GIBSON DUNN

MCLE Program

The Supreme Court's Omnicare Decision: A Key Tool for Defending Securities Litigation Brought Against Life Sciences Companies

Jennifer L. Conn
Jane M. Love, Ph.D.
Lawrence J. Zweifach
Yan Cao, Cornerstone

June 16, 2021

Agenda

- Introduction
- Trends in the Filing of Securities Class Actions Against Life Sciences Companies
- Complex Factual Context in Life Sciences Cases
- Claims That Can Be Asserted in Federal Securities Class Actions
- *Omnicare:* A Key Defense Tool

GIBSON DUNN

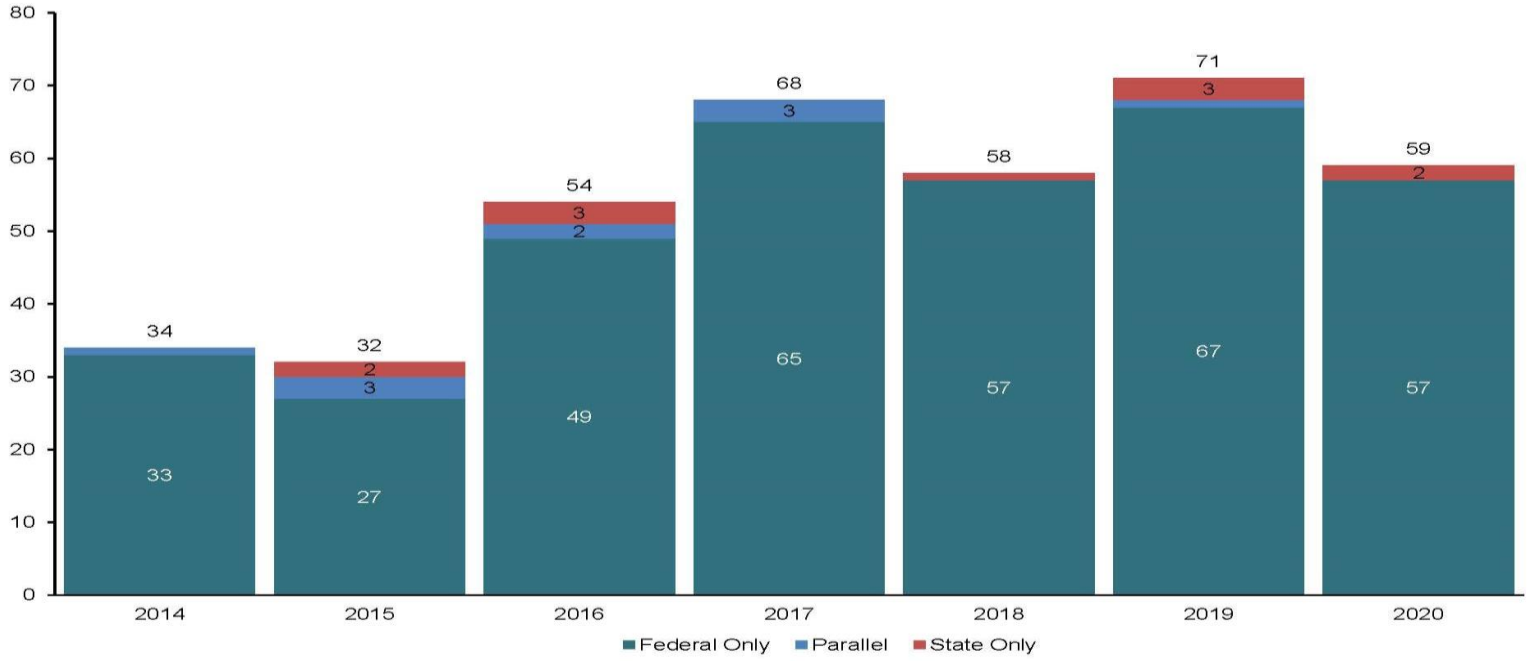
Introduction

GIBSON DUNN

Trends in the Filing of Securities Class Actions Against Life Sciences Companies

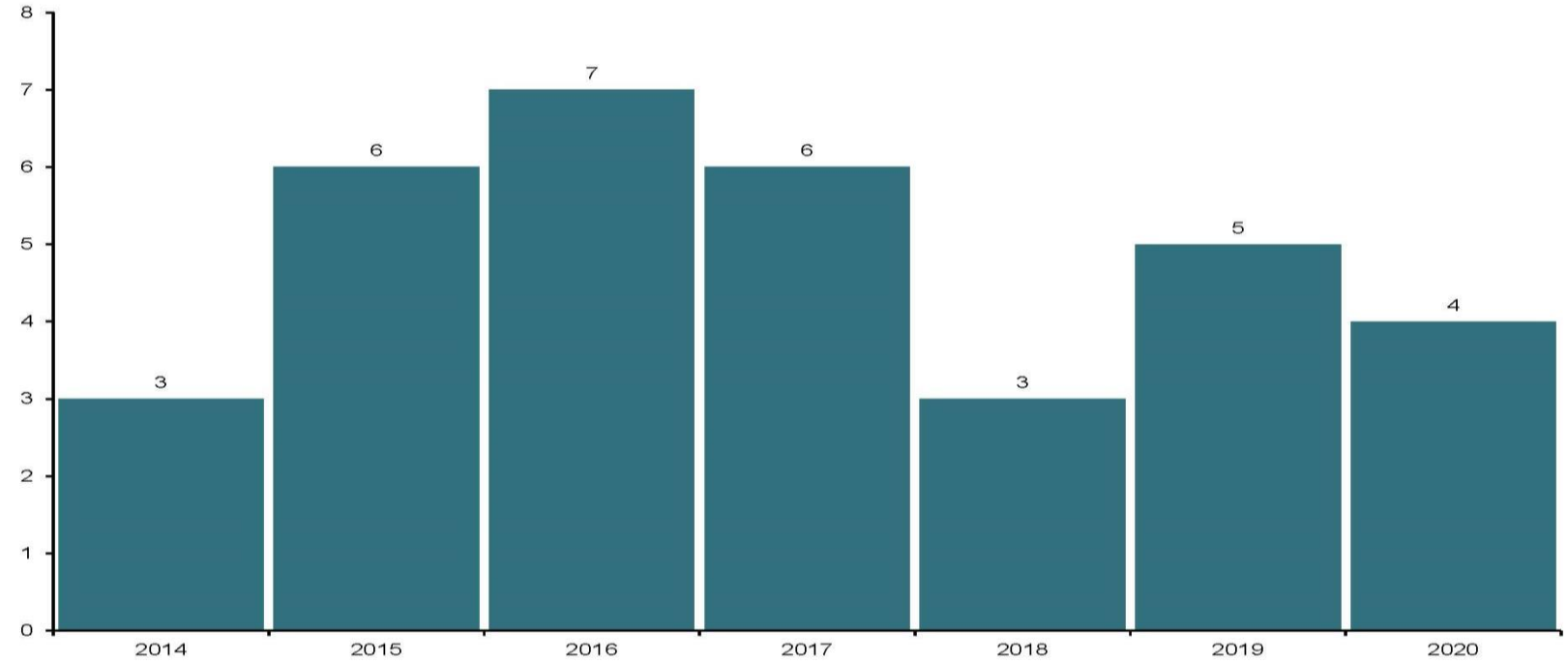
Federal and State Class Action Securities Lawsuits Against Life Sciences Companies by Venue

2014 – 2020



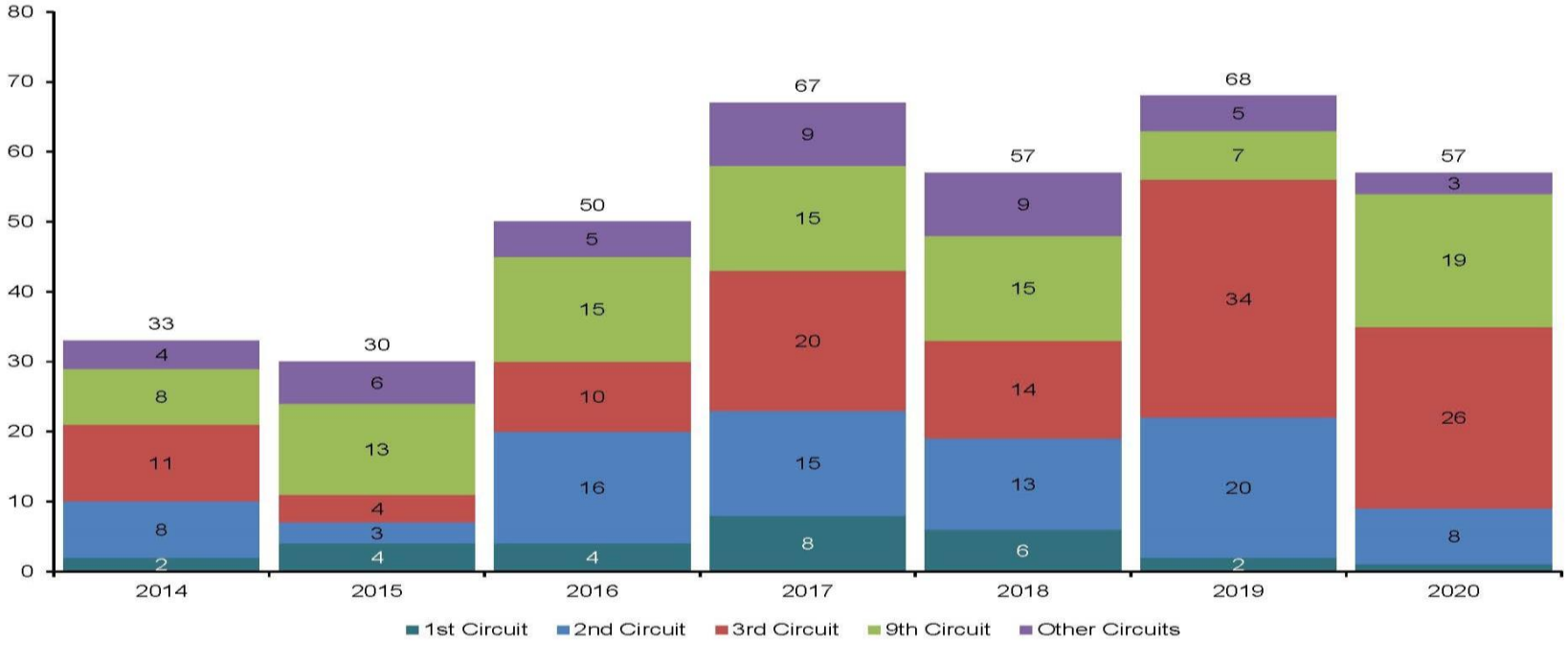
Source: Stanford Securities Clearinghouse and Cornerstone Research

Federal Section 11 and State ’33 Act Class Action Securities Lawsuits Against Life Sciences Companies
2014 – 2020



