Securities Litigation Against Life Sciences & Healthcare Companies

2019 Year In Review

GOODWIN

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Agenda

- 2019 Year in Review Overview
- Securities Litigation Basics
- Cornerstone's Review of Securities Class Action Data for 2019
- Trends in 2019 Court Decisions
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- Other Disclosure-Related Risks
- Best Practices to Reduce Litigation Risk and Increase Likelihood of Success in Litigation
- Action Items If/When Your Company Gets Sued

Overview

- Yet again, a **record number** of securities class action lawsuits were filed in 2019, despite a decline in M&A-related filings.
- Pharmaceutical, biotechnology and healthcare companies were again the most frequent targets of such lawsuits as compared to other industries, with the number of lawsuits against such companies increasing from 2018 to 2019.
- Due to the increase in the number of such lawsuits, there is now an ever-growing body of case law specifically addressing issues that life sciences and healthcare companies most often face.
- This body of case law is generally defendant-friendly, but this increasingly varies depending on the jurisdiction.
- Percentage of 2019 cases dismissed by year-end dropped to **9.5%** (down from a year-end dismissal rate of 16.1% for 2018 cases).
- 2019 saw a substantial increase (**40%**) in class actions filed in state courts premised on alleged violations of the Securities Act of 1933.
- Scrutiny of disclosures by life sciences and healthcare companies by the SEC, FINRA and short sellers compounds litigation risks.

Securities Litigation Basics

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Securities Exchange Act of 1934 Claims

- **Section 10(b) and SEC Rule 10b-5** anti-fraud provisions make it unlawful to use or employ any manipulative or deceptive device, in connection with the purchase or sale of any security, including to make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
- **Section 20(a)** establishes "control person liability" against individuals.
- Tends to be industry-specific and event-driven disclosure claims.
- PSLRA **automatic discovery stay** applies upon filing of motion to dismiss.
- Jurisdiction: federal court.

Typical Section 10(b)/ Rule 10b-5 Claim

- Plaintiffs' lawyers monitor the market or offer "portfolio monitoring" and press release "investigations" following negative news where stock price drops.
- Fraud by hindsight claims that defendants knew or must have known the bad news when they made prior alleged misstatements or failed to disclose the negative information.
- Typically challenge statements in SEC filings, press releases, earnings calls / analyst calls, presentations or discussions.
- Plaintiffs' lawyers do homework via FOIA requests for FDA material and talk to "confidential witnesses" (typically former disgruntled employees).
- "The truth is revealed" when negative news ultimately disclosed.
- Plaintiffs allege stock price artificially inflated based on misstatements or omissions.
- Plaintiff class = all purchasers during the relevant class period.

Elements of a Rule 10b-5 Claim

- Claims brought under Section 10(b) and SEC Rule 10b-5:
  - a misstatement or omission
  - of a material fact
  - in connection with the purchase or sale of a security
  - made with scienter (intent to defraud)
  - upon which the plaintiff relied and
  - loss causation.
- Subject to heightened pleading standards under Rule 9(b) and PSLRA: Must allege **specific facts** that give rise to a **"strong inference"** that defendant(s) acted with intent to defraud.

Securities Act of 1933 Claims

- **Sections 11 and Section 12(a)(2)** make issuers liable for registration statements that contain "an untrue statement of a material fact or omit to state a material fact required...to make the statements there in not misleading."
- While purchaser can sue issuer, underwriter, or subsequent seller, all defendants but the issuer have a "due diligence" defense.
- Key distinction from 10b-5 claims: **No scienter is required**, so even unintentional material misstatements or omissions can give rise to a successful 1933 Act claim.
- Reliance is also presumed in Section 11 cases.
- Jurisdiction: state court or federal court *(Cyan)*.

Securities Act of 1933 Claims

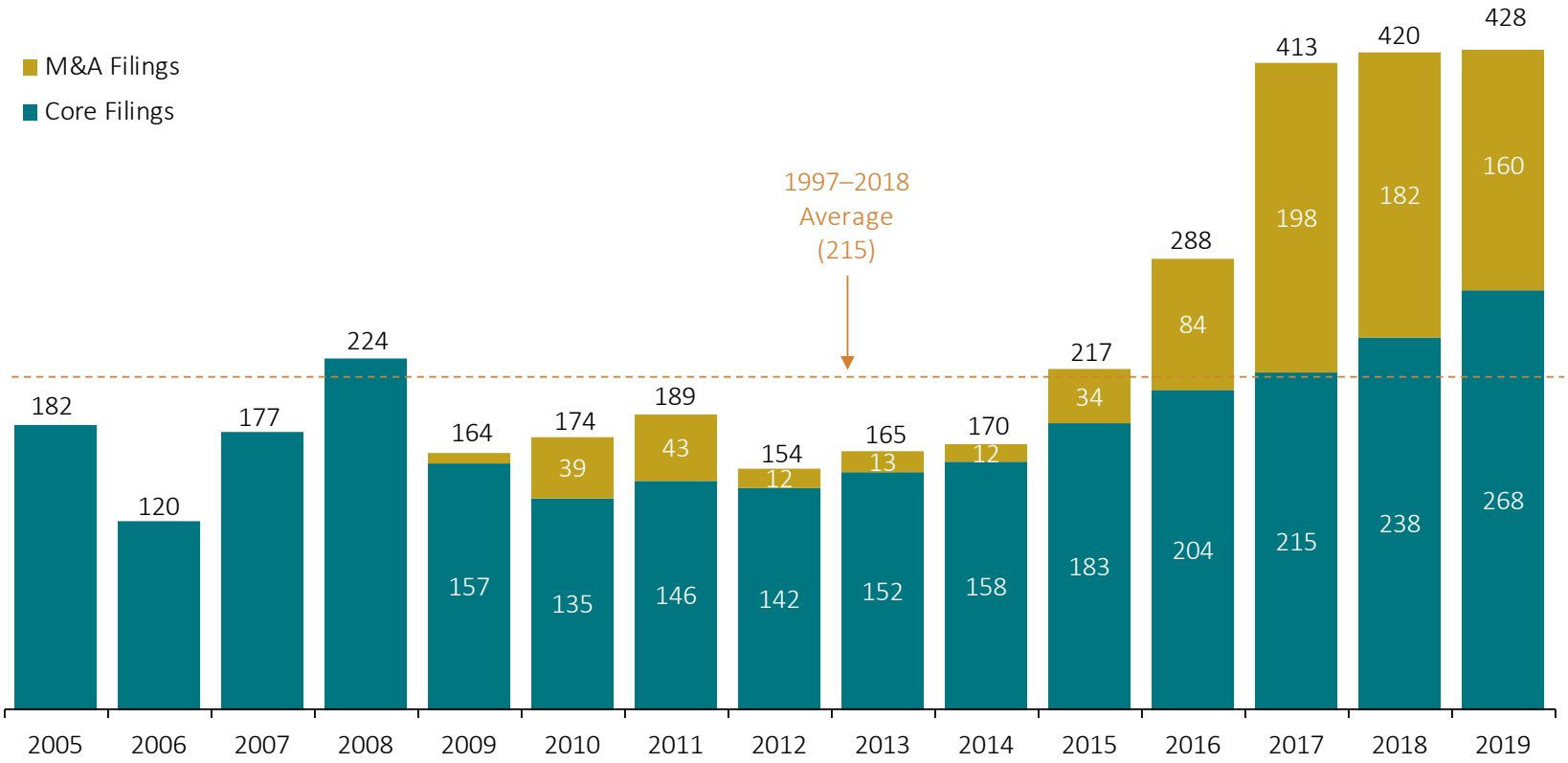
- In its March 2018 decision in *Cyan*, the United States Supreme Court held that class actions under the 1933 Act can be brought in **state court** and are not removable to federal court.
- In 2019, there was a **40% increase** in class actions alleging violations of the 1933 Act filed in state court from 2018.
- The majority of these cases were filed in **New York and California** state courts, but the number of such cases filed in other states across the country almost tripled from 2018 to 2019.
- The rush to state courts is in part due to plaintiff-friendly decisions by courts in New York declining to apply the PSLRA discovery stay.
- Many state court 1933 Act filings are accompanied by parallel federal court filings, forcing defendants to litigate on two fronts.
- Many public companies instituted **exclusive federal forum provisions** in their bylaws, mandating that 1933 Act claims be brought in federal court only, but the Delaware Chancery Court ruled such provisions invalid under Delaware law; issue is currently before Delaware Supreme Court.

