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Market Conditions

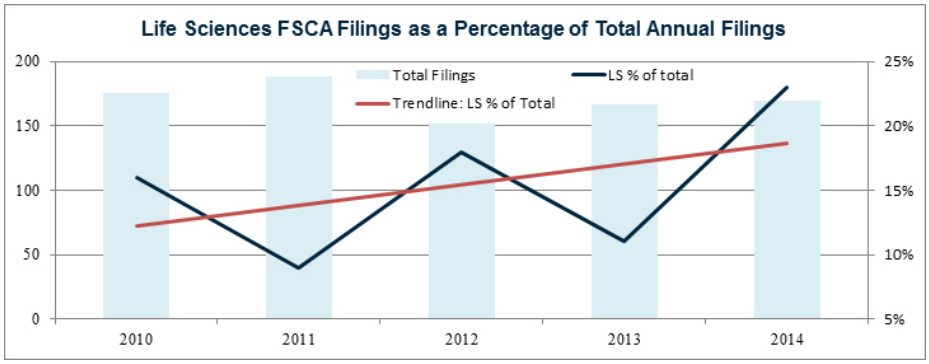
MARCH 2016

Directors & Officers Liability for Life Sciences Marketplace

By Jennifer Sharkey

In 2015, the D&O market as a whole experienced a competitive environment, with new and increased capacity leading to healthy premium decreases for some companies.

The public D&O insurance market for life sciences companies, however, continues to evolve, with the industry still a prime target of Federal Securities Class Action (FSCA) lawsuits. In 2014, a total of 170 FSCA lawsuits were filed, including 39 complaints against 38 companies in the life sciences sector. At 23% of all 2014 FSCA filings, this represents a noteworthy increase over recent years.



The heightened regulatory environment and the increase in investigations and enforcement actions by the Department of Justice (DOJ) and Securities and Exchange Commission (SEC) – perhaps most notably in the SEC's increased targeting of individuals – has presented more complex and costly exposures for life sciences companies. As discussed in a 2015 Dechert survey, life sciences companies are more likely to experience industry-specific allegations, vs. generalized claims of financial improprieties, since 2011. These allegations include: disclosure/prospects/timing of FDA approval, alleged misrepresentations or omissions regarding marketing practices, product efficacy, product safety, manufacturing and other healthcare-related allegations such as timing/completion of clinical trials. In 2014, 56% of claims against life sciences companies alleged misrepresentations or non-disclosure regarding product efficacy or prospects/timing of FDA approval; 44% alleged inaccurate financial reports/accounting improprieties. It was also not uncommon for both allegation types to be listed in the same lawsuit.[1]

Though heavily targeted by the plaintiffs' bar, it should be noted that the trend in industry-specific allegations against life sciences companies has allowed defendants in these cases to achieve a relatively high rate of dismissal. This could be because courts are unwilling to accept vague or conclusory allegations of securities fraud against a life sciences company;[1] as the U.S. Supreme Court said in its 2011 ruling in *Matrixx v. Siracusano*,[2] "[t]here is no bright-line rule for determining materiality." For example, courts have ruled that disclosure is required when necessary to make other statements made, in light of the circumstances under which they were made, not misleading; thus, disclosure of top-line data, followed later by more detailed information, does not render such disclosures false or misleading. It is equally worth noting, however, that securities fraud lawsuits still carry a substantial risk of exposure, and even when settled can result in very large payments, as illustrated by Pfizer's January 2015 agreement to pay $400 million to settle allegations of off-label marketing.[1]

It is unlikely that the plaintiffs' bar will back down in 2016, having become more adept at leveraging certain methods, such as books-and-records demands, in their efforts to battle motions to dismiss by submitting more detailed complaints. Though many dismissals are granted because their complaints were deemed too vague to overcome strong "risk factor" disclosures in a company's public filings, attorneys seek to offset this by pushing hard for large settlements when dismissal is denied.