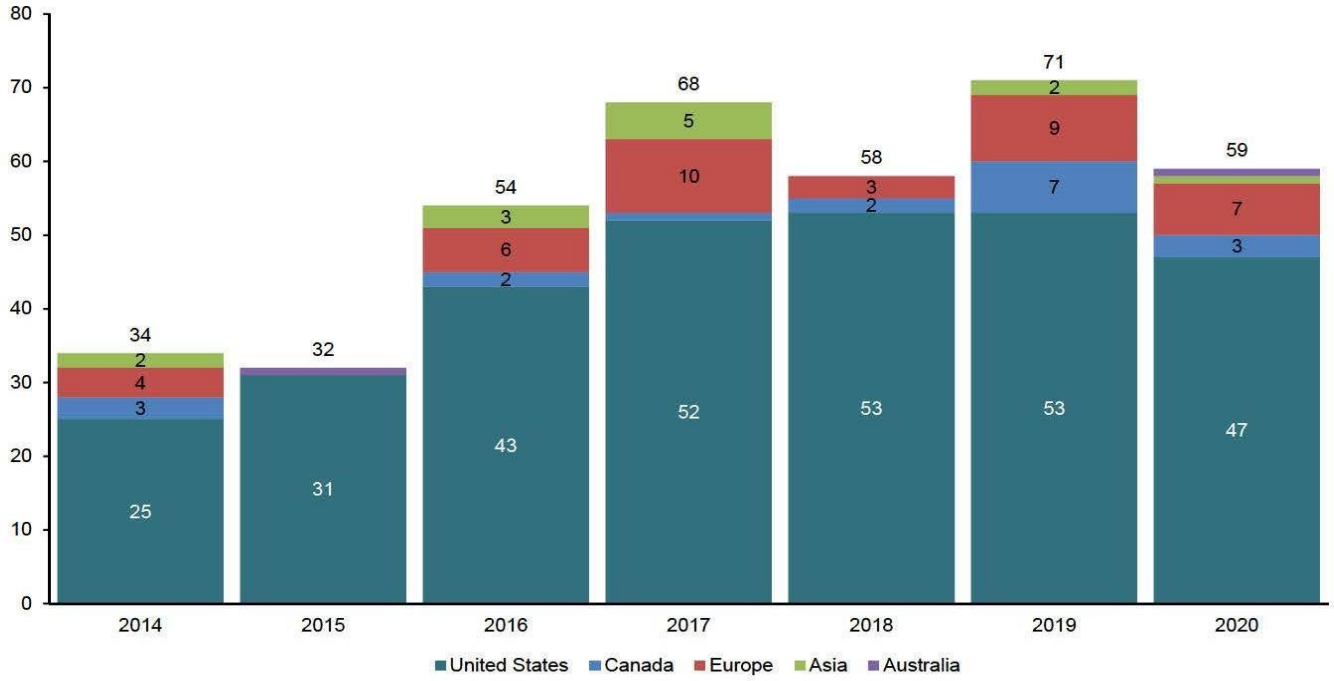
Source: Stanford Securities Clearinghouse and Cornerstone Research

Federal Class Action Securities Lawsuits Against Life Sciences Companies by Federal Circuit
2014 – 2020



Source: Stanford Securities Clearinghouse and Cornerstone Research

Federal and State Class Action Securities Lawsuits Against Life Sciences Companies by Location
2014 – 2020



Source: Stanford Securities Clearinghouse and Cornerstone Research

Note: Counts include federal securities class actions and state actions involving 1933 Securities Act claims.

Percentage of Life Sciences Companies Subject to Core Federal Filings
2016 – 2020

	Average 2016–2020	2016	2017	2018	2019	2020
Life Science Companies	12.4%	18.5%	7.7%	20.0%	11.5%	4.2%
All S&P 500 Companies	6.8%	6.6%	6.4%	9.4%	7.2%	4.4%

0%	0–5%	5–15%	15–25%	25%+

Note:
1. The chart is based on the composition of the S&P 500 as of the last trading day of the previous year.
2. Life Science filings include filings against companies with a primary focus in Biotechnology or Pharmaceuticals.
3. Percentage of Companies Subject to New Filings equals the number of companies subject to new securities class action filings in federal courts in each sector divided by the total number of companies in that sector.

Allegations Box Score for Securities Lawsuits Against Life Sciences Companies[1]
2018-2020

	Percentage and Count of Filings[2]					
	2018		2019		2020	
Allegations in Core Federal Filings[3]						
Rule 10b-5 Claims	41	100%	38	93%	36	100%
Section 11 Claims	2	5%	2	5%	2	6%
Section 12(a) Claims	1	2%	2	5%	1	3%
Misrepresentations in Financial Documents	41	100%	41	100%	34	94%
False Forward-Looking Statements	21	51%	13	32%	16	44%
Trading by Company Insiders	0	0%	2	5%	2	6%
Accounting Violations[4]	3	7%	4	10%	5	14%
Announced Restatement[5]	0	0%	0	0%	2	6%
Internal Control Weaknesses[6]	4	10%	2	5%	3	8%
Announced Internal Control Weaknesses[7]	2	5%	1	2%	1	3%
Underwriter Defendant	2	5%	2	5%	2	6%
Auditor Defendant	0	0%	0	0%	0	0%

Source: Cornerstone Research and Stanford Law School Securities Class Action Clearinghouse

Note:
1. Life Science filings include filings against companies with a primary focus in Biotechnology or Pharmaceuticals.
2. The percentages do not add to 100 percent because complaints may include multiple allegations.
3. Core federal filings are all federal securities class actions excluding those defined as M&A filings.
4. First identified complaint (FIC) includes allegations of U.S. GAAP violations or violations of other reporting standards such as IFRS. In some cases, plaintiff(s) may not have expressly referenced violations of U.S. GAAP or other reporting standards; however, the allegations, if true, would represent violations of U.S. GAAP or other reporting standards.
5. FIC includes allegations of Accounting Violations and refers to an announcement during or subsequent to the class period that the company will restate, may restate, or has unreliable financial statements.
6. FIC includes allegations of internal control weaknesses over financial reporting.
7. FIC includes allegations of internal control weaknesses and refers to an announcement during or subsequent to the class period that the company has internal control weaknesses over financial reporting.