Cornerstone Research:
Review of 2019 Securities Class Action Filings

2019 Securities Class Action Filings Overview

- 428 Securities Class Action Filings in 2019.
  - Increase in core filings since 2018, creating a historic high.
  - Second year with a decline in M&A-related cases however, M&A-related cases are still 37% of all filings.
- Securities Act of 1933 claims in state courts rose to 49 in 2019, a 40% increase from the previous year. Almost half of these had parallel actions in federal court.
- Likelihood of core filings targeting companies listed on U.S. exchanges was also at its highest in 2019. In 2019, approximately 1 in 14 S&P 500 companies were sued.
- Both Disclosure Dollar Loss (DDL) and Maximum Dollar Loss (MDL) decreased in 2019. DDL fell by 14% to $285 billion, and MDL by 9% to $1,199 billion as the size of the typical filing decreased.

CAF Index®—Annual Number of Class Action Filings
2005 –2019

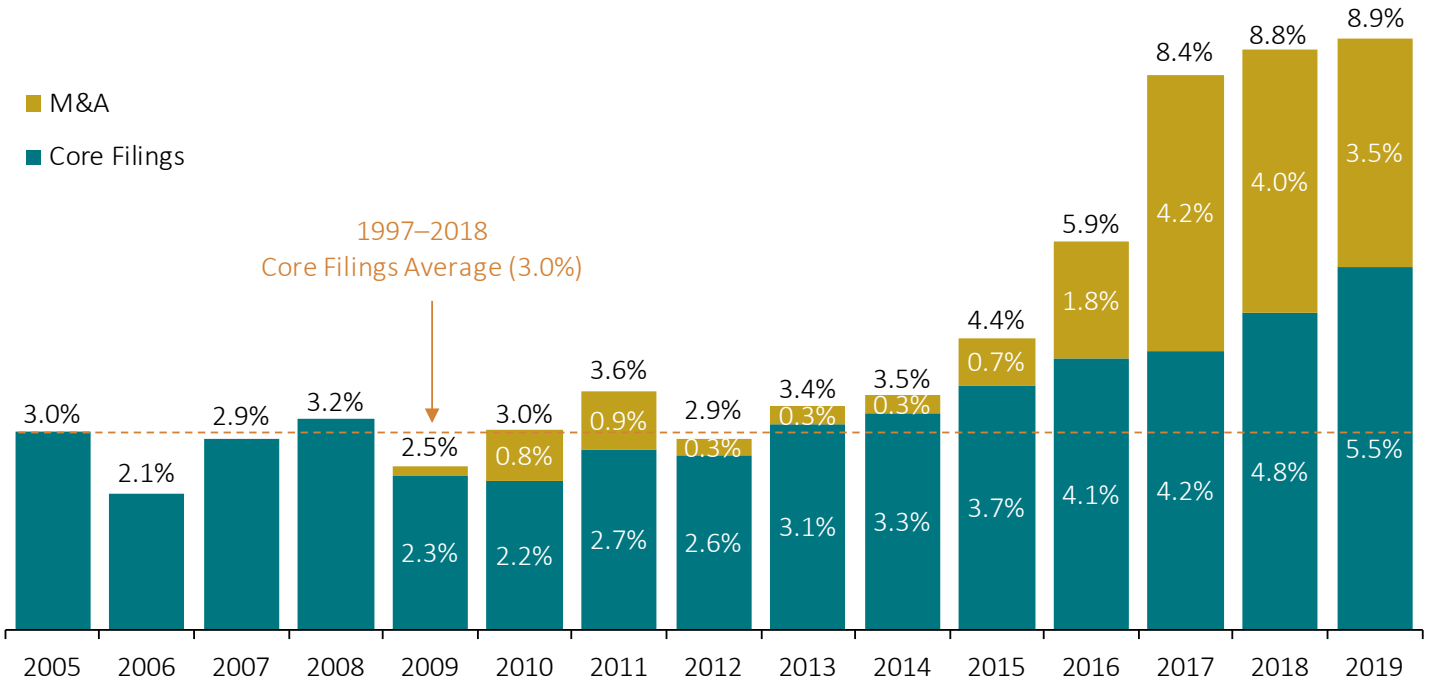


Note: This figure begins including state 1933 Act filings in the annual counts in 2010. Parallel class actions are only reflected as a single filing.

Source: *Securities Class Action Filings: 2019 Year in Review*, Figure 4. © 2020 Cornerstone Research. All rights reserved.

Percentage of U.S. Exchange-Listed Companies Subject to Federal or State Filings

By Case Type: 2005–2019



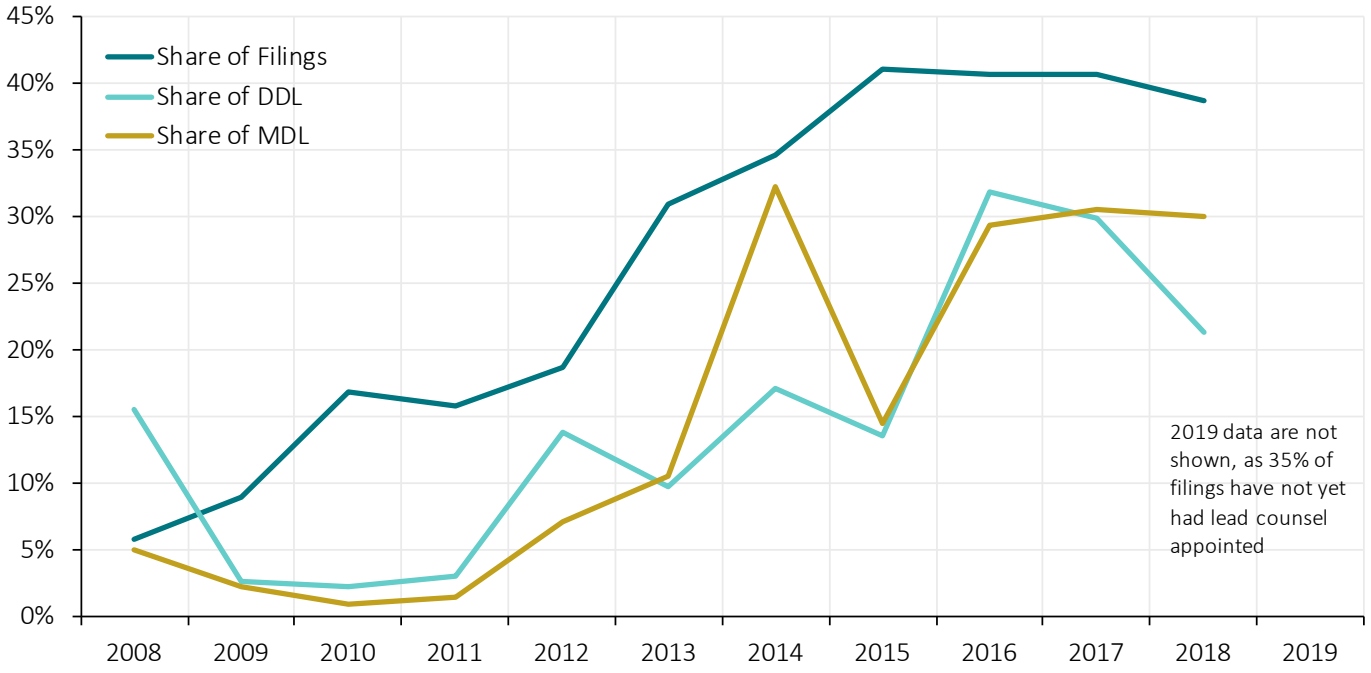
	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Number of Firms	5,593	5,525	5,467	5,339	5,042	4,764	4,660	4,529	4,411	4,416	4,578	4,593	4,411	4,406	4,318
Percent Change	(0.9%)	(1.2%)	(1.0%)	(2.3%)	(5.6%)	(5.5%)	(2.2%)	(2.8%)	(2.6%)	0.1%	3.7%	0.3%	(4.0%)	(0.1%)	(2.0%)

