV-08259, 2016 WL 6654457 (C.D. Cal. Nov. 6, 2016); Complaint, *Arslanian v. Allergan PLC et al.*, No. 2:16-CV-08254, 2016 WL 6576875 (C.D. Cal. Nov. 4, 2016) dismissed (C.D. Cal. Jan. 2, 2017); Complaint, *Speakes v. Taro Pharm. Indus. Ltd. et al.*, No. 1:16-CV-08318, 2016 WL 6245617 (S.D.N.Y. Oct. 25, 2016).

when in fact, the companies were being investigated for alleged price fixing.²⁴ Typically, these claims were filed after the respective company disclosed that criminal investigations were being conducted for the company's alleged antitrust violations. Other examples include allegations of inappropriate director and officer conduct in connection with proposed mergers,²⁵ and inaccurate financial reporting.²⁶

24 Complaint ¶ 19, *Nunez, Jr. v. Impax Lab., Inc. et al.*, No. 3:16-CV-08420 (MAS) (TJB) (D. N.J. Nov. 10, 2016).

25 Complaint, *Lavrenov v. Raptor Pharm. Corp. et al.*, No. 1:16-CV-00901 (D. Del. Oct. 5, 2016) dismissed (D. Del. Dec. 6, 2016) (plaintiff alleged defendants omitted positive details about company from investors and violated fiduciary duties by undervaluing company during proposed merger); Complaint, *Klein v. Medivation, Inc. et al.*, No. 3:16-CV-05154-WHA, 2016 WL 4702778 (N.D. Cal. Sep. 07, 2016) dismissed (N.D. Cal. Dec. 7, 2016) (plaintiff alleged defendants omitted positive information from recommendation statement in proposed merger, undervaluing the company).

26 Complaint, *Jie v. Ligand Pharm. Inc. et al.*, No. 1:16-CV-2832 GPC MDD, 2016 WL 6828192 (S.D. Cal. Nov. 17, 2016) (plaintiff alleged defendants made misleading statements about company's financial state; stock dropped after the company revealed that it did not have effective control over its financial reporting); Complaint, *Scalfani v. Misonix Inc. et al.*, No. 2:16-CV-05218 (E.D.N.Y. Sep. 19, 2016) (plaintiff alleged defendants omitted details of financial reporting deficiencies; stock dropped after news that the company

These trends highlight the challenges that life sciences companies face when selling securities. First, this year's filings show that unfavorable results of clinical trials are a common vehicle for plaintiffs to claim securities fraud violations. Secondly, investors – and plaintiff's firms – take negative communication from the FDA seriously when deciding whether to file a claim, particularly when that communication has not been conveyed to the investors. These filings also indicate, however, that life sciences companies can still be targeted for claims arising under more generalized securities fraud complaints such as those involving inaccurate financial reports and allegations of violating fiduciary duties.

Next are the decisions that were rendered in class action securities fraud cases against life sciences companies in 2016. The analysis of many of the cases that were decided in 2016 involved much of the same issues observed in the cases already noted.

would delay filing its 10-K due to those deficiencies); Complaint, *Bulcock v. Unilife Corp. et al.*, No. 1:16-CV-03976-RA, 2016 WL 3094477 (S.D.N.Y. May 26, 2016) (plaintiffs alleged defendants misrepresented their internal controls over accounting and financial reporting; stock dropped after company reported that it would delay filing its 10-Q).



2016 class action securities fraud decisions in the life sciences sector

The securities litigation bar also saw a large number of decisions rendered in 2016 involving life sciences companies. The cases are comprised of two broad categories: (i) cases involving claims that arose in the development phase before the company's product had gone to market, and (ii) claims that arose after the company's product had already been approved by the FDA. Coincidentally, a large majority of these decisions involve claims brought under Section 10(b) of the Securities Exchange Act of 1934. And several of the claims involved statements of opinions analyzed under *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*.²⁷

Court decisions regarding misrepresentation during product development

The development stage of a drug, device or product is a challenging period for life sciences companies, particularly due to uncertainties that often translate into unsuccessful or disappointing clinical trial results or adverse FDA decisions. Thus, in 19 out of the 37 decisions we reviewed this year, the courts analyzed