GIBSON DUNN

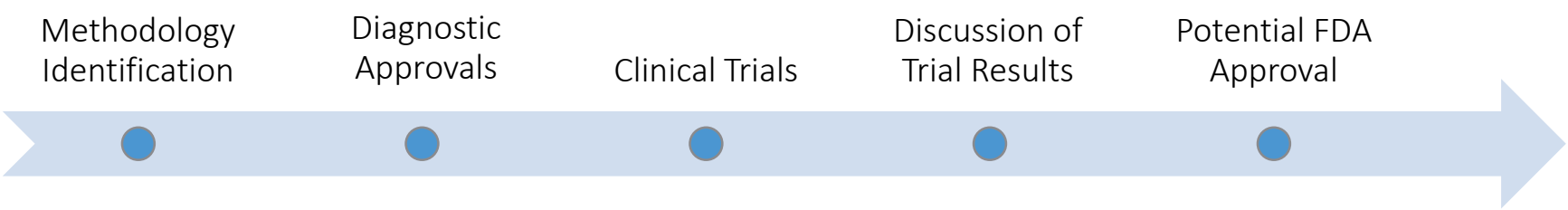
Complex Factual Context in Life Sciences Cases

Factual Context Is Unique and Complicated

Most securities fraud lawsuits are based on allegations that statements or omissions in a company's public disclosures make those disclosures false or misleading. In the life sciences context, there are many uncertainties relating to clinical trials and FDA approvals that make a company's public disclosures more challenging.

- Clinical trials are tests and the results are unknown until the test is complete. Various uncertainties impact effectiveness and safety of new drug products.
- Teams of experts needed to design, run, and interpret clinical trials (physicians, pharmacologists, statisticians, and others).
- FDA permits conduct of clinical trials if there is an underlying rationale to support the trial and to bring one to equipoise – an ethical principle guiding enrollment of humans in trials.
- Role of FDA is to protect the safety of the public; it provides guidance to the sponsor company, but the company makes decisions on design and conduct of clinical trial.

Complex Facts and Unpredictable Outcomes



Examples of Unknowns and Uncertainties at Play	
Statistics	Mechanism of action of drug
Pharmacology	Natural error rates
Clinical medical judgment	Experience of patient cohort
Disease progression	Clinical trial design

Statements / Omissions Typically Targeted in Allegations

Clinical trial statements

- Overstated success of clinical trial
- Failed to timely disclose unsuccessful outcome
- Failed to timely disclose FDA expressions of concern regarding methodology or results

Statements about FDA

- FDA approval signaled, but approval not given or withdrawn due to change in circumstances

Statements about drug product

- Efficacy and/or safety overstated
- Touted as better than competitors without data
- Serious Adverse Events (SAE) downplayed

Statements / Omissions Typically Targeted in Allegations

Manufacturing process

- Process claimed to be in compliance when FDA issues warning letter and approval withheld

Commercial Prospects

- FDA review turns up additional requirements
- Additional clinical trial required by FDA changing marketing timeline
- Altered patient recommendations that impacts sales, such as multiple pre-treatment doctors visits that makes use of drug product less convenient

GIBSON DUNN

Claims That Are Frequently Asserted in Federal Securities Class Actions

Key Claims Under the Federal Securities Laws

Key Claims Under the Securities Exchange Act of 1934

Section 10(b) / Rule 10b-5:

- Makes it unlawful to:

  a) Employ any device, scheme or artifice to defraud; or

  b) Make any untrue statement of material fact or omit to state a material fact necessary in order to make the statements made not misleading; or

  c) Engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security

Section 20(a)

- Action against "control persons" of primary violators of the Exchange Act

Key Claims Under the Federal Securities Laws

Elements of 10b-5 misrepresentation or omission claim:

1. a material misrepresentation or omission by the defendant
2. scienter
3. a connection between the misrepresentation or omission and the purchase or sale of a security
4. reliance upon the misrepresentation or omission
5. economic loss, and
6. loss causation

Key Claims Under Federal Securities Laws

Key Claims Under the Securities Act of 1933

- **Section 11** – Civil remedy for material misstatements and omissions in registration statements
- **Section 12(a)(2)** – Civil remedy for purchasers who are sold a security in a public offering "by means of a prospectus or oral communication" that included a material misstatement or omission
- **Section 14(a)/Rule 14a-9** – Implied right of action for misstatements and omissions in proxy materials
- **Section 15** – Action against "control persons" of primary violators of Sections 11 or 12

Key Common Law Claims

Common law fraud

- In New York, the elements are similar to a Rule 10b5 claim: Misrepresentation of a material fact; falsity; scienter or intent to defraud; reasonable reliance on the representation; damages caused by reliance

Misrepresentation

Negligence

GIBSON DUNN

Omnicare: A Key Defense Tool

Statements of Opinion: The Pre-*Omnicare* Landscape

Statements of Opinion

- Like objective statements of material fact, subjective statements of opinion can be actionable.
- Prior to *Omnicare*, courts were divided on how to evaluate alleged misleading statements of opinion in securities cases.

