2019 Year End Wrap-up for Life Sciences

December 11, 2019
Forward Looking Statements

This presentation contains Forward Looking Statements and other information designed to convey our projections and expectations regarding future results.

There are a number of factors which could cause our actual results to vary materially from those projected in this presentation. The principal risk factors that may cause these differences are described in various documents we file with the Securities and Exchange Commission, such as our Current Reports on Form 8-K, and our regular reports on Forms 10-Q and 10-K, particularly in “Item 1A, Risk Factors.” Please review this presentation in conjunction with a thorough reading and understanding of these risk factors.

Non-GAAP Measures

This presentation contains Non-GAAP measures, and we may reference Non-GAAP measures in our remarks and discussions with investors.

The primary Non-GAAP measure we reference is Non-GAAP operating income, a Non-GAAP financial measure that is widely used to evaluate performance within the insurance sector. In calculating Non-GAAP operating income, we have excluded the after-tax effects of net realized investment gains or losses and guaranty fund assessments or recoupments that do not reflect normal operating results. We believe Non-GAAP operating income presents a useful view of the performance of our insurance operations, but should be considered in conjunction with net income computed in accordance with GAAP. A reconciliation of these measures to GAAP measures is available in our regular reports on Forms 10-Q and 10-K and in our latest quarterly news release, all of which are available in the Investor Relations section of our website, Investor.ProAssurance.com.
Agenda

- Litigation and Claim Trends
- Case Law Trends
- Regulatory Roundup
- Update on Mass Torts
- Future Trends—what we should worry about
Litigation and Claims Trends
Vengeful Verdicts in 2019

Jury Awards on the Rise & Vengeful Increase in Punitive Damages Awards—Why?

- Public Distrust of Big Corp;
- Jury Attention Span less than a Goldfish;
- Influence of Social Media & Proliferation of Fake News;
- “Mockumentaries”;
- Sympathy Trumps Science;
- Judicial Hellholes & Venue.
Public Distrust

WE ADVOCATE FOR DRUG SAFETY
Informing the public about the hidden risks of drugs

BIG PHARMA BY THE NUMBERS:

$240 MILLION LOBBYING COSTS
600 DRUG LOBBYISTS
$1.05 TRILLION - GLOBAL PHARMACEUTICAL REVENUE, 2015
21% HEALTHCARE PROFIT MARGIN
$5.2 BILLION SPENT ON DRUG ADVERTISING IN 2015

10% SIDE EFFECTS REPORTED TO FDA

With so much spent on lobbying and advertising
With so little side effects reported to the FDA
Where do consumers get the truth?

TRULAW
trulaw.com
Dwindling Attention Spans: Goldfish—True or Carp?

12 seconds

THE AVERAGE HUMAN ATTENTION SPAN IN 2000

8 seconds

THE AVERAGE HUMAN ATTENTION SPAN IN 2013

9 seconds

THE AVERAGE ATTENTION SPAN OF A GOLDFISH
Punitive Damages Awards

![Bar chart showing the percentage of all punitive awards by type of liability](image)

**Source:** RAND Institute for Civil Justice analysis of jury trends, 1996.
Some Examples of Punishing Verdicts

- Risperdal;
- Monsanto Round Up Weedkiller;
- Talc;
- IVC Filters.
October 2019: Philadelphia Jury Hits J&J with $8BN Punitive Damages Award

- Janssen Pharmaceuticals Inc. allegedly downplayed the risks of abnormal breast growth, a condition known as gynecomastia, associated with Risperdal and had pressed ahead with aggressive efforts to market the powerful antipsychotic drug.
- Scientific data pointed to a lack of any statistically significant connection between Risperdal and gynecomastia.
- Original Award: $1.75M (reduced to $680,000 under MD law).
- Punitive phase: $8BN for single plaintiff.
2005 Survey of Median Damage Awards

2005 Median Damages Awarded To Successful Plaintiff By Trial Type

Source: U.S. Department of Justice, Bureau of Justice Statistics
Plaintiff’s Success vs. Jury’s Wealth Status