Note: 1. Percentages are calculated by dividing the count of issuers on the NYSE or Nasdaq subject to filings by the number of companies listed on the NYSE or Nasdaq as of the beginning of the year.
2. Listed companies were identified by taking the count of listed securities at the beginning of each year and accounting for cross-listed companies or companies with more than one security traded on a given exchange. Securities were counted if they were classified as common stock or American Depository Receipts (ADRs) and listed on the NYSE or Nasdaq.
3. Percentages may not sum due to rounding.
4. This figure begins including state 1933 Act filings in the annual counts in 2010. Parallel class actions are only reflected as a single filing.

Source: *Securities Class Action Filings: 2019 Year in Review*, Figure 10.

Frequency of Three Law Firms' Appointment as Lead or Co-Lead Plaintiff Counsel

Core Federal Filings: 2008–2019

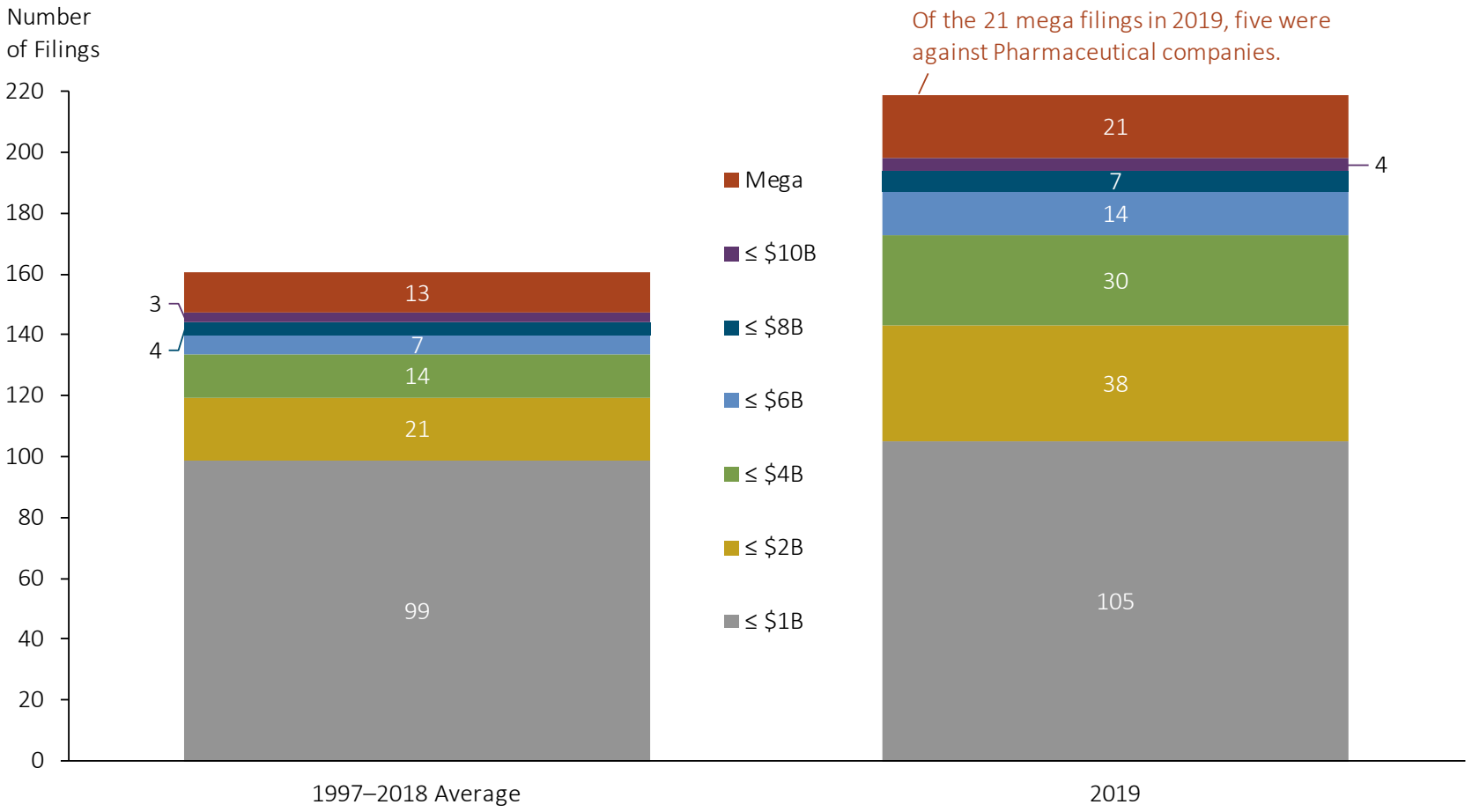


Frequency of These Firms as the Counsel of Record on the First Identified Complaint	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Number of Core Filings	22	23	26	35	40	66	83	104	122	126	119	151
% of Total Core Filings	10%	15%	19%	24%	29%	43%	53%	60%	65%	59%	54%	62%

Note: 1. This analysis considers law firms that were appointed lead or co-lead counsel by the court. For filings in which the case was resolved prior to the appointment of lead counsel, the counsel listed on the first identified complaint (FIC) are considered the lead counsel.
2. One percent of core federal filings in 2017, two percent of core federal filings in 2018, and 35 percent of core federal filings in 2019 have not yet had lead counsel appointed.
3. The counts in the table include circumstances when the FIC includes one or any of these law firms, regardless of whether other plaintiff counsel are also listed on the complaint.