Statements of Opinion: The Pre-*Omnicare* Landscape

- The Sixth Circuit held, in the decision reviewed by the Supreme Court in *Omnicare*, that it was sufficient to allege that the stated beliefs were objectively false, even if genuinely believed to be true, because claims under Section 11 of the Securities Act that are based on misstatements of fact do not require a showing of scienter.
- The Second, Third and Ninth Circuits, on the other hand, required plaintiffs to allege both objective and subjective falsity. Thus, opinion statements would be actionable only to the extent that the statement was objectively false and disbelieved by the defendant at the time the opinion was expressed.

Omnicare's Standard For Opinion-Based Liability

In *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 184-85, 189 (2015), the Supreme Court held that statements of opinion are actionable in only three limited circumstances:

- the speaker did not actually hold the belief she professed;
- the opinion contained embedded statements of untrue facts; or
- the speaker omitted information whose omission made the statement misleading to a reasonable investor.

Omnicare's Standard For Opinion-Based Liability

- Several courts have held that the *Omnicare* standard applies to securities fraud claims brought under Section 10(b) of the Exchange Act even though *Omnicare* involved a Section 11 claim.

  See, *e.g.*, *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307 (11th Cir. 2019); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605 (9th Cir. 2017); *Nakkhumpun v. Taylor*, 782 F.3d 1142 (10th Cir. 2015).

- Courts also have held that *Omnicare* applies to SEC enforcement actions.

  See, e.g, *SEC v. Thompson, 238 F. Supp. 3d 575, 601 & n. 13 (S.D.N.Y 2017); SEC v. Arrayit Corp. and Rene Schena*, No. 5:21-cv-01053 (N.D. Cal. Feb. 11, 2021); *SEC v. Salix Pharm., Ltd.*, No. 1:18-cv-08886 (S.D.N.Y. Sept. 28, 2018).

Defending Securities Actions Based On Opinion Statements

- Plaintiffs' law firms are continuing to target life science companies in securities class actions.
- Moreover, the SEC has brought numerous enforcement actions against life science companies over the years, and it continues to do so.
- Given that these private actions and government enforcement proceedings are frequently based on alleged misstatements of opinion, the *Omnicare* framework is a critical tool for defending these actions.
- Since the Supreme Court issued its *Omnicare* decision in 2015, lower courts have applied the *Omnicare* standard to a wide variety of different factual contexts in securities cases brought against life science companies.
- This body of decisional law interpreting *Omnicare*, as well as the *Omnicare* decision itself, have spawned important principles that can be utilized by defense counsel to make successful motions to dismiss or motions for summary judgment.

Defending Securities Actions Based On Opinion Statements

The context of a statement is critical

- As discussed earlier, the facts in securities actions brought against life science companies are typically complex and nuanced.
- The *Omnicare* Court emphasized that "whether an omission makes an expression of opinion misleading always depends on context." *Omnicare*, 575 U.S. at 190.
- "[A]n investor reads each statement within [a registration statement], whether of fact or opinion, in light of all of its surrounding text, including hedges, disclaimers and apparently conflicting information." *Id.*
- "So an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once the statement is considered, as is appropriate, in a broader frame. The reasonable investor understands a statement of opinion in its full context, and § 11 creates liability only for the omission of material facts that cannot be squared with such a reading." *Id.* at 190-91.

Defending Securities Actions Based On Opinion Statements

Claims alleging "fraud by hindsight" will be dismissed

- It is not sufficient to allege that "an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." Courts have consistently rejected this "fraud by hindsight" approach. *See, e.g.*, *In re Aratana Therapeutics Inc. Secs. Litig.*, 315 F. Supp. 3d 737, 754 (S.D.N.Y. 2018) (internal quotations and citation omitted).
- In *Lehmann v. Ohr Pharmaceutical Inc*., the District Court stated that "[i]n the face of uncertainty, an opinion can still be reasonable even if new facts later undermine it." 2019 WL 4572765, at *5. In support of this statement, the Court quoted the *Omnicare* Court's explanation that Section 11 was not "an invitation to Monday morning quarterback an issuer's opinions," and that this statute "does not allow investors to second-guess inherently subjective and uncertain assessments." *Id.* (internal quotations omitted).

Defending Securities Actions Based On Opinion Statements

Omnicare's omissions theory is limited in its scope

- In *Omnicare*, the Supreme Court instructed that its omission theory of liability should not be given an "overly expansive reading." *Sanofi*, 816 F.3d at 210; *see also Omnicare*, 575 U.S. at 189-90.
- Moreover, the Supreme Court cautioned that establishing liability on the basis of omitted material facts "is no small task for an investor." *Omnicare*, 575 U.S. at 194.
- Lower courts that have been applying the *Omnicare* standard to securities claims against life science companies have been following this guidance by the Supreme Court. *See, e.g.*, *Aratana Therapeutics*, 315 F. Supp. 3d at 755; *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 397 (S.D.N.Y. 2018); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 578 (S.D.N.Y. 2016).

Defending Securities Actions Based On Opinion Statements

An opinion statement is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way.