In addition to the FSCA lawsuits noted above, there is also an increasing number of Section 11 securities class action cases filed against life sciences companies that went public using the Jumpstart Our Business Startups (JOBS) Act. With no reliance requirement and a strict liability standard, Section 11 claims can be brought up to one year after initial public offering (IPO) completion and typically experience low dismissal rates.

1. Dechert Survey of Securities Fraud Class Actions Brought Against U.S. Life Sciences Companies, March 2015
2. Matrixx Initiatives, Inc. v. Siracusano, 1, slip opinion at http://www.supremecourt.gov/opinions/10pdf/09-1156.pdf

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In 2014, 14% of all FSCA filings contained Section 11 allegations.[3]

Startup life sciences companies are particularly vulnerable to such allegations as much of their disclosures are non-factual statements and opinions about the development of their product. The March 2015 *Omnicare*[4] decision, however, should reduce Section 11 claims about honestly-held opinions that turn out to be wrong, although it may lead plaintiffs to assert that their claims should be allowed to proceed because the issuer failed to sufficiently disclose the material facts underlying those opinions.

Since its inception in April 2012, over 800 companies have gone public on major U.S. exchanges via the JOBS Act;[5] according to WilmerHale's 2015 IPO Report, over 80% of those companies qualify as emerging growth companies (EGCs). Which facets of the JOBS Act EGCs choose to adopt varies; WilmerHale's 2015 IPO Report provides the following assessment of adoption rates with respect to several key items of EGC relief:

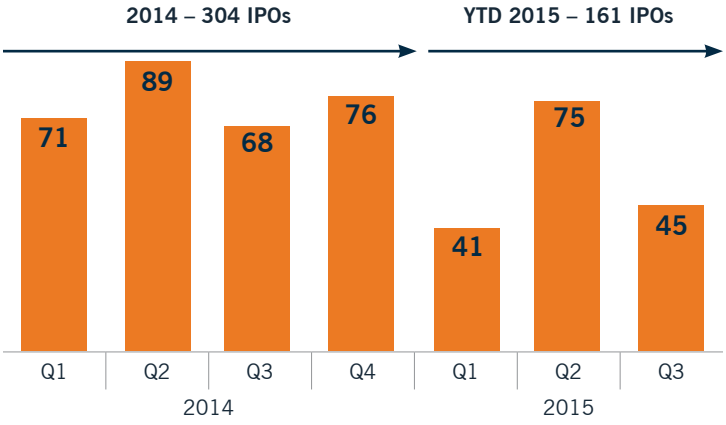
ITEM	LIFE SCIENCES COMPANIES	TECH COMPANIES	OTHER COMPANIES
Confidential submission of Form S-1	93%	94%	88%
Two years of audited financial statements	87%	28%	51%
Deferred application of new or revised accounting standards	13%	13%	10%
Omission of CD&A	100%	98%	94%

Based on IPOs initiated after enactment of the JOBS Act and completed by EGCs through 2014

With approximately 31% of these IPOs in the healthcare sector, the life sciences industry seems to have profited the most from the JOBS Act; the technology and financial institutions industries were next, representing approximately 20% and 16%, respectively.[5]

Concerned with the concentration of new business in the life sciences industry, underwriters began reducing capacity and increasing rates in the third quarter of 2014. The additional Section 11 exposure, combined with the saturation of life sciences IPOs in the market since Q2 2012, led to a tightening of the IPO D&O insurance market for life sciences companies.

Market volatility continues to increase amid global economic and political turbulence, impacting U.S. financing activity and affecting a general slowdown in IPOs, as indicated in the following review of year-over-year quarterly IPO volume.



Source: PricewaterhouseCoopers; IPO Watch: Q3 2015 Update

The IPO market could stabilize, however, as the marketplace settles and investors regain confidence, with investor support going to the most promising new issuers.

2016 EXPECTATIONS

For 2016, life sciences companies will continue to experience a bifurcated marketplace between their primary and excess layers. As the chart below illustrates, biotech companies have experienced a continuous increase in both the frequency and severity of FSCA lawsuits; as a fair representation of the overall life sciences industry, this is an excellent marker for the concerns underwriters have when underwriting these risks.