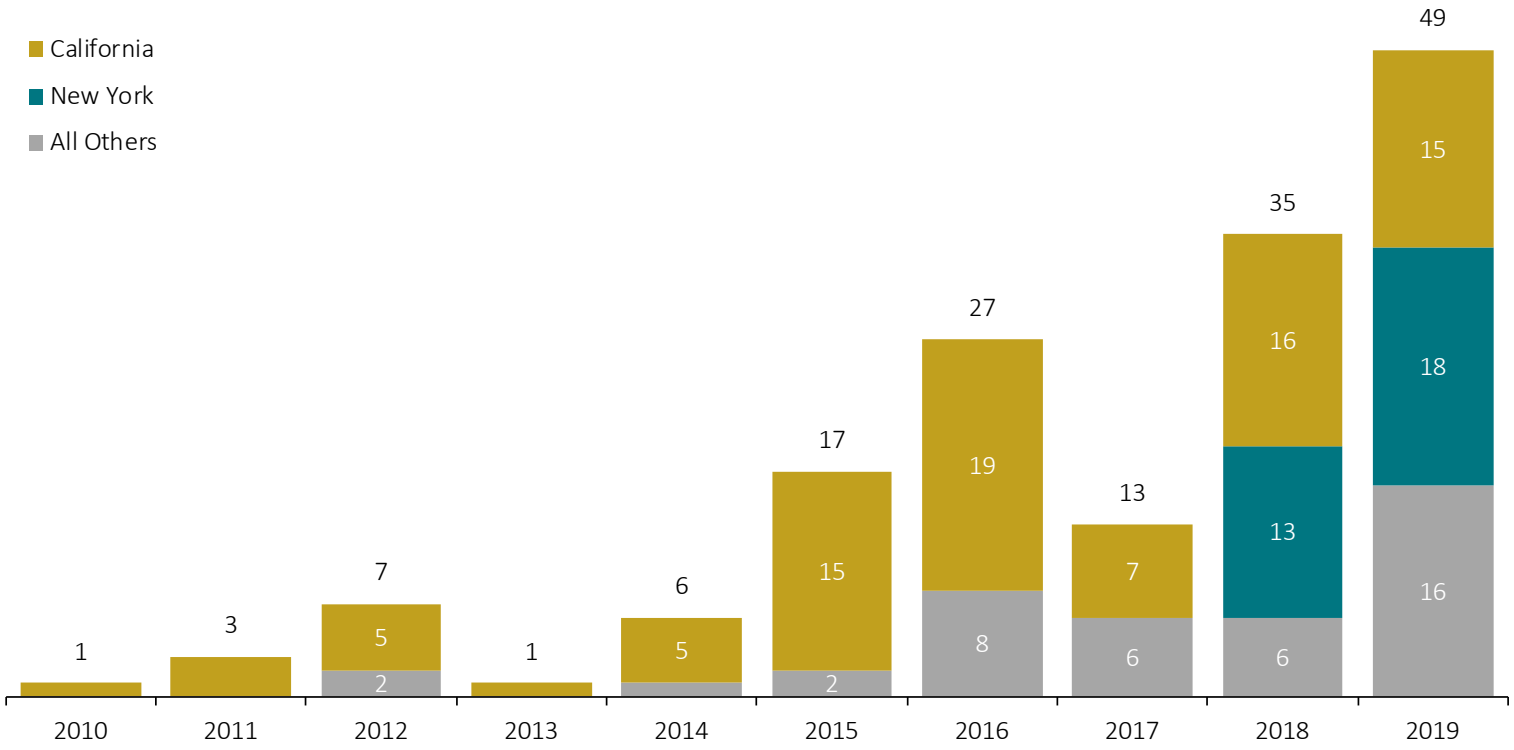
Source: *Securities Class Action Filings: 2019 Year in Review*, Figure 38.

Distribution of Filings Based on MDL Size
Core Federal Filings



Source: *Securities Class Action Filings: 2019 Year in Review*, Figure 34. © 2020 Cornerstone Research. All rights reserved.

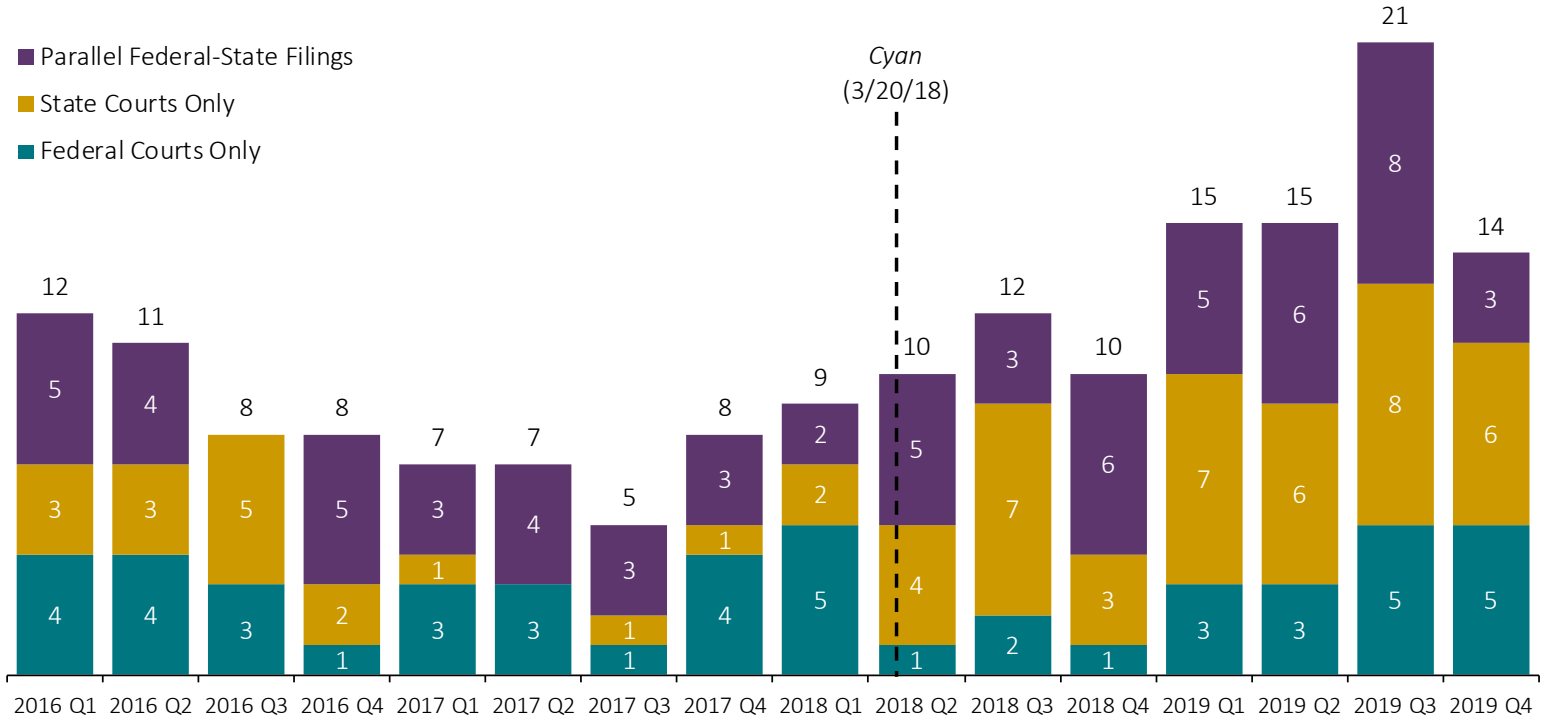
State 1933 Act Filings by State
2010–2019



Source: Stanford Law School and Securities Class Action Clearinghouse; Bloomberg Law; Institutional Shareholder Services' Securities Class Action Services (ISS' SCAS)
Note:
1. All others contains filings in Alabama, Arizona, Colorado, Florida, Georgia, Illinois, Iowa, Massachusetts, Michigan, Nevada, New Hampshire, New Jersey, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Washington, West Virginia, and Wisconsin.
2. Beginning in 2018, California state filings may contain either Section 11 or Section 12 claims. Of the 16 filings in California in 2018, six filings contained Section 12 claims without also containing Section 11 claims.

Securities Class Action Filings—2019 Year in Review, Figure 18.