²⁷ 135 S. Ct. 1318, 1332 (2015) (holding that "a plaintiff challenging an omission in a defendant's statement of opinion "must identify particular (and material) facts"). In those cases where opinion statements were challenged under the *Omnicare* standard, plaintiffs typically had difficulty adequately alleging that the defendants' opinion statements were in conflict with information defendants had received in such a way as to render the opinion statements misleading. See, e.g., *Cody v. Conformis, Inc.*, No. CV 15-13295-GAO, 2016 WL 4132204, at *9 (D. Mass. Aug. 3, 2016) (finding plaintiff had not shown how defendants' opinion statements about belief in their compliance with FDA quality regulations were either untrue or not honestly believed, and so did not contain a misleading "embedded statement of fact"). But see, e.g., *Rihn v. Acadia Pharm., Inc.*, No. 15-CV-00575 (BTM) (DHB), 2016 WL 5076147 (S.D. Cal. Sep. 19, 2016) (finding defendants' opinion statements potentially misleading when defendants gave the impression they were on track for drug approval while not making the manufacturing preparations necessary to be approved).

claims dealing with facts underlying the development stage. Court decisions in 2016 relating to misrepresentations during the development stage include: claims involving a drop in the company's stock value immediately following unsuccessful clinical tests; and claims involving a drop in the company's stock following the company's receipt of negative feedback from the FDA. Generally, these cases involve representations the company made to investors implying that its product would be successful in either its clinical trials or the FDA approval process, which caused the company's stock to drop when investors were disappointed with adverse news.

Decisions involving stock drops immediately following failed clinical trials.

The development stage for a life sciences company is inherently risky because despite the company's good faith assessment of and belief in its clinical trials, those trials ultimately may be unsuccessful. An unsuccessful clinical trial will often trigger shareholder securities fraud class actions claiming investors were somehow misled. Over the last year, however, courts more often sided with the company's judgment when evaluating whether the positive and optimistic statements the company communicated to investors constituted securities fraud.

For example, in *Kelley v. Aerie Pharmaceuticals, Incorporated*,²⁸ the court dismissed the complaint, despite Aerie's positive statements being based on arguably bad science. Aerie conveyed to investors its expectations regarding how successfully its development stage drug would compete against two competing drugs on the market.²⁹ Aerie had based its expectations on the results from its Phase 2b trial comparing its drug to one of the other drugs on the market and a medical study

²⁸ No. 15-3007, 2016 WL 3437603 (D.N.J. June 20, 2016).

²⁹ *Id.* at *1.

conducted in the 1990s comparing the two competing drugs to each other.³⁰ Aerie then conducted a Phase 3 trial to compare its drug to the second competing drug.³¹ Aerie's Phase 3 trial failed to meet its expectations, and its stock price dropped significantly.³² The plaintiffs filed their suit six days after the announcement of the results, claiming that the clinical trial failed due to differences between it and the 1990 study of which Aerie should have been aware, and that Aerie's positive statements were misleading because they did not communicate those differences to investors.³³ The court did not find the plaintiffs' argument persuasive, particularly because they could not show that Aerie was aware of the allegedly critical differences between the two studies.³⁴ The complaint thus failed to show an intent by Aerie to mislead the investors and the court declined to second guess Aerie's optimistic expectations simply because they were found to be wrong or based on incorrect assumptions.³⁵

Courts did not uniformly accept every company's justification for its statements, however, as found in *Hsu v. Puma Biotechnology, Incorporated*.³⁶ Puma conveyed to investors that it was experiencing positive and improving results from its drug trial.³⁷ The court believed that Puma had stated various false or misleading facts to investors – e.g., the disease-free survival rate for the placebo in its trial was “around mid to high 80s” when it was actually 91.6% – and so there was sufficient evidence to survive a motion to dismiss.³⁸ Puma argued that its positive statements about its drug and its long term success were not false, despite the inaccurate numbers Puma disclosed, because the statements were based on an alternative method of measuring improvement in disease-free survival rates.³⁹ Regardless of Puma's alternative justification, the court found that there was enough of a

difference between the information conveyed to investors and the actual results for the plaintiffs' complaint to survive a motion to dismiss.⁴⁰