3. Cornerstore Research–Securities Class Action Filings 2014 Year in Review
4. Omnicare, Inc. et al. v. Laborers District Council Construction Industry Pension Fund, et al., slip opinion at http://www.supremecourt.gov/opinions/14pdf/13-435_8o6b.pdf.
5. PricewaterhouseCoopers; IPO Watch: Q3 2015 Update

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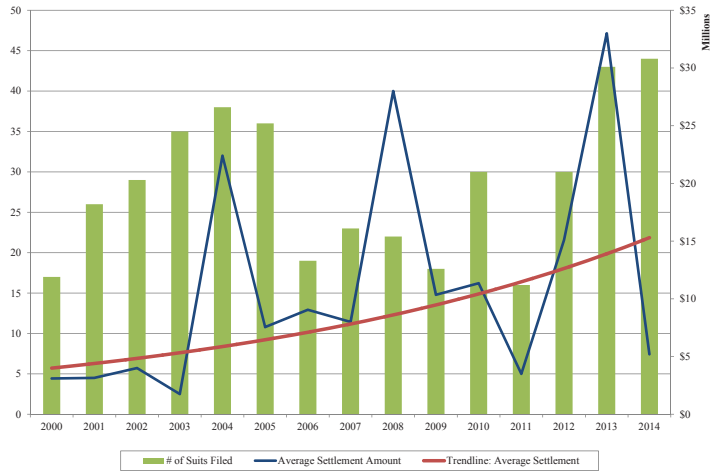
Frequency vs. Severity of Securities Class Action Suits: Biotech Industry



Source: Advisen Quarterly D&O Claims Trends: Q2 2015

Primary premium levels for life sciences companies are increasingly driven by each company's distinct risk profile and market capitalization. Taking this factor into consideration, along with limited primary capacity in the marketplace, we do not anticipate significant adjustments to the primary market. We do, however, expect contract language enhancements for life sciences companies to continue, providing broader, more comprehensive protection tailored to this industry's specific risks. The life sciences universe is diverse – large pharmaceutical, biopharmaceutical and medical device companies all buy D&O programs differently. Companies with complex securities litigation, investigations, or that are approaching commercialization or IPO (particularly one-product biopharmaceutical companies conducting later stage clinical trials) may experience firmer primary pricing. Underwriters may also look to increase securities and M&A retentions for some accounts as a way to offset increasing premium rates; the tradeoff of increasing retention versus premium needs to be carefully considered and evaluated.

Within 2015, the higher layer excess rates and Side A premiums have declined; this trend should continue in 2016. There is a significant amount of excess capacity available for life sciences companies in the marketplace, although excess rates, if not already at a minimum, will inevitably bottom out in 2016 as excess insurers are closely assessing the risk assumed for the premiums collected. Primary and excess insurers are also looking to obtain more premium within D&O programs by seeking to participate in additional layers higher up in the D&O tower. It is imperative for clients to closely consider their insurer partners for these placements – experience in underwriting and understanding life sciences companies, claims paying ability, financial strength, longevity and commitment to the sector should all be taken into consideration.

Jennifer Sharkey is an Area Executive Vice President of the Northeast region in Arthur J. Gallagher & Co.'s Management Liability Practice. This practice focuses on providing insurance and risk management solutions related to executive and management liability issues for a broad array of industries. Ms. Sharkey has over 20 years' experience in the insurance industry and is responsible for consulting, marketing and negotiating coverages for Directors & Officers Liability, General Partnership Liability, Private Equity/VCAP, Fiduciary Liability, Fidelity, Kidnap/Ransom & Extortion, Employment Practices Liability and Professional Errors & Omissions Liability. Focusing on placements for complex risks on behalf of the Fortune 1000, she has a great deal of experience working with clients in the technology, manufacturing, retail and life sciences sectors. For additional information, please contact Jennifer at Jennifer_Sharkey@ajg.com or visit www.ajg.com/mlp.