Pre and Post-*Cyan* Quarterly Federal Section 11 and State 1933 Act Filings
2015–2019



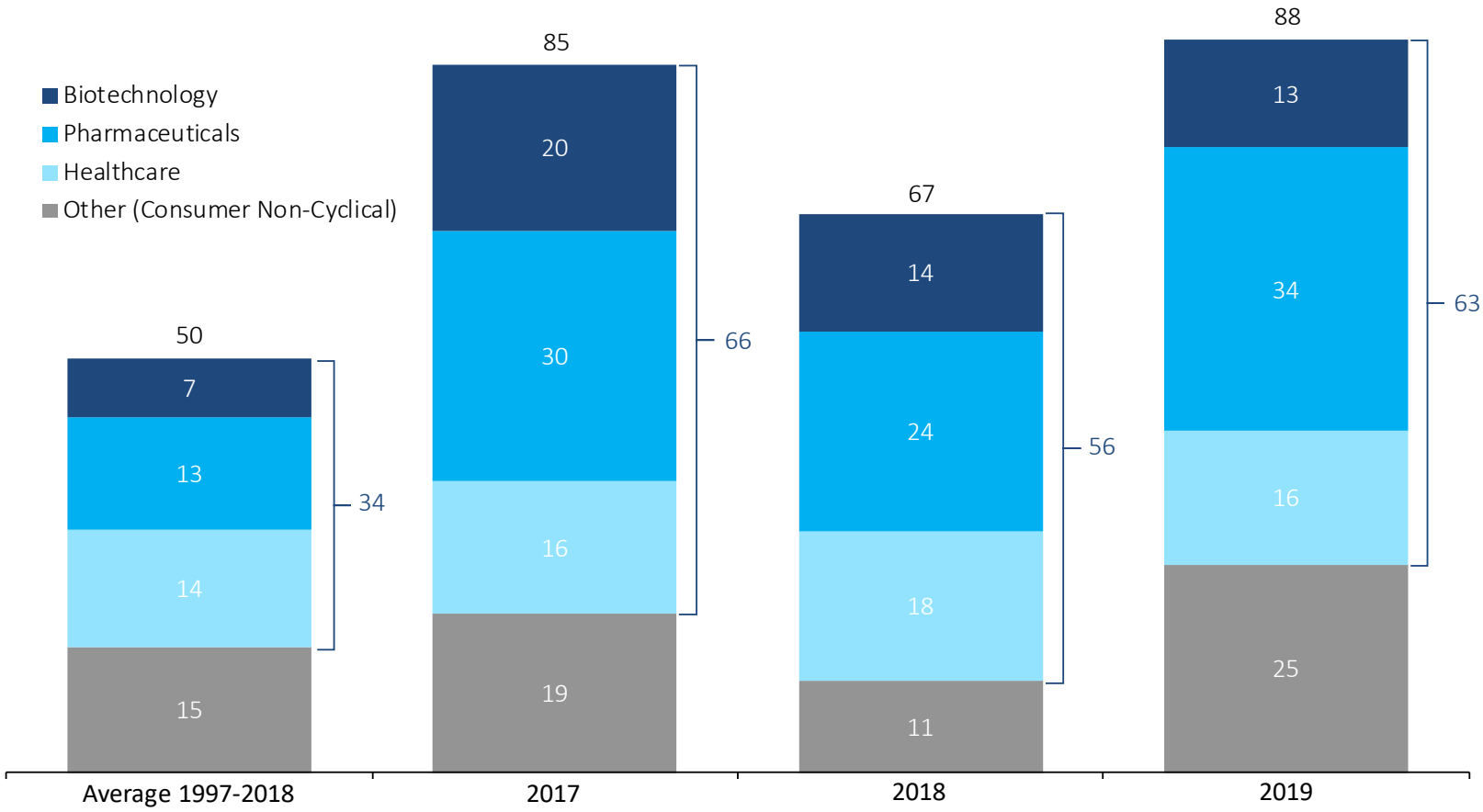
Source: Stanford Law School and Securities Class Action Clearinghouse; Bloomberg Law; ISS' SCAS
Note:
1. The federal Section 11 filings displayed may include Rule 10b-5 claims, but state 1933 Act filings do not.
2. Section 11 filings in federal courts may include parallel (or related) cases filed in state courts. When these cases are filed in different quarters, the earliest filing is counted. If filings against the same company are brought in different states in addition to a filing brought in federal court, the parallel filing is counted as a unique case and the state-only filing is treated as a unique case. Filings against the same company brought in different states without a parallel filing brought in federal court are counted as unique state filings.
3. Beginning in 2018, California state filings may contain either Section 11 or Section 12 claims. Of the 16 filings in California in 2018, six filings contained Section 12 claims without also containing Section 11 claims.

Securities Class Action Filings—2019 Year in Review, Figure 21. © 2020 Cornerstone Research. All rights reserved.

2019 Consumer Non-Cyclical Class Action Filings Overview

- 63 core filings in the in Biotechnology, Pharmaceuticals and Healthcare sectors in 2019, up from 56 in 2018. This compares to 66 filings in 2017.
- Pharmaceutical filings made up the largest portion of Consumer Non-Cyclical filings in 2019 with 34 core federal filings, but those against biotechnology and healthcare companies decreased for the second year straight.
- 9.5 percent of Life Sciences cases filed in 2019 have already been dismissed.

Consumer Non-Cyclical Sector
Core Federal Filings



Note: 1. Sectors and subsectors are based on the Bloomberg Industry Classification System.
2. The Other category is a grouping primarily encompassing the Agriculture, Beverage, Commercial Services, and Food subsectors.
3. Average figures may not sum due to rounding.

Pharmaceutical, Biotechnology, and Healthcare Subsectors
Core Federal Filings

Year	Filings	Circuit					Case Status			
		1st	2nd	3rd	9th	Other	Percent Dismissed	Percent Settled	Percent Remanded	Percent Ongoing
2005	32	5	4	4	3	16	56.3%	43.8%	0.0%	0.0%
2006	25	0	5	3	3	14	44.0%	56.0%	0.0%	0.0%
2007	29	0	11	2	7	9	58.6%	41.4%	0.0%	0.0%
2008	25	5	5	2	2	11	40.0%	60.0%	0.0%	0.0%
2009	22	1	1	2	11	7	36.4%	63.6%	0.0%	0.0%
2010	33	3	7	2	15	6	45.5%	51.5%	3.0%	0.0%
2011	21	0	5	0	6	10	57.1%	38.1%	4.8%	0.0%
2012	28	2	5	5	5	11	57.1%	42.9%	0.0%	0.0%
2013	34	2	10	5	11	6	41.2%	58.8%	0.0%	0.0%
2014	38	3	8	11	11	5	52.6%	44.7%	0.0%	2.6%
2015	42	6	4	5	18	9	54.8%	38.1%	7.1%	0.0%
2016	65	5	22	8	20	10	47.7%	30.8%	1.5%	20.0%
2017	66	7	17	16	13	13	53.0%	16.7%	3.0%	27.3%
2018	56	3	15	11	15	12	28.6%	7.1%	0.0%	64.3%
2019	63	3	23	13	11	13	9.5%	0.0%	0.0%	90.5%
Average (1997–2018)	35	3	7	5	9	11	44.3%	49.6%	0.9%	5.2%

Note: 1. Sectors and subsectors are based on the Bloomberg Industry Classification System.

Pharmaceutical, Biotechnology, and Healthcare Subsectors
Core Federal Filings

	Average 1997–2018						2017						2018						2019					
		Circuit						Circuit						Circuit						Circuit				
Sector	Filings	1st	2nd	3rd	9th	Other	Filings	1st	2nd	3rd	9th	Other	Filings	1st	2nd	3rd	9th	Other	Filings	1st	2nd	3rd	9th	Other
Biotechnology	7	1	1	1	3	1	20	4	6	4	3	3	14	2	2	3	4	3	13	1	5	3	1	3
Healthcare	14	1	2	1	4	6	16	2	3	0	5	6	18	0	5	3	5	5	16	0	2	2	4	8
Pharmaceuticals	13	1	4	3	3	3	30	1	8	12	5	4	24	1	8	5	6	4	34	2	16	8	6	2
Combined	35	3	7	5	9	11	66	7	17	16	13	13	56	3	15	11	15	12	63	3	23	13	11	13

Note: 1. Sectors and subsectors are based on the Bloomberg Industry Classification System.
2. Average figures may not sum due to rounding.

