Explanatory Notes

• All the information discussed is based on publicly available information

• None of the information we share today about identifiable companies reflects non-public or “inside” information

• Some of the information discussed today is based on settlement documents, complaints, DOJ statements, and related materials

• Caution is appropriate with respect to whether these documents provide a complete, accurate, and/or fair depiction of the conduct of any company or individual
Agenda

• **1. Surveying the Landscape: Current Enforcement Climate**

• 2. Cast of Characters: Ongoing Enforcement Impact of Changes at DOJ

• 3. Windmills or Giants - Core Theories: Kickbacks, Bribes, and Corrupt Payments

• 4. New Adventures: Emergent Theories of Liability

• 5. Trusty Companions: Compliance, Litigation & Risk Strategies
1. Landscape
## 1. Landscape: Selected Recent Resolutions

<table>
<thead>
<tr>
<th>Company</th>
<th>Settlement</th>
<th>Year</th>
<th>Alleged Conduct</th>
</tr>
</thead>
</table>
| Insys Therapeutics | $150 million “agreement in principle” announced by Company | 2018   | Honest Services Mail/Wire Fraud – based in part on kickbacks to HCPs (Speaker Programs, Administrative & Reimbursement Support/PAServices, Discounts)  
Controlled Substance Act Violation (including DEA/SOM Evasion)  
Mail/Wire Fraud – false statements to insurers |
| Lundbeck      | $52 million “agreement in principle” announced by Company | 2018   | Kickbacks - Supporting non-profit patient assistance programs                                                                                                                                                  |
| Pfizer        | $24 million                     | 2018   | Kickbacks - Supporting non-profit patient assistance programs                                                                                                                                                  |
| Abiomed       | $3.1 million                    | 2018   | Kickbacks – Allegations of lavish meals to HCPs and spouses                                                                                                                                                     |
| Allergan      | $3.5 million                    | 2018   | False Claims – Alleged misrepresentations of facts concerning cause of access port leaks  
Kickbacks – Alleged compensation to HCPS for speaker fees and reports                                                                                                                                       |
| Stryker       | $7.8 million (2018) and $13.2 million (2013) | 2018   | FCPA – Alleged bribes and violations of books and records provisions                                                                                                                                             |
| Alere, Inc.   | $33.2 million                   | 2018   | False Claims/FDCA – Allegedly sold unreliable point-of-care testing devices and failed to timely take appropriate corrective actions                                                                                   |
| Amerisource   | $885 million                    | 2017   | FDCA - Misdemeanor distribution of misbranded product; sterility and safety issues  
False Claims Act: $625 million in civil resolution                                                                                                                                                    |
| ABH           | $350 million                    | 2017   | Kickbacks - Allegations of lavish meals, entertainment, cash, credits, and rebates; three high-level executives and numerous healthcare providers have been criminally convicted                                                   |
| United Therapeutics | $210 million                | 2017   | Kickbacks - Supporting non-profit patient assistance programs                                                                                                                                                  |
| Mylan         | $465 million                    | 2017   | Pricing - Misclassification of product to avoid paying rebates                                                                                                                                                  |
| Celgene Corp. | $280 million                    | 2017   | Off-Label Promotion  
Kickbacks - Speaker programs, grants, entertainment, non-profit support                                                                                                                                 |

*All values are in millions of dollars.*
1. Landscape: Corporate Resolutions Tapering Off?

*Trip Report*

Trump Administration Spares Corporate Wrongdoers Billions in Penalties

The New York Times

Nov. 3, 2018

A Wall Street Watchdog’s Lighter Touch

In the final 20 months of the Obama administration, the S.E.C. launched scores of big-money enforcement actions. The penalties have fallen since President Trump took office, in part because of philosophical differences between the two administrations, but the agency also says a recent Supreme Court decision limits punishment in some cases. New York Times analysis of S.E.C. records.
1. Landscape: DOJ Appropriations Up; Recoveries Declining

Federal Healthcare Recoveries ($M)

Congressional Appropriations ($M)

Source: HHS/DOJ Annual Reports - Health Care Fraud and Abuse Control Program, FY 2005 – FY 2017
1. Landscape: DOJ New Criminal Healthcare Investigations: Steady, Full Pipeline