- A reasonable investor does not expect that every fact known to an issuer supports its opinion statement.
- "Reasonable investors understand that opinions sometimes rest on a weighing of competing facts; indeed the presence of such facts is one reason why an issuer may frame a statement as an opinion, thus conveying uncertainty." *Omnicare*, 575 U.S. at 189-90.
- A reasonable investor expects that an issuer's opinion statement "fairly aligns with the information in the issuer's possession at the time." *Omnicare*, 575 U.S. at 189.
- "The core inquiry is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" *Sanofi*, 816 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 189).

Defending Securities Actions Based On Opinion Statements

Reasonable investors are expected to take into account the customs and practices of the relevant industry when evaluating an issuer's statement of opinion.

- The Supreme Court in *Omnicare* acknowledged that investors take into account "the customs and practices of the relevant industry." *Omnicare*, 575 U.S. at 190.

- In *Tongue v. Sanofi*, where the Second Circuit considered the sophistication of the investors, it stated that such investors—accustomed to the customs and practices of the pharmaceutical industry—"would fully expect that Defendants and the FDA were engaged in a dialogue, as they were here, about the sufficiency of various aspects of the clinical trials and that inherent in the nature of a dialogue are differing views." *Sanofi*, 816 F.3d at 211.

- The Second Circuit further stated that such investors would be aware that projections provided by issuers are synthesized from a wide variety of information, and that "some of the underlying facts may be in tension with the ultimate projection set forth by the issuer." *Id.*

Defending Securities Actions Based On Opinion Statements

- Significantly, the Court noted that the fact that Defendants and the FDA were engaged in an ongoing dialogue "did not prevent Defendants from expressing optimism, even exceptional optimism, about the likelihood of drug approval." The Court explained that "[w]hile a layperson, unaccustomed to the subtleties and intricacies of the pharmaceutical industry and registration statements, may have misinterpreted Defendants' statements as evincing assurance of success, Plaintiffs here can claim no such ignorance." *Sanofi*, 816 F.3d at 211-12.
- Thus, when defending securities cases brought against life science companies that are based on statements of opinion, it is important that defense counsel make sure that the court is aware of the process for obtaining FDA approval, the customs and practices of the pharmaceutical industry, and the sophistication of the investors.

Defending Securities Actions Based On Opinion Statements

Counsel may use several different means of bringing background information to attention of the court.

- Customs and practices of the pharmaceutical industry, as well as FDA rules, processes, and procedures may be necessary to place the alleged misleading statements or omissions in the proper context.
- For example, a court may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing a lawsuit. *Lehmann*, 2019 WL 4572765, at *2 (citation omitted).

Defending Securities Actions Based On Opinion Statements

- Moreover, a court may take judicial notice of certain information.
- For example, the Third Circuit has held that the district court could take judicial notice of an FDA memorandum. *Spizzirri v. Zyla Life Scis.,* 802 F. App'x 738, 739 (3d Cir. 2020). The court reasoned that the district court was entitled to consider this document because the memo was both a matter of public record and an authentic document 'integral to or explicitly relied upon in the complaint,'" because (1) the public had "unqualified access" to it online, and (2) the claims were based on this memo "even if it is not explicitly cited to." *Id.*

Defending Securities Actions Based On Opinion Statements

Statements of opinion vs. statements of fact

- A threshold issue in defending securities litigation is whether the alleged statements are factual assertions or opinions.
- To the extent that a plaintiff can persuade a court that the statements at issue are factual assertions, she will be able to avoid the pleading challenges presented by *Omnicare*.
- When litigating fact vs. opinion issues, defense counsel should consider the substantial body of law on this subject that has been developed both pre-and post-*Omnicare.* Pre-*Omnicare* law continues to be relevant for these purposes.
- Defense counsel also should bring to the court's attention the relevant industry customs and practices, clinical trial processes and procedures, FDA rules, regulations and procedures, and similar context for the statement at issue—which can illuminate whether it is really a factual assertion or an opinion.

Defending Securities Actions Based On Opinion Statements

- The *Omnicare* decision discusses this issue, and it provides a few helpful examples to demonstrate the difference between facts and opinions. The opinion notes that a statement of fact "expresses certainty about a thing," whereas a statement of opinion does not, and "that [this] difference between the two is so ingrained in our everyday ways of speaking and thinking as to make resort to old dictionaries seem a mite silly." *Omnicare*, 575 U.S. at 176, 183.
- Judge Engelmayer's decision in *In re Aratana Therapeutics Inc. Securities Litigation* is also instructive. *In re Aratana Therapeutics Inc. Secs. Litig.*, 315 F. Supp. 3d 737 (S.D.N.Y. 2018). The Court explained that statements of opinion "include subjective statements that reflect judgments as to values that [are] not objectively determinable." The Court also noted that "[s]tatements that express expectations about the future rather than presently existing, objective facts are also statements of opinion." *Id.* at 758 (internal quotations and citation omitted).

Defending Securities Actions Based On Opinion Statements

Disputes over the interpretation of data

- Commenting on the actionability of opinions regarding trial results, the Second Circuit noted that it previously rejected a dispute about the proper interpretation of data as a basis for liability. *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2016).

Defending Securities Actions Based On Opinion Statements

Issuers are not obligated to disclose all FDA information

- Issuers are not obligated to disclose all interim feedback received from the FDA, even if such feedback tends to cut against the issuer's own optimistic projections. *See, Tongue v Sanofi*, 816 F.3d at 212.
- The Court explained that "Defendants need not have disclosed the FDA feedback merely because it tended to cut against their projections – Plaintiffs were not entitled to so much information as might have been desired to make their own determination about the likelihood of FDA approval by a particular date. Certainly, Plaintiffs would have been interested in knowing about the FDA feedback, and perhaps would have acted otherwise had the feedback been disclosed, but *Omnicare* does not impose liability merely because an issuer failed to disclose information that runs counter to an opinion expressed in the registration statement." Id.