Overall Trends in 2019 Court Decisions

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Overall Trends in 2019 Court Decisions

- We analyzed decisions issued in 2019 in securities class actions against life sciences and healthcare companies by courts in the following federal jurisdictions, all hotbeds of life sciences and healthcare companies:
  - First Circuit;
  - District of Massachusetts;
  - Second Circuit;
  - New York District Courts;
  - Ninth Circuit; and
  - California District Courts.
- Overall, the decisions are favorable for defendants, but decidedly less so in the Ninth Circuit and California, where courts are less inclined to dismiss complaints and far more inclined to allow plaintiffs an opportunity to amend their defective complaints.
- Most of the dismissals are again based primarily on a lack of scienter—*i.e.*, the failure by plaintiffs to allege particularized facts giving rise to a strong inference that defendants **knew at the time of the alleged disclosure** that it was false and misleading.
- Courts have reaffirmed that risk factors and other detailed statements or warnings by companies are important to undercut an inference of scienter.

Typical Factual Allegations in 2019 Complaints

- Pre-Development Phase
  - Communications with the FDA, which include both formal (Form 483s, NDA letters) and informal (oral statements during an in-person inspection) communications.
- Clinical Testing Phase
  - Lead product trial enrollment delays
  - Safety and serious adverse events (SAEs)
  - Negative clinical trial efficacy results
  - Prospects of FDA approval
- Post-FDA Approval Phase
  - FDA or other agency communications or investigations
  - Sales and marketing practices
  - Billing and reimbursement issues
  - Manufacturing problems
  - Anticompetitive conduct

Key Decisions Issued in the Ninth Circuit

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Hsu v. Puma Biotechnology, Inc. (C.D. Cal.) – Inaccurate Clinical Trial Results

- Puma owns the rights to neratinib, a breast cancer treatment drug. In 2014, Puma issued a press release announcing the results of neratinib's ExteNET trial, a large-scale human trial of the drug's ability to prevent a certain type of breast cancer from coming back after surgery.
- On an investor call the same day, in response to an analyst's questions, Puma's CEO confirmed that the disease free survival ("DFS") rate among placebo patients was "around 86%," and that neratinib patients' DFS rate was "around 90% or 91%."
- The CEO also stated during the call that Kaplan-Meier curves reflecting neratinib's effectiveness "are continuing to separate" year-over-year, even beyond the ExteNET trial's two-year cutoff. In addition, the CEO stated on the call that although Puma had not "yet fully validated" the trial data, Puma anticipated that "the grade 3 diarrhea rate" among trial patients "would be in line with the 29 to 30%" seen in "prior studies of neratinib." Finally, the CEO stated that the dropout rate due to adverse events was 5% to 10%.
- Puma's stock price skyrocketed from $59.03 per share before the call to $233.43 per share after the call.

Hsu v. Puma Biotechnology, Inc. (C.D. Cal.) – Inaccurate Clinical Trial Results

- Later, during an American Society of Clinical Oncology ("ASCO") conference in 2015, ASCO released a summary of the ExteNET trial's data, which showed:
  - DFS rates of 91.6% among placebo patients and 93.9% among neratinib patients; and
  - grade 3 diarrhea in 40% of neratinib patients.
- Puma's stock price fell by almost $40 on this news.
- At the ASCO conference, an independent oncologist who presented the ExteNET trial data showed the trial's actual Kaplan-Meier curves, which narrowed (*i.e.*, showed decreasing effectiveness of neratinib) over certain periods of time. The presenter also revealed that the dropout rate due to diarrhea alone was 16.8%.
- Puma's stock price fell by $48.80 per share on this news.

Hsu v. Puma Biotechnology, Inc. (C.D. Cal.) – Inaccurate Clinical Trial Results

- Investors filed suit against Puma, its CEO, and its Senior VP of Finance and Administration, alleging violations of Sections 10(b) and 20(a) based on the Company's 2014 press release and the CEO's allegedly false statements made during the 2014 investor call.
- Defendants moved to dismiss in November 2015, and the district court denied that motion in September 2016. After the case proceeded into discovery, lead plaintiff amended its complaint. Defendants again moved to dismiss, and the court again denied that motion.
- In July 2018, lead plaintiff and defendants moved for summary judgment. In October 2018, the court granted in part and denied in part those motions; among other things, the court entered judgment in favor of Puma's Senior VP of Finance and Administration because lead plaintiff failed to establish that he acted with scienter.

Hsu v. Puma Biotechnology, Inc. (C.D. Cal.) – Inaccurate Clinical Trial Results

- The case then proceeded into trial, which began in January 2019.
- In just the fifteenth securities class action to reach a jury verdict since the passage of the PSLRA in 1995, on February 4, 2019, the jury found that Puma's CEO knowingly made a materially false statement about the ExteNET trial's results by stating that the DFS rate among neratinib patients was approximately 91% compared to 86% among placebo patients.
- Notably, however, the jury awarded damages of $4.50 per share based on this false statement, which was only approximately 5% or less of the total damages sought.
- The jury found for defendants on the remaining alleged misstatements related to Kaplan-Meier curves, grade 3 diarrhea rates, and dropout rates.

N.Y. Hotel Trades Council & Hotel Ass'n of New York City, Inc. Pension Fund v. Impax Laboratories Inc. (N.D. Cal.) – Anticompetitive Conduct Concerning Generics

- Beginning in 2013, Impax and its competitors began raising the prices of generic drugs: first, digoxin, and later, pyridostigmine bromide. Impax stated thereafter that the generics market was competitive.
- In May 2015, Impax disclosed that it had received a grand jury subpoena from the U.S. Department of Justice concerning pricing and marketing of four generic drugs, including digoxin.
- In 2016, Impax made statements concerning two other generic drugs: diclofenac and budesonide. As to diclofenac, Impax: (1) affirmed optimistic revenue guidance based, in part, on anticipated higher diclofenac sales; (2) stated that Impax had "defended share"; and (3) failed to warn that Impax would record a $15 million diclofenac shelf-stock adjustment.
- As to budesonide, after Impax purchased the drug and other generics through a $586 million acquisition, Impax made optimistic statements about budesonide's positive outlook and integration into the company's portfolio. Impax later impaired the valuation of the drugs it had acquired in this transaction by $241 million.

N.Y. Hotel Trades Council & Hotel Ass'n of New York City, Inc. Pension Fund v. Impax Laboratories Inc. (N.D. Cal.) – Anticompetitive Conduct Concerning Generics

- Investors filed suit against Impax and its officers, alleging violations of Sections 10(b) and 20(a). After dismissing the first complaint and allowing plaintiffs leave to amend, the court granted defendants' motion to dismiss the amended complaint with prejudice.
- With respect to plaintiffs' price-fixing allegations concerning digoxin and pyridostigmine, the court held that plaintiffs failed to plead loss causation. Reaffirming the Ninth Circuit's 2014 decision in *Loos v. Immersion Corp.,* the court held that the mere fact that Impax disclosed a regulatory investigation, alone, was not a revelation that any prior Impax statement was fraudulent.
- The district court also held that Impax's revenue guidance-related statements were forward-looking and protected by the PSLRA's safe harbor, and that Impax's statements concerning "defending share" in the diclofenac market were non-actionable corporate puffery. The court also held that plaintiffs failed to establish that Impax had a duty to disclose the future shelf-stock adjustment related to diclofenac.
- As to budesonide, the court held that plaintiffs failed to allege facts establishing that any defendant knew that the acquisition by which Impax obtained the drug was overpriced. The court held that the "far more reasonable—and non-culpable—inference" was that defendants simply overvalued the acquired drugs.