Plaintiffs' Success vs. Jury's Wealth Status

- California
- Florida
- New York
- Texas

- Below $20,000
- $20,000 to $30,000
- Above $30,000
## Recent Roundup Verdicts

<table>
<thead>
<tr>
<th>Date</th>
<th>Compensatory</th>
<th>Punitive</th>
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<tbody>
<tr>
<td>August 2018</td>
<td>$39.25M</td>
<td>$250M</td>
</tr>
<tr>
<td>March 2019</td>
<td>$5.2M</td>
<td>$75M (reduced to $20M)</td>
</tr>
<tr>
<td>May 13, 2019</td>
<td>$55M</td>
<td>$2BN (reduced to $86.7M)</td>
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42,700 plaintiffs have sued the company as of October 11, 2019—up from 18,400 three months prior.
Talcum Powder

TALCUM POWDER TIMELINE OF LOSSES

4.7 BILLION IN PUNITIVE DAMAGES

Because jurors believe that J&J should have warned of the risk of cancer with the use of their talcum products.

- **FEBRUARY 2016**
  - Jackie Fox Awarded $72 Million

- **MAY 2016**
  - Gloria Ristesund Awarded $55 Million

- **OCTOBER 2016**
  - Deborah Giannecchini Awarded $70 Million

- **MAY 2017**
  - Lois Slemp Awarded $110 Million

- **AUGUST 2017**
  - Eva Echeverria Awarded $417 Million

- **APRIL 2018**
  - Steven Lanzo Awarded $117 Million

- **MAY 2018**
  - Joanne Anderson Awarded $25.7 Million

- **JULY 2018**
  - 22 women in St. Louis Court Awarded $550 Million

5.5 BILLION IN LOSSES
September 2019—J&J $40M Talcum Powder Verdict

“Potential” risks persuaded jury that J&J failed to warn of those risks which may have caused injuries.

Jury found J&J did not negligently design or sell or that the products failed to perform as safely as a reasonable consumer would have expected.

Sympathy over Science.
15,500 Talc Lawsuits

On March 14, 2019, a jury in California ordered J&J to pay more than $29 million to a woman who claimed that asbestos in its talc-based powder products had caused her cancer.

J&J said in a regulatory filing last month that it had received subpoenas from the Justice Department and the Securities and Exchange Commission for more details about its talc products.

In July 2018, a jury in Missouri awarded $4.69 billion to 22 women who claimed that asbestos in J&J products, including its signature baby powder, caused them to develop ovarian cancer.
IVC Filter Verdicts

- May 2018: A Texas jury awarded a firefighter $1.2M against CR Bard.
- March 2018: An Arizona Bellwether Trial - $1.6M and $2M in Punitive Damages.
- Feb 2019: Indianapolis jury awarded $3M (Cook).
Other Reasons Why . . .
Erosion of Trust in the FDA

- The NY Times Editorial article from May 4, 2019
- The Danger from Within:
  - Non-fiction book attacking the FDA approval of medical devices.
- The Bleeding Edge:
  - Netflix documentary.
- Industry Response.
Drug Manufacturers and Distributors are not immune

- **Bottle of Lies: The Inside Story of the Generic Drug Boom**
  - Author: K. Eban, NY Times best seller list, 5/19.

- **China Rx: Exposing the Risks of America’s Dependence on China for Medicine**
  - Author: R. Gibson and J. Singh

- **Dreamland**
  - Author: Sam Quinones
  - Non-fiction account of the opioid epidemic ravaging Ohio, West Virginia and other states.
The Trump Administration’s Changing Views of Drug Companies:

- President Trump: “Drug companies are getting away with murder:”
  - “American Patients First” strategy;
  - Improve competition;
  - Create a framework for better negotiations with drug manufacturers;
  - Provide incentives to lower the list prices of drugs; and
  - Reduce patients out of pocket expenses.
General Claims Trends

Increased Severity in both Products liability and Medical Malpractice Lines of Business

Causes:

• Plaintiff’s medical history:
  › Obesity;
  › Addiction Issues.

