

The Recent Wave of Healthcare Sector Litigation:

Assessing the Fallout for Institutional Investors

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Executive Summary

- ▶ A wave of scandals at pharmaceutical and other healthcare companies has prompted an increased focus by lawmakers and other stakeholders on the drivers of the skyrocketing costs of healthcare.
- ▶ This misconduct has not only cost patients and governments – it has also triggered significant investment losses for institutional investors.
- ▶ Institutional investors should consider how these practices impact their healthcare sector investments, and the remedies available to recover losses caused by fraud.

Martin Shkreli

- ▶ Martin Shkreli's Turing raised the price of a critical AIDS medication by 5,000%, from \$13 to \$750 per pill. Shkreli said the price increases were legitimate:



- *“This isn’t the greedy drug company trying to gouge patients, it is us trying to stay in business.”*
- ▶ But when called to testify at a congressional hearing on drug price hikes, Shkreli invoked the 5th Amendment.
- ▶ He was later convicted of securities fraud arising from his prior involvement in pharmaceutical company Retrophin, and two hedge funds that Shkreli managed.

The EpiPen

Shkreli's Turing was not an outlier....

- ▶ Mylan raised the price of EpiPen, the life-saving injection used to treat allergic reactions, by about 500% since acquiring it in 2007.
- ▶ While Mylan's CEO claimed the hikes were legitimate, investigators found the company had misled government programs and misclassified the drug to boost profits.
- ▶ Mylan paid \$465 million to settle claims it overcharged the government for its EpiPen allergy treatment.
- ▶ Mylan shares declined by 20%, **wiping out \$5 billion in shareholder value**, after several Senators criticized the classification of the EpiPen and CMS revealed that it had notified the company that it could be subject to substantial liability.



Valeant Uses Secret Pharmacy Network To Manipulate Drug Sales

- ▶ Valeant inflated sales of its high-priced branded drugs by directing sales through specialty pharmacies, which it secretly owned.
- ▶ Valeant placed its own employees—using fake names—at the specialty pharmacies, lied to regulators about its ownership of the pharmacies, and fraudulently altered prescriptions to inflate sales of its branded medication.
- ▶ Beginning in September 2015, Valeant’s control of the pharmacies was revealed to investors.
- ▶ Investors also learned that the Company’s massive growth was largely—if not completely—attributable to its scheme.

Disclosure Of Valeant's Scheme Caused Billions In Losses

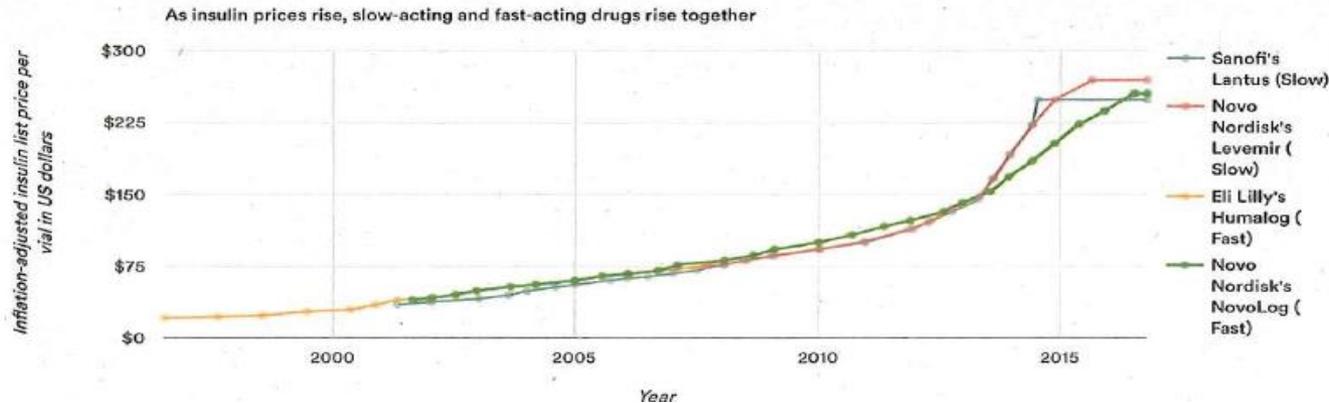
- ▶ Disclosures caused Valeant stock to decline by over **\$50 billion**.



- ▶ Lawsuits are filed:
 - Securities actions on behalf of Valeant investors.
 - RICO class action on behalf of third-party payors.

Diabetes Medication

These practices have impacted drugs from insulin...



- ▶ Insulin prices have steadily increased, often in lock-step, raising significant concerns about anticompetitive conduct.
- ▶ One diabetes manufacturer, Novo Nordisk, was subpoenaed over price increases and its relationships with PBMs.
- ▶ The value of Novo Nordisk ADRs declined by **\$3.2 billion** after the company was forced to cut its growth targets by 50% and disclosed that it was subpoenaed by federal prosecutors.

Generic Drug Price-fixing

...to dermatology products and other “specialty” drugs.

- ▶ While not all drug price increases are illegal, regulators have focused on potential price-fixing and other violations of the antitrust laws:
 - Attorneys general from 45 states and the District of Columbia sued 18 generic drug manufacturers for conspiring to manipulate the prices of 15 generic drugs.
 - Two former executives have already pleaded guilty to criminal charges.
 - Congressional investigators have also focused on the practices of PBMs and their relationships with pharmaceutical companies, and whether PBMs have improperly pushed higher cost drugs to pharmacies to boost profits.