Defending Securities Actions Based On Opinion Statements

When evaluating a claim that an issuer did not actually believe its optimistic statements of opinion about a new drug, courts sometimes consider the investment that the issuer has made in seeking FDA approval.

- *See, e.g., In re Sanofi Sec. Litig.*, 87 F.Supp.3d 510, 531-32 (S.D.N.Y. 2015), (*citing City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) ("[T]he initiation of Phase 3 cost millions of dollars and required FDA approval, rendering it improbable that defendants would have continued if they did not believe their interpretation of the interim results or if they thought the drug a complete failure."); *Gillis v QRX Pharma Ltd*., 197 F. Supp 3d 557, 589 (S.D.N.Y. 2016).

Other Available Defenses for Opinion Statements: Puffery

Mere Puffery

- Although the issue of whether a statement is "mere puffery" is not part of the *Omnicare* framework, it is often raised in litigation regarding opinion statements.
- Generic, indefinite statements of corporate optimism are typically held to not be actionable, because reasonable investors do not place substantial reliance on such generalizations. Thus, the Second Circuit has held statements such as "encouraging" and "an improvement" when describing Phase 2 results to be puffery—and therefore non-actionable—unless the speaker knew the contrary was true. *Abramson v. Newlink Genetics Corp.*, 965 F. 3d 165, 173-74 (2d Cir. 2020).

Other Available Defenses for Opinion Statements: Puffery

- The following are examples of the types of statements that courts have deemed to be mere puffery: the "competitive advantage" of an issuer; statements regarding integrity, credibility, and objectivity; claims that a company was a leader in developing cancer therapies and delivering therapeutic outcomes that dramatically changed patients' lives; and claims of experience and expertise. *Gregory*, 297 F. Supp. 3d at 399.
- The U. S. District Court for the Southern District of New York held that the term "clinically meaningful" was puffery, analogizing the term to the word "success." *Lehmann v. Ohr Pharm. Inc.*, 2019 WL 4572765, at *4 (S.D.N.Y. Sept. 20, 2019).

Other Available Defenses for Opinion Statements: PSLRA Safe Harbor

PSLRA Safe Harbor for Forward-Looking Statements

- The PSLRA's safe harbor for forward looking statements is applicable to statements of opinion that fall within its statutory definition.
- Forward-looking statements are defined as those that contain, among other things, a projection of revenues, income, or earnings; plans and objectives of management for future operations; or a statement of future economic performance. 15 U.S.C. § 78u–5(i)(1); *Gregory*, 297 F. Supp. 3d at 397.
- "A forward-looking statement is not actionable if it 'is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading.'" *Gregory*, 297 F. Supp. 3d at 397 (*quoting Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010)).

Other Available Defenses for Opinion Statements: PSLRA Safe Harbor

- Issuers' statements as to their expectations regarding FDA approval and the timeline for commercial release of a drug are often framed as opinions and/or forward-looking statements. See, *e.g.*, *Aratana Therapeutics*, 315 F. Supp. 3d at 758.

GIBSON DUNN

Presenter Profiles

Jennifer L. Conn

200 Park Avenue, New York, NY 10166-0193
Tel +1 212.351.4086
JConn@gibsondunn.com

Jennifer L. Conn is a litigation partner in the New York office of Gibson, Dunn & Crutcher. She is a member of Gibson Dunn's Securities Litigation, Securities Enforcement, Appellate, and Privacy, Cybersecurity and Data Innovation Practice Groups.

Ms. Conn is a commercial litigator, who has extensive experience in a wide range of complex commercial litigation matters, with a particular focus on those matters involving securities, financial services, accounting, antitrust, and information technology.

Prior to joining Gibson Dunn, Ms. Conn was an associate with Cravath, Swaine & Moore in New York. She also was a law clerk for the Honorable Lawrence M. McKenna, United States District Judge for the Southern District of New York.

Ms. Conn received her Juris Doctor from Columbia University School of Law in 1995, where she was a Harlan Fiske Stone Scholar. She graduated, *cum laude* with distinction in all subjects, from Cornell University, College of Arts and Sciences, in 1992, with a Bachelor of Arts in Government.

Ms. Conn regularly writes and speaks on various subjects, particularly those relating to securities litigation. She is the co-editor and a co-author of the Firm's Practicing Law Institute Treatise, Securities Litigation: A Practitioner's Guide.

In addition, Ms. Conn is an Adjunct Professor of Law at Columbia University School of Law, lecturing on securities litigation.

Jane M. Love, Ph.D.

200 Park Avenue, New York, NY 10166-0193
Tel +1 212.351.3922
JLove@gibsondunn.com

Jane M. Love, Ph.D. is a partner and Chair of the Life Sciences and the Intellectual Property Litigation practices at Gibson Dunn & Crutcher LLP. Dr. Love is resident in the New York office.

Dr. Love is a first-chair litigator who handles high value patent litigation for pharma and biotech companies including global litigation coordination. She has extensive experience in Hatch-Waxman and BPCIA litigation. As a registered patent attorney, Jane is often lead counsel in concurrent Patent Office proceedings. Jane routinely offers strategic patent prosecution advice and patent diligence advice in connection with high value transactions.