CLE ANNOUNCEMENT

Key Decisions Issued in the First Circuit

Metzler Asset Mgmt. GMBH v. Kingsley ("Biogen II") (1st Cir.) – Post-Approval SAEs and Impact on Commercial Prospects

- Tecfidera is one of Biogen's four principal MS drugs. Since Tecfidera's FDA approval in March 2013, the Company warned that it "may cause lymphopenia," a condition involving low counts of a certain type of white blood cells (lymphocytes).
- In August 2014, the Shepard Center, a leading MS clinic and Tecfidera prescriber, stopped prescribing the drug after internal studies revealed that Tecfidera lowered lymphocyte counts in 30% of patients and notified Biogen.
- In October 2014, Biogen announced that an MS patient who had taken Tecfidera for several years died from an infection associated with low lymphocyte counts called PML. Thereafter, Biogen added information related to the risk of PML to Tecfidera's label.
- Although Biogen had stated that it had "always expected [that] Tecfidera's growth rate would moderate over time," in January 2015 it stated that it "believ[ed] Tecfidera [was] on track to become the most-prescribed therapy for MS worldwide."
- During the months that followed, however, Tecfidera's sales declined. In July 2015, Biogen revised its full-year projections, cutting expected revenue growth in half, attributing the change to diminished expectations for growth of Tecfidera.
- Biogen's stock price fell 22% the same day.

Metzler Asset Mgmt. GMBH v. Kingsley ("Biogen II") (1st Cir.) – Post-Approval SAEs and Impact on Commercial Prospects

- Investors filed suit, alleging that Biogen misled investors by misrepresenting and concealing the lymphocyte risk and the subsequent impact of the PML death on sales, in violation of Sections 10(b) and 20(a) of the 1934 Act.
- Specifically, the complaint alleged 31 statements and omissions made by defendants either failed to account for the Shepard Center's discontinuation of Tecfidera prescriptions and the drug's known tendency to deplete lymphocyte levels, or understated the effect that the PML death was having on Tecfidera sales and usage rates following the October 2014 PML death.
- In support of these allegations, plaintiffs relied upon statements from 17 former Biogen employees acting as confidential witnesses.
- As to the drug's effect on lymphocytes, plaintiffs cited statements from the director of the Shepard Center and a neurologist who confirmed Tecfidera's effect on lymphocytes through a study of his own in February 2015.

Metzler Asset Mgmt. GMBH v. Kingsley ("Biogen II") (1st Cir.) – Post-Approval SAEs and Impact on Commercial Prospects

- While the district court held that plaintiffs had plausibly alleged at least 6 of the 31 statements regarding Tecfidera's safety profile and usage rate were false or misleading, it nevertheless granted defendants' motion to dismiss, holding that plaintiffs failed to allege scienter.
- The First Circuit affirmed the district court's dismissal on the same failure to plead scienter basis.
- The Court reviewed the 6 alleged misstatements in context and credited Biogen's disclosures that Tecfidera was associated with higher risk of low lymphocyte counts, the PML death, and higher-than-expected discontinuation rates, holding that they undermined an inference of scienter.
- The court found the confidential witness statements unpersuasive because they "were imprecise, did not contain information that was directly communicated to the individual defendants, or concerned events that occurred after the individual defendants made the plausibly misleading statements at issue in that case."
- Finally, the court rejected plaintiffs' secondary "core operations" and "corporate scienter" theories.

Wu v. Tokai Pharmaceuticals, Inc. (Mass. Super. Ct.) – Trial Enrollment Numbers and Trial Discontinuation

- As of its 2014 IPO, Tokai Pharmaceuticals, Inc. was focused on the development and commercialization of Galeterone, a therapy intended to treat a specific class of cancer patients with metastatic castration-resistant prostate cancer ("CRPC").
- Two competitor drugs had already obtained FDA approval by the time Galeterone entered Phase 2 clinical trials, but published research showed that the competitor drugs were ineffective for treating "AR-V7 positive" patients, a subcategory of CRPC patients.
- Rather than initiating a new Phase 2 trial focused on these patients, Tokai conducted a retrospective analysis of its Phase 2 trial results, and specifically, the 7 of 87 CRPC patients that were AR-V7 positive.
- Based on this analysis of 7 patients, Tokai concluded that Galeterone was successful in the AR-V7 patient population, and elected to proceed to Phase 3 trials focused on AR-V7 patients.
- Post-IPO, Tokai encountered severe difficulties in patient enrollment and discontinued the Phase 3 trials. At the time of discontinuation, Tokai had discovered only 73 CRPC patients that were AR-V7 positive, and of those 73, only 38 enrolled in the trial.

Wu v. Tokai Pharmaceuticals, Inc. (Mass. Super. Ct.) – Trial Enrollment Numbers and Trial Discontinuation

- Investors filed a class action in Massachusetts state court, alleging that Tokai's IPO registration statement and prospectus included misrepresentations and omissions regarding enrollment difficulties in violation of the 1933 Act.
- Holding that the heightened pleading standards of Rule 9(b) did not apply, the court denied Tokai's motion to dismiss. The court found that Tokai's disclosures did not adequately disclose the following facts indicating enrollment difficulties:
  - the inadequacy of the data it reviewed to support proceeding into Phase 3 trials;
  - 2 of the 6 AR-V7 positive patients reviewed ceased treatment after the Phase 2 trial;
  - the risk that existing alternative treatments could inhibit Phase 3 patient enrollment;
  - the Phase 3 trials of the competitor drugs had each enrolled nearly 1,200 patients, as compared to Tokai's estimate that it would enroll up to 170 AR-V7 positive patients (suggesting that there would be insufficient data for approval).
- The court refused to consider documents cited by Tokai but not referenced in the complaint and publicly-available information to refute plaintiffs' allegations.
- It also rejected Tokai's argument that statements that its Phase 2 data supported proceeding to Phase 3 trials was an inactionable opinion, stating that "the line between an opinion and a statement of fact is not an easy one to draw," and that alleged misstatements could be actionable if the company had possession of information that undermined its opinion.

Key Decisions Issued in the Second Circuit

Micholle v. Ophthotech Corp. (S.D.N.Y.) – Clinical Trial Eligibility Modifications

- Ophthotech completed a successful Phase 2b trial for its eye disease treatment Fovista, which was designed to reduce lesions that cause blurred vision.
- The company cautioned that the control group in the Phase 2b trial, on average, had larger baseline lesions than those in the Fovista group, but initially did not disclose the exact percentage difference.
- The company announced that there would be slight modifications to the methodologies used to determine patient eligibility in Phase 3 trials, but declined to disclose those differences in detail, emphasizing that the differences were not "material or significant in any way."

Micholle v. Ophthotech Corp. (S.D.N.Y.) – Clinical Trial Eligibility Modifications

- After announcing that the Phase 3 trial was unsuccessful, Ophthotech disclosed that the eligibility modification resulted in a ~20% increase in patient eligibility for the Phase 3 trial.
- Following an 86% stock price decline, investors filed suit, alleging that the company misled investors about the differences in (i) Phase 2(b) baseline lesion size between the control and Fovista groups, and (ii) trial eligibility between Phase 3 and Phase 2b studies.
- The court held that the failure to disclose the precise percentage difference between the baseline lesion size in the treatment and control groups was not misleading due to the company's cautionary disclosures.
- However, the court concluded that the ~20% difference in Phase 3 trial eligibility versus Phase 2 (a fact known to the defendants) rendered their statements—*i.e.*, that there were no "meaningful" or "significant" changes to eligibility requirements—recklessly misleading.