Pending Criminal Investigations

New Criminal Investigations


Source: HHS/DOJ Annual Reports - Health Care Fraud and Abuse Control Program, FY 2005 – FY 2017
1. Landscape: DOJ New Civil Healthcare Investigations: Steady, Full Pipeline

Pending Civil Investigations

New Civil Investigations

Source: HHS/DOJ Annual Reports - Health Care Fraud and Abuse Control Program, FY 2005 – FY 2017
1. Landscape: New FCA Qui Tam Complaints (more Plaintiff lawyers, fueled by more data/transparency/open records)

Agenda

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• 5. Trusty Companions: Compliance, Litigation & Risk Strategies
2. Cast
2. Cast: New DOJ Memos Emphasize Coordination and Economy of Resources in an Era of Non-Intervened Qui Tams

January 10, 2018

PRIVILEGED AND CONFIDENTIAL: FOR INTERNAL GOVERNMENT USE ONLY

MEMORANDUM

TO: Attorneys
Commercial Litigation Branch, Fraud Section

Assistant U.S. Attorneys Handling False Claims Act Cases
Offices of the U.S. Attorneys

FROM: Michael D. Granston
Director
Commercial Litigation Branch, Fraud Section

SUBJECT: Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)

Introduction

Over the last several years, the Department has seen record increases in qui tam actions filed under the False Claims Act (FCA), 31 U.S.C. § 3729 et seq., with annual totals approaching or exceeding 600 new matters. Although the number of filings has increased substantially over time, the rate of intervention has remained relatively static. Even in non-intervened cases, the government expends significant resources in monitoring these cases and sometimes must produce discovery or otherwise participate. If the cases lack substantial merit, they can generate adverse decisions that affect the government’s ability to enforce the FCA. Thus, when evaluating a recommendation to decline intervention in a qui tam action, attorneys should also consider whether the government’s interests are served, in addition, by seeking dismissal pursuant to 31 U.S.C. § 3730(c)(2)(A).

Factors for Evaluating FCA Dismissal (1/10/18)

May 9, 2018

U.S. Department of Justice
Office of the Deputy Attorney General

The Deputy Attorney General
Washinton, D.C. 20530

TO: Heads of Department Components
United States Attorneys

FROM: Rod J. Rosenstein
Deputy Attorney General

SUBJECT: Policy on Coordination of Corporate Resolution Penalties

Corporate enforcement, like other criminal and civil enforcement, must be guided by the rule of law. In reaching corporate resolutions, the Department should consider the validity of fines, penalties, and/or forfeitures imposed by all Department components as well as other law enforcement agencies and regulators in an effort to achieve an equitable result.

Attached for your attention are new provisions to be incorporated in the U.S. Attorneys’ Manual. These provisions recognize the Department’s commitment to fairness, as well as the strength of our partnerships with law enforcement agencies and regulators in the United States and abroad.

Coordination of Corporate Resolution Penalties (5/9/18)
2. Cast: Brand Memo: DOJ Cannot End-Run Notice & Comment

Accordingly, effective immediately for ACE cases, the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules.

Likewise, Department litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable law in ACE cases.
2. Cast: Instability & Departures: Discontent at DOJ?

Rachel Brand Stepping Down as Justice Department’s No. 3
Associate attorney general will take a senior job at Walmart

DOJ's Scott Schools Heads to Uber as Chief Compliance Officer

Justice Dept. Rank-and-File Tell of Discontent Over Sessions’s Approach

Now, discontent and infighting have taken hold at the Justice Department, in part because Mr. Sessions was so determined to carry out that transformation that he ignored dissent, at times putting the Trump administration on track to lose in court and prompting high-level departures, according to interviews over several months with two dozen current and former career department lawyers who worked under Mr. Sessions. Most asked not to be named for fear of retribution.