In these and other cases decided this year, the courts looked for circumstantial details in deciding whether the purported fraud should survive a motion to dismiss and beyond. A company that communicates positive expectations about its drug after designing clinical studies with input from the FDA, and receiving encouraging feedback from the FDA because of its successful results, for example, will not likely be found to have designed a fraudulent study or intended to mislead investors, even if its final results are different than what it anticipated.⁴¹ A company that opts to use a particular reasonable methodology in conducting its trials will also not likely later be found by the court to have committed fraud solely because the plaintiffs show that other research scientists disagree with that methodology.⁴² The life sciences field is complex and uncertain. Where the defendants had communicated the results of their trials accurately and the risks of failure were adequately explained, the courts showed reluctance to find fault in the defendants' optimism about the potential success of their trials. These cases show the deference courts give to defendant companies in the design of their trials.

30 *Id.*

31 *Id.*

32 *Id.*

33 *Id.* at *2.

34 *Id.* at *7.

35 *Id.* at *9-10.

36 No. SACV 15-0865 AG (JCGx), 2016 WL 5859000 (C.D. Cal. Sep. 30, 2016).

37 *Id.* at *8.

38 *Id.* at *8-9.

39 *Id.* at *8.

40 *Id.* at *8-9.

41 *Tadros v. Celladon Corp.*, No. 15-CV-1458 AJB (DHB), 2016 WL 5870002 (S.D. Cal. Oct. 7, 2016) (granting motion to dismiss and rejecting claim defendants misled investors about the likely success of Phase 2a trial, causing stock to drop when the trial failed to meet its efficacy endpoint; statements were not false or misleading, and instead were inactionable optimism); *Sapir v. Averbach*, No. CV-14-7331 (JLL) (JAD), 2016 WL 554581 (D.N.J. Feb. 10, 2016) (granting motion to dismiss and rejecting claim that defendants knowingly designed studies to produce misleading results, and then disclosed those results in order to keep market interest in trial product high, causing stock drop after disappointing results were revealed; plaintiff failed to allege an intent to deceive where defendants involved FDA in study design, informed market of progress, and immediately disclosed negative results).

42 *Zagami v. Cellceutix Corp.*, No. 15 CIV. 7194 (KPF), 2016 WL 3199531 (S.D.N.Y. June 8, 2016), *appeal withdrawn* (Sep. 6, 2016) (finding statements about the potential applications of pre-approval drugs following anonymous article calling company a “sham” were not misleading because they were either true or not misleading in context, or non-actionable medical opinions, and defendants' disclosures rendered statements not misleading).

Decisions arising out of stock drops following news of negative FDA feedback.

One of the most significant risks companies in the development stage face is receiving negative feedback, or worse, an adverse decision from the FDA. Approval for life sciences products requires companies to engage with the FDA throughout the entire process. News that a company withheld seemingly negative feedback from the FDA from investors often will result in a subsequent claim for securities fraud. Allegations in this category followed a pattern, whereby the company made positive statements to investors about its development stage product, but failed to disclose that the FDA had simultaneously communicated questions or concerns that it had with the product. Once something went wrong in development, the stock dropped and investors filed suit claiming the company withheld material information. Two contrasting cases this year highlight what courts have looked to in determining whether the company misled investors by not disclosing its communications with the FDA; *Vallabhaneni v. Endocyte, Incorporated*,⁴³ and the Ninth Circuit case *Schueneman v. Arena Pharmaceuticals, Incorporated*.⁴⁴

In *Vallabhaneni*, the company was allegedly misleading investors about its likelihood of receiving approval for its cancer treatment drug.⁴⁵ After Endocyte had received positive results from its Phase 2 trial, it began to develop its Phase 3 trial with the assistance of the FDA.⁴⁶ The FDA questioned the Phase 2 study design and results and recommended that Endocyte amend its next study to incorporate a more stringent efficacy goal point.⁴⁷ Endocyte incorporated those recommendations and began the study while promoting the results from the Phase 2 study.⁴⁸ The Phase 3 study eventually failed to meet the amended efficacy goals and the study was terminated.⁴⁹ The plaintiffs claimed that Endocyte knew

43 No. 1:14-CV-01048-TWP-MJD, 2016 WL 51260 (S.D. Ind. Jan. 4, 2016) appeal dismissed (Mar. 31, 2016).

44 840 F.3d 698 (9th Cir. 2016).