Investors In Generic Drug Makers Incur Massive Losses

- ▶ Disclosure that the DOJ was planning to sue generic drug manufacturers for illicit price-fixing causes substantial investment losses:
 - **Teva** – ADSs declined by 10%, representing a \$3.2 billion market capitalization loss.
 - **Endo** – shares declined by 20%, representing a \$780 million market capitalization loss.
 - **Mylan** – shares declined by 7%, representing a \$1.4 billion market capitalization loss.



Opioid Epidemic Fueled By Drug Manufacturers

- ▶ Prescription opioids are powerful narcotic pain killers that, historically, were only prescribed to treat short-term pain or for end-of-life care.
- ▶ Manufacturers sought to reverse the medical understanding of opioids to expand the market for the drugs.
- ▶ Manufacturers entered into arrangements with seemingly independent patient advocacy groups and doctors, using these relationships to promote the use of opioids for chronic pain.
- ▶ Manufacturers made misrepresentations in marketing materials and through speakers bureaus to amplify the false message that opioids are safe and beneficial when used to treat chronic pain.



Opioid Manufacturers Face Regulatory Scrutiny

- ▶ The FDA and CDC declared in their March 2016 Guideline for Prescribing Opioids for Chronic Pain that “while opioids can reduce pain during short-term use, ***there is no good evidence that opioids improve pain or function with long-term use.***”
- ▶ Pennsylvania Attorney General Josh Shapiro is one of dozens of state attorneys general who have launched investigations into opioid manufacturers:
 - *Opioid manufacturers “put a desire for an insatiable profit over public health and public safety . . . And perhaps over the law. And that’s what we will get to the bottom of.” – Josh Shapiro*
- ▶ Over two dozen actions were filed by public entities, including several Pennsylvania counties (including Delaware, Beaver, and Lackawanna), as well as Ohio, Mississippi, Oklahoma, Missouri, New Mexico, New Hampshire, and South Carolina.

Opioid Distributors Provided “Rocket Fuel” For The Crisis

- ▶ “60 Minutes” recently interviewed a former DEA agent who revealed that the opioid crisis was aided, in large part, by a drug distribution industry that shipped, almost unchecked, hundreds of millions of pills to rogue pharmacies and pain clinics.

“This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.”

- Joe Rannazzisi, former DEA agent

- ▶ Rannazzisi accused distributors of fueling the opioid epidemic by turning a blind eye to pain pills being diverted to illicit use.
- ▶ Shareholder derivative lawsuit filed against Board and executives of drug distributor McKesson for ignoring suspicious orders to boost profits from opioid sales.

“Traditional” Securities Fraud

And some allegedly engaged in “traditional” securities fraud.

- ▶ ***In re Allergan, Inc. Proxy Violation Securities Litigation*** – Alleged insider-trading scheme by billionaire hedge fund manager Bill Ackman and Valeant Pharmaceuticals.



- ▶ ***In re Salix Pharmaceuticals, Ltd. Securities Litigation*** – Alleged accounting fraud and channel stuffing scheme.

Impact on Institutional Investors

- ▶ Misconduct in the health care industry has led to significant investment losses for institutional investors.
- ▶ The health care sector comprises about 15% of the S&P 500 index – a market capitalization of nearly **\$3 trillion**.
- ▶ In 2016, the health care sector was the **worst performing** sector in the S&P 500 index.
- ▶ Securities fraud lawsuits against healthcare companies filed over this period seek **tens of billions of dollars in damages**.



Source: *Thompson Reuters*, S&P 500 Healthcare Sector Index Price Return August-December 2016

Potential Remedies

- ▶ Investors may possess claims under the federal securities laws to recover these losses.
- ▶ Healthcare companies and their executives may have made false and misleading statements about:
 - The true drivers of reported earnings and revenue growth;
 - Compliance with laws and regulations;
 - Relationships with PBMs or specialty pharmacies; and
 - Other known “risks” concerning their business.
- ▶ To prove fraud, investors must show these statements were made with a culpable intent to deceive, and that their losses were in fact caused by the alleged fraud.
- ▶ RICO and derivative claims are also possibilities.



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Ms. Ross is widely recognized by industry observers for her professional achievements. Named one of “500 Leading Lawyers in America,” the exclusive list of the top practitioners in the nation compiled by leading legal journal *Lawdragon*, she has also been named a “Future Star” and one of the “Top 250 Women in Litigation” in the nation by *Benchmark*, and has earned praise from *Legal 500 US* as one of handful of notable practitioners in the country. Ms. Ross has been a key member and leader of trial teams that have recovered billions of dollars for the firm’s investor clients.

Among her many achievements, she was a senior member of the trial team that prosecuted *In re Bank of America Securities Litigation*, which resulted in the landmark settlement of \$2.43 billion shortly before trial, one of the largest recoveries ever obtained, and by far the largest recovery achieved in a litigation arising from the financial crisis. Ms. Ross was also a senior member of the trial team that prosecuted the case against MF Global, which recovered \$234.3 million on behalf of investors. She also played a critical role in the securities litigations against: Nortel Networks, which recovered \$1.07 billion for investors, also one of the top recoveries in history; Washington Mutual, which settled for \$225 million and the largest recovery ever achieved in a securities class action in the Western District of Washington; and The Mills Corporation, which settled for \$203 million, one of the largest recoveries ever achieved in a securities class action in Virginia and in the Fourth Circuit.

She is currently prosecuting a number of high-profile securities class actions, including the litigations arising from the failure of major mid-Atlantic bank Wilmington Trust.