“To mark this significant undertaking, and to emphasize that the Manual applies beyond the United States Attorneys’ Offices, we have renamed it the Justice Manual. Though the name has changed, the Manual will continue as a valuable means of improving efficiency, promoting consistency, and ensuring that applicable Department policies remain readily available to all employees as they carry out the Department’s vital mission.” – Deputy Attorney General Rod Rosenstein

New “Justice Manual” Highlights:

- *Granston* Memo on False Claims Act dismissal incorporated
- Features guidance to DOJ attorneys to avoid “piling on” by seeking excessive and duplicative fines, penalties and/or forfeitures against the subjects of an investigation or defendants in a lawsuit
- Includes provisions regarding non-negotiation of press releases and transparency in settlements (*e.g.*, no confidentiality)
- *Yates* Memo Included without changes
2. Cast: A “Quixotic” DOJ: Mission or Misdirection?

Rod Rosenstein Sees Crime-Fighting as Justice’s Overlooked Strong Suit

“Mr. Rosenstein insisted department officials are focused on the priorities he and Mr. Sessions outlined when they took office, centered on fighting the drug-abuse crisis and quelling crime increases in some big cities.”

“While frustrating some DOJ officials, that has allowed Messrs. Rosenstein and Sessions to make some policy changes in immigration and criminal justice with less scrutiny from lawmakers, who are more interested in the department’s handling of politically charged probes into Russian meddling and Hillary Clinton’s emails.”

“[I]n terms of the day-to-day work of the deputy’s office, we are completely focused on the work of the department,” he said as he sat at a long table in his conference room alongside several aides, with a pile of charts and numbers in front of him.”
2. Cast: Presidential Shakeup

‘I don’t have an attorney general’: Trump escalates his attacks on Jeff Sessions

Rod Rosenstein expects to be fired

Trump talked with Jeff Sessions’s own chief of staff about replacing him as attorney general

Trump Cabinet exodus likely after midterms
2. Cast: Presidential Shakeup

Attorney General Jeff Sessions resigns at Trump’s request

The team we assembled embraced your directive to be a law and order Department of Justice. We prosecuted the largest number of violent offenders and firearm defendants in our country’s history. We took on transnational gangs that are bringing violence and death across our borders and protected national security. We did our part to restore immigration enforcement. We targeted the opioid epidemic by prosecuting doctors, pharmacists, and anyone else who contributes to this crisis with new law enforcement tools and determination. And we have seen results. After two years of rising violent crime and homicides prior to this administration, those trends have reversed—thanks to the hard work of our prosecutors and law enforcement around the country.

Most importantly, in my time as Attorney General, I have restored and upheld the rule of law—a glorious tradition that each of us has a responsibility to safeguard. We have operated with integrity and have lawfully and aggressively advanced the policy agenda of this administration.

I have been honored to serve in Attorney General and have worked to implement the law enforcement agenda based on the rule of law that formed a central part of your campaign for the Presidency.

Thank you for the opportunity, Mr. President.

Jefferson B. Sessions III
Attorney General

Office of the Attorney General
Washington, D.C. 20530

Nov. 7, 2018
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• 5. Trusty Companions: Compliance, Litigation & Risk Strategies
3. Core Theories
3. Core Theories: AKS-Patient Assistance Dwindles; OIG Asks for Free Product

A decision on 2018 financial assistance

Since I last wrote, the Caring Voice Coalition Board of Directors has evaluated all options available to our organization regarding financial assistance requests in light of the decision by the U.S. Department of Health and Human Services Office of Inspector General to rescind our Advisory Opinion. After considering all options and our current circumstances, I deeply regret to announce that CVC will not open financial assistance for any disease fund in 2018.

We are grateful to have been able to help chronic illnesses and remain committed to improving the lives of patients with chronic illnesses. Where we can, we will continue to provide free drugs to Federal health care program beneficiaries impacted by CVC’s decision.

We understand that some patients affected by this decision may face significant financial barriers to obtaining critical drugs. The Office of Inspector General (OIG) will not pursue administrative sanctions against any Drug Company for providing free drugs during 2018 to Federal health care program beneficiaries who received these drugs for 2018.