45 2016 WL 51260 at *10-12

46 *Id.* at *2-3.

47 *Id.*

48 *Id.* at *3-4.

49 *Id.* at *6.



its study was flawed based upon the feedback it had received from the FDA and that it should have therefore disclosed that feedback.⁵⁰ The court, applying *Omnicare*, found the plaintiffs had not shown that the defendants' opinions based on the FDA's feedback lacked a reasonable basis and so were not misleading. The court noted that "where a study's methods are reasonable and the defendant has accurately described those methods ... a defendant pharmaceutical company does not have to ... disclose all potentially relevant information or findings, or reveal potential flaws to study design or data analysis methodology."⁵¹

By contrast, in *Schueneman*, the FDA expressed concern to Arena about the rate that its drug was causing cancer in rats during animal tests.⁵² The FDA made the "highly unusual" request for bi-monthly updates on the cancer

50 *Id.* at *11-12.

51 *Id.* at *14.

52 *Schueneman*, 840 F.3d at 701-03.

rates in rats and a year later asked for an updated final report on Arena's rat studies.⁵³ After submitting its report to the FDA, but before receiving feedback on it, Arena communicated to investors that it was confident its drug would be approved based on several factors, including all the animal studies that it had done.⁵⁴ The FDA later published briefing documents in preparation for Arena's new drug application on its website that included, for the first time, its concerns about the drug's propensity to cause cancer in rats.⁵⁵

What differentiates these cases is what the respective companies conveyed to investors in their positive statements. After receiving feedback from the FDA, Endocyte changed its methodology and disclosed its changes to the public accurately.⁵⁶ The court was unwilling to find that Endocyte committed fraud by omitting the FDA's comments while disclosing the final product of those comments accurately.⁵⁷ This point is reemphasized in *Schueneman*: Arena was communicating positive expectations about its chances of FDA approval based on the success of all of its animal studies when it knew that the FDA's concerns with its rat study could

potentially stand in its way.⁵⁸ Unlike Endocyte, Arena did not communicate the effect of the FDA's negative comments accurately, and thus created a duty to include information it had to make its statements not misleading.⁵⁹

Any communication from the FDA could potentially be material for investors, as the FDA is the gateway in deciding whether the company's products receive approval. These cases demonstrate that "disclosure is required ... only when necessary to make statements" not misleading,⁶⁰ and so the question is not only whether investors would have found the communication with the FDA material, but also whether the company's statements were misleading without disclosing the FDA's communication.⁶¹ Communication with the FDA is continuous and can add additional hurdles that a development stage company must overcome before being approved. The cases in this category show that, so long as the company accurately conveys its processes and addresses potential risks head on, it is unlikely that the court will subsequently find liability.⁶²

53 *Id.*

54 *Id.* at 702.

55 *Id.* at 703.

56 *Vallabhaneni*, 2016 WL 51260, at *14.

57 *Id.*

58 *Schueneman*, 840 F.3d at 707-08.

59 *Id.*

60 *Matrixx Initiatives v. Siracusano*, 131 S. Ct 1309, 1321 (2011) (internal quotations and citations omitted).

61 *Colyer v. Acelrx Pharm., Inc.*, No. 14-CV-04416-LHK, 2015 WL 7566809, at *9 (N.D. Cal. Nov. 25, 2015).

62 *In re Amarin Corp. PLC Sec. Litig.*, No. CV-13-6663 (FLW) (TJB), 2016 WL 1644623, at *9 (D.N.J. Apr. 26, 2016).

Court decisions regarding misrepresentations after product development

After the FDA has approved a company's product, there is still the possibility that investors will claim the company misrepresented the risks it was facing when an adverse event occurs. The cases against companies in the post-approval phase can be broken into three categories: (i) complaints that the company's representations regarding market projections of its product were misleading; (ii) complaints that the company misrepresented its inappropriate promotional activities; and (iii) complaints that the company misrepresented problems that arose after the product had already been approved.

Litigation claiming market projections were materially false or misleading.