Gagnon v. Alkermes plc (S.D.N.Y.) – Statements Concerning Organic Sales Growth and Drug's Effectiveness

- In 2010, Alkermes obtained FDA-approval for Vivitrol, a once-monthly, non-narcotic, injectable treatment for the prevention of relapse to opioid dependence.
- In contrast to existing "agonist" treatments like methadone, which reduce drug cravings by activating opioid receptors in the brain, Vivitrol is an "antagonist" treatment, meaning that it blocks the ability of opioids to activate opioid receptors in the brain.
- In response to inquiries as the opioid crisis worsened, Alkermes educated personnel responsible for criminal justice reentry programs, drug courts, and other policymakers about Vivitrol's benefits as a non-addictive treatment with no history of diversion.

Gagnon v. Alkermes plc (S.D.N.Y.) – Statements Concerning Organic Sales Growth and Drug's Effectiveness

- Following a few negative press articles criticizing the company's marketing, investors filed suit following a temporary stock price decline alleging misrepresentations about (i) Vivitrol's "organic growth" in comparison to its marketing, and (ii) Vivitrol's efficacy.
- The court held that 17 of the 18 alleged misrepresentations were not actionable, including all of the alleged misrepresentations about Vivitrol's efficacy on its own and in comparison to agonist treatments.
- As to the one potential actionable "half-truth," it held that the complaint failed to allege facts supporting a strong inference of motive to defraud, or that the defendants knew facts contradicting their public statements about Vivitrol's "organic growth."

Other Disclosure-Related Risks

Other Disclosure-Related Risks: SEC Scrutiny

- Government regulators, including the SEC, have also been scrutinizing disclosures of life sciences and healthcare companies.
  - "One significant type of key event that we see causing problems with disclosure in your industry is disclosures on your dealings with the FDA. **Accuracy of reporting in your dealings with the FDA is critical** to getting investors the information they need." - Andrew Ceresney.
  - "[A] company and its officers are required to be honest in their public communications, including about **matters as critical as communications with regulators about approval of a key product**." - Stephanie Avakian and Steven Peikin.
- Following the filing of class actions, the SEC has initiated its own investigations to examine the accuracy of the statements challenged by the plaintiffs, typically seeking documents and perhaps testimony pursuant to subpoenas.
- Unlike class action plaintiffs, the SEC is not subject to the PSLRA automatic stay of discovery and, thus, have the ability to obtain internal company documents.

Other Disclosure-Related Risks: Reg FD (Fair Disclosure)

- Reg FD prohibits selective disclosure to material non-public information to selective market participants.
- SEC had not brought a Reg FD enforcement action in over five years, but in August 2019 announced that it had settled enforcement action claims against TherapeuticsMD.
- The SEC found that TherapeuticsMD made **two selective disclosures** of material nonpublic information to sell-side research analysts concerning FDA approval of TX-004HR.
  - June 15/16, 2017: Company sent emails to six sell-side analysts describing a June 14 FDA meeting as "very positive and productive." Next day, price increased by 19.4%.
  - July 17, 2017: Company filed an 8-K and press release concerning TX-004HR's regulatory approval status following its receipt of formal minutes from the June 14 FDA meeting. Less than an hour later, company held a prescheduled call with sell-side analysts discussing details of June 14 meeting and information provided by company to FDA. Disclosed same information on its August 3 earnings call.
- SEC Order required Company to cease and desist from Reg FD violations and pay a **$200,000 civil money penalty**.

Other Disclosure-Related Risks: Short Sellers

- In the last few years, including 2019, publicly traded companies – particularly life sciences and healthcare companies – have been the target of short sellers and negative reports published or precipitated by short sellers.
- Certain well-known short sellers such as Kerrisdale Capital and Muddy Waters Research have focused on **single drug pipeline companies** in their campaigns.
- Short seller attacks (and resulting stock drops) can precipitate securities class actions and plaintiffs are increasingly relying on short seller reports to support securities fraud claims.
- Courts have held that "[i]t is permissible for Plaintiffs to rely on a short seller report . . . to allege falsity at the pleading stage," reasoning that short seller reports do not implicate the same skepticism as a traditional anonymous source. *See e.g.*, *In re Banc of California Sec. Litig.*, 2017 WL 3972456 (C.D. Cal. Sept. 6, 2017).
- Courts have also allowed securities class action plaintiffs to rely on such reports, even when *anonymous*, where the author identified himself as a short seller and that the report was exhaustively detailed and supported by photos, graphs and charts.

Best Practices to Reduce Litigation Risk

Best Practices: Formulate a Disclosure Plan

- Volatility in stock price for life sciences companies is due to both predictable and unpredictable events.
- No duty to continuously update investors, but under the Supreme Court's decision in *Matrixx*, **once you choose to speak, you must speak completely**.
- Formulate a disclosure plan for known or predicted events, including quarterly SEC filings, presentations at conferences (*e.g.*, JP Morgan or medical conferences), expected completion of clinical trials, data releases, etc.
- Plan should balance liquidity goals and risk profile, including lockup expirations, expected clinical and regulatory events, and potential offerings, collaborations or M&A transactions.
- Provide yourself with flexibility for future expected and unexpected events.
- Regularly analyze risk disclosures to ensure that they are updated to reflect any changes.

Best Practices: Disclosure of Unexpected Events

- When unexpected events occur, such as unexpected clinical trial results, FDA communications, enrollment changes, or an adverse event, conduct a materiality analysis.
- Unsure whether it is “material information”? Ask yourself if **you** would trade on the information.
- Review existing disclosures related to event/topic/risks.
- Manage team including management, disclosure committee, outside IR/legal advisors.
- Partners to update? Consider what collaboration partners will disclose.
- Consider any 8-K items triggered by event.
- Draft press release/8-K responding to event.
- Obtain board input on public announcement/response.
- Consider impact on future disclosures, presentations and level of detail.

Best Practices: Disclosure Controls

- Ensure that external communications—including medical conference presentations—are consistent and aligned with prior disclosures and underlying regulatory notifications or communications.
- Carefully consider who at the Company should have access to clinical data and any other MNPI when for both trading and disclosure purposes and carefully track internal access.
- Understand existing processes for obtaining facts, vetting disclosures and coordination among regulatory, clinical, medical, legal, executive team, and IR.
- Be careful with emails, text messages, and instant messages.
- Be conscious of protecting attorney-client privilege and avoiding leaks.
- Be thoughtful about social media.

Best Practices: Action Items When Litigation Is Threatened or Filed

- **Docket Monitoring**: Once a law firm issues the first press release "trolling" for shareholder plaintiffs, monitor court dockets for newly filed actions.
- **Insurance Coverage**: You will want to consider whether it's necessary to submit a Notice of Circumstances (NOC) to your D&O insurance carrier based on a "trolling" press release. Once a complaint is filed, you will either need to update that NOC or if no NOC submitted, submit a Notice of Claim.
- **Document preservation**: If a case is filed, the Company must preserve both paper and electronic documents relevant to the case.
- **No public statements on litigation**: If a case is filed, we recommend against issuing any public statement on the litigation, and respond to questions that the Company's policy is not to comment on pending litigation.
- **Disclosure review**: It is important to continue to review carefully all public statements before they are filed/presented, in one on one meetings, etc., so as not to create fodder for plaintiffs' lawyers.

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