Dr. Love has litigated patent issues in many jurisdictions around the country including Delaware, New Jersey, California, Massachusetts, and others. Her cases have spanned a wide variety of technologies but of late focus on biologics, therapeutic nucleic acids, and small molecules. She has advised clients on antibodies, immunotherapies, genetics, vaccines, protein therapies, blood factors, medical devices, diagnostics, gene therapies, RNA therapies, bioinformatics and nanotechnology. She is a patent attorney registered to practice before the U.S. Patent and Trademark Office and has prosecuted hundreds of patent applications.

Dr. Love is *Chambers*-rated for Intellectual Property, and has twice been named "Life Sciences MVP" by *Law360* (2017 and 2019). *The National Law Journal* named her a 2020 Health Care/Life Science Trailblazer in recognition for her work representing Novartis AG's multiple sclerosis drug Gilenya in cases impacting patent owners and challengers across the pharmaceutical and biotech industries. She and her team won "Hatch-Waxman Impact Case of the Year" in 2019 for a case related to patent term extensions and terminal disclaimers which Dr. Love won in Delaware District court and argued before the Federal Circuit. She is consistently named an "IP Star" by *Managing IP* and is recognized as one of the "world's leading patent professionals" by *IAM Patent*. Dr. Love was recognized as "Best in Patent" at the 2018 *Euromoney* Legal Media Group Women in Business Law Awards. In addition, she has been named in 2017 and 2020 in Legal Media Group's Expert Guides *Guide to the World's Leading Women in Business Law* for Patents. Dr. Love has been named a "Life Sciences Star" for Intellectual Property by *LMG Life Sciences*. She was named one of the "Top 250 Women in IP" by *Managing IP* in its six most recent lists and was named one of the IP attorneys in the "Top 50 Under 45" list by *IP Law & Business* in 20

Before joining Gibson Dunn, Dr. Love was the Co-Vice Chair of the Intellectual Property Department of Wilmer Hale and associated with that firm in New York since 2001. For seven years before that, Dr. Love practiced in an IP boutique law firm in New York.

Dr. Love received her Juris Doctor from Fordham University School of Law. Before practicing law, Dr. Love was a Ph.D. graduate student at the University of Pennsylvania and Thomas Jefferson Medical School in Philadelphia and was a Post-Doctoral Research Fellow at Cornell University Weill Medical College in New York City in molecular biology, pharmacology and cell and developmental biology. Dr. Love served as a Captain in the U.S. Army Reserve Medical Service Corp from 1991 to 1997.

Lawrence J. Zweifach

200 Park Avenue, New York, NY 10166-0193
Tel +1 212.351.2625
LZweifach@gibsondunn.com

Lawrence J. Zweifach is a litigation partner in the New York office of Gibson, Dunn & Crutcher, and he is a member of the Firm's Securities Litigation and Securities Enforcement Practice Groups. Mr. Zweifach is a nationally recognized trial lawyer, a Fellow of the American College of Trial Lawyers, and he has been acclaimed as one of the country's best litigators in *Lawdragon's "500 Leading Lawyers in America Hall of Fame."* Mr. Zweifach's practice includes defending companies in securities class actions and SEC enforcement investigations. *Chambers USA: America's Leading Lawyers for Business* ranked Mr. Zweifach among the top Securities Enforcement lawyers in the country, among the leading Securities Litigators in New York, and among the leading White Collar Criminal Defense Lawyers in New York. He also has been recognized as a National and Local "Litigation Star" and has been listed in the "Top 100 Trial Lawyers in America" by *Benchmark Litigation*.

Yan Cao

Vice President, Cornerstone Research
212.605.5406 New York
ycao@cornerstone.com

Yan Cao is a Vice President at Cornerstone Research's New York office. Dr. Cao specializes in issues related to financial economics and financial reporting across a range of complex litigation and regulatory proceedings. Her experience covers securities, market manipulation, M&A, and bankruptcy matters. Dr. Cao's case experience spans a wide range of industries. She has led large teams and worked with multiple experts in all stages of the litigation process. Dr. Cao's work includes substantial trial experience. Dr. Cao is a Chartered Financial Analysist (CFA) and a Certified Public Accountant (CPA).

Dr. Cao had fifteen years of experience consulting on securities class actions that cover a wide variety of industries, including a number of matters involving life science companies. Dr. Cao has experiences analyzing issues related to market efficiency, price formation, price impact, loss causation, and damages. She worked on notable securities class action cases such as In re Moody's Securities Litigation, in which the court denied class certification and granted summary judgment for defendants; and IBEW Local 90 Pension Fund v. Deutsche Bank AG et al., in which the court denied class certification.

She also focuses on regulatory investigation and enforcement matters led by the SEC, the CFTC, the DOJ, the NY Fed, and state AGs. She has presented analysis before the regulatory enforcement staff on behalf of clients. She has extensive experience analyzing alleged market manipulation and disruptive trading violations such as spoofing, wash trades, barrier options, front running, benchmark manipulation claims in various financial markets (fixed income, FX, equity, commodity futures, structured products, and derivatives) for broker-dealer and individual clients. She has also assisted counsel on issues related to valuation, financial reporting, internal control, and disclosures in the context of internal and regulatory inquiries, including cross-border and multi-jurisdiction investigations.

In a number of restructuring and bankruptcy-related proceedings, Dr. Cao has consulted on matters involving solvency, business forecasts, contract disputes, risk management, credit rating and credit risk. She has also analyzed a range of issues such as corporate governance, deal process, valuation, and damages on matters related to corporate transactions such as M&A, hedge fund activism, and going-private transactions.