The three cases in this category involve complaints that the company portrayed positive expectations about its product's success on the market. At some point, the company failed to meet its projections for reasons that were allegedly unknown or misrepresented to investors. These cases are also similar in their ultimate conclusions: market projections are expectations about future events that by their nature are forward-looking and often optimistic. Market projections are therefore unlikely to be considered misleading unless they conflict with known information. The nature of market projections coupled with the company's disclosure of potential risks are what assisted the courts in their decisions.

All of these complaints arose after an issue that the company had disclosed to investors impacted sales more than the company originally believed it would. In one,⁶³ it was the death of a patient using the company's product.

⁶³ *In re Biogen Inc. Sec. Litig.*, Civ. A. No. 15-13189-FDS, 2016 WL 3541538 (D. Mass. June 23, 2016) *appeal filed* (July 28, 2016) (granting motion to dismiss where defendants' statements about the extent to which sales projections were effected following a patient's death were either protected by safe harbor or were corporate optimism regarding market growth the company anticipated).

In the second,⁶⁴ the issue was an additional medical test that needed to be performed on patients prior to being prescribed the drug. And in the last,⁶⁵ the issue was the possibility that the company would lose one of its distributors. In all three cases, the courts ruled in the defendant's favor finding the defendants had adequately disclosed the potential risk to their investors,⁶⁶ and their opinions were honestly held.⁶⁷ As these cases demonstrate, courts look carefully at how defendants construct statements about their projections, particularly with regard to the discussion of possible risks, to determine if the projections were possibly misleading.

Litigation claiming promotional practices were false or misleading.

This category of cases involves claims that the company inappropriately promoted its product while simultaneously representing to investors that its conduct was proper. Three cases in particular highlight what facts courts looked to when considering whether the defendants' promotional practices were inappropriate. These cases involved claims that defendants were inappropriately using stock promoters to inflate the value

⁶⁴ *Ardolino v. Mannkind Corp.*, Civ. A. No. 2:16-CV-00348-RGK-GJS, 2016 WL 4505172 (C.D. Cal. Aug. 23, 2016) (granting motion to dismiss where defendants led investors to believe that market projections were not negatively affected by their drug's burdensome prescription screening tests, finding the statements were not misleading because they confirmed issues were problematic and several of the other statements included inactionable puffery).

⁶⁵ *Silverstein v. Globus Med., Inc.*, Civ. A. No. CV 15-5386, 2016 WL 4478826 (E.D. Pa. Aug. 25, 2016) (granting motion to dismiss where defendants issued revenue forecasts but omitted decision to terminate a distributor agreement, finding that complaint contained no facts showing that projections incorporated revenue from distributor or how significant that revenue would have been; the projections were protected by the safe harbor; and there was insufficient evidence to show that defendants knew their projections would be false).

⁶⁶ *In re Biogen Inc. Sec. Litig.*, Civ. A. No. 15-13189-FDS, 2016 WL 3541538, at *28 (D. Mass. June 23, 2016); *Ardolino v. Mannkind Corp.*, Civ. A. No. 2:16-CV-00348-RGK-GJS, 2016 WL 4505172, at *6 (C.D. Cal. Aug. 23, 2016); *Silverstein v. Globus Med., Inc.*, Civ. A. No. 15-5386, 2016 WL 4478826, at *6-7 (E.D. Pa. Aug. 25, 2016).

⁶⁷ 2016 WL 3541538, at *28-29; 2016 WL 4505172, at *6; 2016 WL 4478826, at *6-7.

of their stock,⁶⁸ and a claim that the defendants promoted their product while failing to correct false and misleading statements made by third parties.⁶⁹

The two cases involving stock promoters are straightforward in their reasoning; both start with the general premise that using stock promoters is not inappropriate by itself, and find that the duty to disclose stock promoter payments falls on the party that receives the payments.⁷⁰ In *Bonanno*, the promoters had disclosed their connection with the company and, therefore, that information was considered “public” and there was nothing more that investors needed to make that information not misleading.⁷¹ The defendants therefore did not have a duty to affirm they were using stock promoters.⁷² *Galectin* can be distinguished from *Bonanno*, because the company represented that it would not “manipulate” its stock price – which plaintiffs argued was misleading – and two of its stock promoters had not disclosed that they had received payments from Galectin.⁷³ Even so, the court found that it was not Galectin’s duty to disclose the payments, and omitting the payments did not make Galectin’s statements false or misleading, as stock “manipulation” is a term of art referring to actions designed to “create an unnatural and unwarranted appearance of market activity,” which Galectin was not accused of doing.⁷⁴