• Jury Verdicts:
  › Social inflation;
  › Millennials.

• Healthcare’s Skyrocketing Costs;
• Litigation Funding.
Case Law Trends
Supreme Court noted in *Bristol-Myers Squibb*, that ruling was a “straightforward application . . . of settled principles of personal jurisdiction.”

One of these principles dates back long before the *Bristol-Myers Squibb* decision:

“[S]pecific personal jurisdiction does not lie over a nonresident plaintiff’s claim against a defendant not subject to general jurisdiction based solely on the close relationship between that claim and a claim brought in the same case by a resident plaintiff.”
Is BMS Limited to Mass Torts?

Southern District of California held that *Bristol-Myers Squibb* was not limited to mass tort and that personal jurisdiction challenges can be made in other types of cases.

- *McCurley v. Royal Seas Cruises, Inc. (Jan 2019).*

Central District of California recently denied a motion to dismiss class action claims, agreeing with the plaintiff that “*Bristol-Myers* applies to mass tort actions, not class actions.”

State Courts Bound by BMS

Forum Shopping Thwarted in the Wake of Bristol Meyer Squibb Decision at least in State Courts and in Federal Mass Tort Actions.

In re Amiodarone – JCCP (Alameda Superior Court)

- Plaintiffs seek to establish specific jurisdiction based solely on Defendants’ contacts with a California-based distributor.
- Court granted Specially Appearing Defendants Motion to Quash based on lack of Personal Jurisdiction under BMS.
  - (Appeal pending)
Innovator Liability Tempered by Recent SCOTUS Rulings

- USSC Decisions in *Mensing* and *Fosamax* have had a Salutary Impact on Innovator Liability.
- Rejected Theory in almost all other states except California.
- CA Supreme Court endorsed Innovator Liability in 2017.
- **Brand-name manufacturers owe a duty of reasonable care to ensure that product labeling includes adequate warnings**, whether or not the end user is exposed to the brand-name drug or its generic equivalent. The Court also held that a brand-name manufacturer could be liable for failure-to-warn **even after it has stopped manufacturing the product** if a successor manufacturer has failed to update labeling.
Regulatory Roundup
New York Opioid Excise Tax

Effective July 1, 2019, New York State became the first state to place an excise tax on the first sale of an opioid unit by a registrant in New York State.

What is a first sale? A first sale is any transfer of title to an opioid unit for consideration where actual or constructive possession of such opioid unit is transferred by a registrant holding title to such opioid unit to a purchaser or its designee in New York for the first time.

Registrant means any person, firm, corporation or association that holds and transfers title to an opioid unit and is required to register with the NY State Department of Health or is required to register with the NY State Department of Education or is a non-resident establishment excepted from registration with the NYS DOE.
New York Opioid Excise Tax

There are two tax rates:

- .0025 on each morphine milligram equivalent with a wholesale acquisition cost of less than $0.50 per unit;
- .015 on each morphine milligram equivalent with a wholesale acquisition cost of more than $0.50 per unit

Proponents of the Law highlight generating $100 Million in revenue for the State which the Governor has said will be used to help victims of the opioid crisis.

Opponents fear that the tax will increase the costs of the opioids which will be passed to the consumers which will result in patients seeking out opioids on the black market.
The Fairness for Injured Patients Act—MICRA Cap Reform in California

Concerted efforts to reverse tort reform and seek increase from 1970s MICRA caps from $250K for med mal claims.

Plaintiffs’ Bar Lobbying State Legislature for Reform.