68 *Bonanno v. Cellular Biomedicine Group, Inc.*, No. 15-CV-01795-WHO, 2016 WL 4585753 (N.D. Cal. Sep. 2, 2016) (granting motion to dismiss where defendants used promoters to raise stock price, causing the stock to drop when an anonymous investor “revealed” the scheme, finding that plaintiffs could not show that the stock drop was caused specifically by the information revealed); *In re Galectin Therapeutics, Inc. Sec. Litig.*, 843 F.3d 1257 (11th Cir. 2016) (affirming motion to dismiss, finding that defendants were under no duty to disclose third party stock promoters and there was no allegation that any defendant engaged in transactions amounting to stock manipulation).

69 *In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642 (2d Cir. 2016).

70 *In re Galectin Therapeutics, Inc. Sec. Litig.*, 843 F.3d at 1273; *Bonanno v. Cellular Biomedicine Group, Inc.*, 2016 WL 4585753, at *5-6.

71 *Bonanno*, 2016 WL 4585753, at *6.

72 *Bonanno*, 2016 WL 4585753, at *5.

73 *Galectin Therapeutics*, 843 F.3d at 1264, 1266.

74 *Galectin Therapeutics*, 843 F.3d at 1273 (quoting *Santa Fe Indus., Inc. v. Green*, 403 U.S. 462, 476-77 (1977)).

The third case, *In re Pfizer Incorporated Securities Litigation*,⁷⁵ involved a more complicated fact pattern. Plaintiffs had sued Pfizer after independent studies indicated that drugs it had acquired the rights to were linked to increased cardiovascular risks, claiming Pfizer knew of those risks but never disclosed them to investors.⁷⁶ Pfizer argued that the misleading statements at issue were made by employees of the drugs’ previous



75 *Pfizer*, 819 F.3d 642 (2d Cir. 2016).

76 *Pfizer*, 819 F.3d at 647.

owners over which Pfizer had no control.⁷⁷ The plaintiffs' theory, however, was first that Pfizer did have authority over several of the employee statements at issue. Additionally, plaintiffs argued that even if Pfizer could not be liable for the statements made by those employees, Pfizer failed to correct the same misleading information after learning of it and so "maintained" an already inflated stock price.⁷⁸ The court remanded the case, concluding that there were genuine issues of material fact suggesting that Pfizer could be liable for the other company's statements due to the existence of agreements between the companies regarding co-promotional activities as well as evidence that senior management at Pfizer had the authority to approve or disapprove statements to the media made by the third party employees.⁷⁹

Litigation claiming companies' quality controls and manufacturing processes were false and misleading.

The last group of cases pertains to issues that arose for the company after it had already received FDA approval. These cases were all decided on similar reasoning, particularly with regard to the sufficiency of the company's disclosure of potential risks.

The first three cases in this category involve claims that the defendant company had informed investors that its quality and control systems were in compliance with FDA regulations, but after making those statements, investors learned that there were serious problems with those same quality and control systems.⁸⁰ The question at issue in

⁷⁷ *Id.* at 655-56.

⁷⁸ *Id.* at 659.

⁷⁹ *Id.* at 655-58.

⁸⁰ *Cody v. Conformis, Inc.*, Civ. A. No. CV 15-13295-GAO, 2016 WL 4132204 (D. Mass. Aug. 3, 2016) (granting motion to dismiss where defendants led investors to believe company had adequate quality control measures after product recall caused stock to drop, finding defendants had no duty to disclose more information in risk disclosures because at the time there were no ongoing problems, defendants' disclosures and opinions were accurate and plaintiff failed to allege scienter); *Todd v. Staar Surgical Co., et al.*, No. 2:14 CV-05263(MWF) (RZ) (C.D. Cal. July 8, 2014) (denying motion to dismiss where defendants' opinion statements were misleading under *Omnicare* standard by implying compliance with FDA

these cases centered around whether the defendants' risk disclosures adequately described the actual adverse events that later occurred.

Cody provides a clear example of the general principle the courts considered when deciding these cases: forward-looking statements do not protect the defendants from liability if the risks they warn *may* happen are in fact *already* happening.⁸¹ The plaintiffs in *Cody* took issue with the defendants' risk disclosures that they "may encounter ... difficulties ... maintaining quality control and assurance."⁸² The court found, however, that the plaintiffs had not shown that the defendants were experiencing those quality control difficulties as of the date the statements at issue were made, and so the statements were not misleading.⁸³

The other two cases involved similar claims with opposite results: the motions to dismiss, in relevant part, were denied. In both *Todd* and *Flynn* the defendant companies made risk disclosures that the court found potentially misleading because they disclosed risks that the company may face while withholding information that the company was already experiencing those risks.⁸⁴ The defendants in *Todd* gave the impression that their manufacturing processes met with FDA regulations just days after they had received a warning letter from the FDA documenting fifteen separate violations at their manufacturing facility.⁸⁵ Similarly, in *Flynn*, the company disclosed the potential risks it could face – i.e. its products may not be compliant with regulations – but the

manufacturing regulations when numerous issues existed and conflicted with defendants' statements; stock declined after FDA published violations) (citations omitted); *Flynn v. Sientra, Inc.*, No. CV 15-07548 (SJO) (RAOx), 2016 WL 3360676 (C.D. Cal. June 9, 2016) (denying motion to dismiss, in part, where defendants' opinion statements were misleading under *Omnicare* standard by implying compliance with regulations when product was often contaminated, causing stock to drop when sale of product was suspended; while defendants had published risks they did not disclose that the "risks" may have already occurred) (citations omitted).

⁸¹ *Cody*, 2016 WL 4132204, at *6.

⁸² *Id.*

⁸³ *Id.* at *7.

⁸⁴ *Flynn v. Sientra, Inc.*, Civ. A. No. CV 15-07548 SJO (RAOx), 2016 WL 3360676, at *10-12; *Todd v. Staar Surgical Co., et al.*, No. 2:14 CV-05263 (MWF) (RZ) slip op. at 19-20.

⁸⁵ *Todd*, No. 2:14 CV-05263, at 5.

company neglected to inform its investors that the risks had already occurred. Several of the statements for example had been made after the German equivalent of the FDA had issued a 90-day suspension of one of the company's products due to contamination.⁸⁶

The last case in this category involved a parallel fact pattern: the plaintiff claimed defendants' risk disclosures about the company's potential loss in an ongoing litigation were overly positive and misleading due to the fact that the company ultimately lost that litigation.⁸⁷ The court dismissed the action, finding that the defendants'

⁸⁶ *Flynn*, 2016 WL 3360676, at *11.

⁸⁷ *Grobler v. Neovasc Inc.*, Civ. A. No. 16-11038-RGS, 2016 WL 6897760 (D. Mass. Nov. 22, 2016) (granting motion to dismiss, finding that defendants' statements about their expectations regarding ongoing litigation were inactionable because they were "predictions about the future outcome of the pending litigation," and included warnings about the litigation).

statements were "undoubtedly forward-looking" because they were predictions that the company was making about the future outcome of a pending litigation.⁸⁸ Equally important was the fact that Neovasc's SEC filings included specific warnings of risks pertaining to the litigation at issue.⁸⁹

All of the cases in this category thus point to the same general conclusion often seen in other types of cases: forward-looking statements are protected by the PSLRA's safe harbor to the extent that they are predictions based upon events that will be found to be true or false in the future. When the allegedly forward-looking statements are in conflict with facts that the defendants have at the time they make the statements however, there is a possibility that the statements will not be protected.

⁸⁸ *Id.* at *3

⁸⁹ *Id.*

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 all together. 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, the loss of a key commercial partner or an increased percentage of revenues being derived from off-label uses.
- ✓ 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 the 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 analyst calls and media commentary. While soft puffery contains a positive message and image about a company that is not misleading under securities laws, it is upon hard statements of fact that class action lawyers – with the benefit of 20/20 hindsight – will 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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