California’s maximum $250,000 compensation cap was worth $50,768 in 1975. Indexing the $250,000 cap for inflation would raise it to $1,231,084.45 in today’s dollars, according to proponents.
Update on Mass Torts
Opioids, Talc and Mesh...And IVC Filters too

As of December 2019, 200 MDLs pending with greater than 20% involving medical devices and pharmaceutical products. These include:

- Opioids
- Talc
- Zantac
- Risperdal
- Hernia Mesh
- IVC Filters
Future Trends—what to worry about
Supply Chain: Generic Drugs manufactured overseas

- Contamination or fake/counterfeit drugs produced mainly in India and China

- Increasing issue in the US Poor Quality/Substandard
  - Lacking the active pharmaceutical ingredient (API) or containing very little of the API.
  - Contaminated
    - With an ingredient to mimic the API.
    - With a fungal or bacterial component due to inadequate quality control or improper storage.
    - With a carcinogen (NDMA, NDEA) as in generic Diovan products (Valsartan and Zantac).
Counterfeit/Black Market Drugs and Devices

Issues with Counterfeit and Black Market Products:
- Adverse health implications;
- Non-Sterile;
- Poor quality.
- Unknown materials may be inappropriate for use.

International problem.
Statistics

Since the implementation of the FDA’s Safety and Innovation Act in 2012, the Office of Regulatory Affairs has ordered that more than 3.7 million capsules/tablets of illegal and potentially dangerous drugs be destroyed.

Between October 2017 and June 2019:

- The Office of Criminal Investigations made 94 arrests and 88 convictions related to online sale and/or other illegal online activity related to FDA-regulated products;
- More than $45 million in fines and restitution;
- More than $41 million in forfeited assets, including more than 4,000 internet domain names.
Marketing of Black Market Drugs/Devices

Online pharmacies.

Social media—Facebook, Twitter, Instagram:
- Easy to spread the word and gain new customers;
- “Closed Groups” on internet;
- Fake comments for legitimacy;
- Use photographs of genuine products;
- Even if seller/user/group is taken down or blocked, easy to recreate under new name.
Types of Counterfeit Drugs/Devices

- Insulin
- ED drugs (Viagra; Cialis)
- Medical Device Hardware
  - Wires
  - Plates
  - Screws
- Botox
- Oxycodone
Dealing with Counterfeit and Black Market Drugs/Devices

**Prevention:**
- Packaging (holograms, UV identification codes, 2D barcodes, hidden text).

**European Union Medical Device Regulations** – May 2020.

**Detecting counterfeits:**
- Where is the product coming from?
- Check the Unique Device Identification.
Panel Predictions . . .
Sonia’s Prediction . . .

- Antibiotic overuse leading to drug-resistant bacteria.
  - 39,000 deaths from Antibiotic overuse v. 55,000 deaths from opioid overdoses this year.
  - Top 15 cause of death according to the CDC.
  - Cost over $20B in direct health care costs.
  - Drug resistance can occur two ways: antibiotic overuse or through the ingestion of meat that has been subject to antibiotics.
  - Growth in Superbugs which are not responsive to most antibiotics.
Kelly’s Predictions . . .

Potentially Addictive Products:

- High sugar, high-fructose corn syrup
  - Class action filed against Kellogg
    - Recently settled for $20 million, pending approval.

- “Vaping” (Electronic Nicotine Delivery Systems)/E-Cigarettes/JUUL
  - Numerous cases being filed throughout the country.
  - Targeting youth.
  - 7 states have made strides to ban e-cigarettes, mainly flavored (Michigan; New York; Massachusetts; Rhode Island; Washington; Oregon; Montana) as well as San Francisco.

- Lack of regulations:
  - As of 2016, regulated by same FDA regulations as other tobacco products.
Kelly’s Predictions . . .

- Big Data & Social Media Triggering More Life Science Mass Torts:
  - 2000-2017: +/- 13% initiated before or independent of a major regulatory event;
  - 2008-2018: +/- 72% initiated before or independent of a major regulatory event.
Pamela’s Predictions . . .

- First Party Litigation – Drug Addiction, Workers Comp, Drug Related Crime predicated on Nuisance Theories in Opioid MDL

- Cannabis

- Cyber Security Risk for Medical Devices
Thank You! Questions?
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