Greg Smiley
President, CEO
January 4 2018
3. Core Theories: CA3: Another “Taint” Theory Rejected in Medco

“Despite this evidentiary shortcoming, Greenfield insists that the taint of a kickback renders every reimbursement claim false. Because Accredo was violating the Anti-Kickback Statute while submitting federal claims for reimbursement, he argues, the alleged kickbacks need not have any connection to the claims or the underlying medical care. Again we disagree. A kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement.” (emphasis added)
3. Core Theories: Meanwhile... More PAP Enforcement Actions

Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks

Pharmaceutical company Pfizer, Inc. (Pfizer), based in New York, NY, has agreed to pay $23.85 million to resolve claims that it used a foundation as a conduit to pay the copays of Medicare patients taking three Pfizer drugs, in violation of the False Claims Act, the Justice Department announced today.

DOJ charity probe claims another as Lundbeck inks $52.6M settlement with feds

United Therapeutics inks $210M deal to wrap charity kickbacks probe
3. Core Theories: DOJ Charging of Executives: A Continuing Trend?

**Former Valeant Executive And Former Philidor Ceo Convicted For Illegal Kickback Scheme**

TANNER, 40, of Gilbert, Arizona, and DAVENPORT, 50, of Haverford, Pennsylvania, were convicted of four counts: (1) one count of conspiracy to commit honest services wire fraud, which carries a maximum potential penalty of 20 years in prison; (2) one count of honest services wire fraud, which carries a maximum potential penalty of 20 years in prison; (3) one count of conspiracy to violate the Travel Act, which carries a maximum potential penalty of five years in prison; and (4) one count of conspiracy to commit money laundering, which carries a maximum potential penalty of 20 years in prison.

**Theranos Founder Elizabeth Holmes Indicted on Fraud Charges**

The New York Times

**THE UNITED STATES OF AMERICA**

**vs.**

**ELIZABETH A. HOLMES & RAMESH "SUNNY" BALWANI**

**INDICTMENT**

**COUNT 1:** 18 U.S.C. § 1349 – Conspiracy to Commit Wire Fraud against Theranos Investors

**COUNT 2:** 18 U.S.C. § 1349 – Conspiracy to Commit Wire Fraud against Doctors and Theranos Patients

**COUNTS 3-8:** 18 U.S.C. § 1243 – Wire Fraud

**COUNTS 9-11:** 18 U.S.C. § 1243 – Wire Fraud

* A true bill.
3. Core Theories: John Oliver on “Prosecutors Will Decide”
3. Core Theories: “Crazy Way to Charge a Case”: Gov’t Theory Challenged in Prosecution of Insys Execs
3. Core Theories: Insys Execs: USA “Clarifies” in Indictment #3; Shifts Roster

**CRIMINAL NO. 16-CR-1000**

**VIOLATIONS:**

18 U.S.C. § 1962(d)  
(Racketeering Conspiracy)

18 U.S.C. § 1963 (Forfeiture)

24. The **pattern of racketeering activity** through which the defendants, along with others known and unknown to the Grand Jury, agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the enterprise consisted of multiple:

a. acts indictable under Title 18, United States Code, Section 1341 **(mail fraud)**;

b. acts indictable under Title 18, United States Code, Sections 1341 and 1346 **(honest services mail fraud)**;

c. offenses involving the **distribution of controlled substances** in violation of Title 21, United States Code, Section 841(a)(1) ;

d. acts indictable under Title 18, United States Code, Section 1343 **(wire fraud)**; and

e. acts indictable under Title 18, United States Code, Sections 1343 and 1346 **(honest services wire fraud)**.
EXECUTIVE SUMMARY

During the height of the prescription opioid crisis in the United States, Insys Therapeutics, Inc., adopted and intensified sales and marketing techniques Purdue Pharma pioneered in the 1990s for OxyContin and applied them to Insys’ powerful fentanyl drug Subsys. Like Purdue, Insys aggressively used speakers programs—in which the company paid physicians to discuss Subsys with colleagues—and compensation programs for sales representatives to boost sales for Subsys.

Based on a review of 1.6 million pages of internal Insys documents provided in response to March 2017 requests from Ranking Member McCaskill, this report discusses how the interplay between compensation—for physicians on the one hand and their assigned sales representatives on the other—drove explosive growth for Insys. Alongside speakers programs, Insys also established several other sales and marketing practices that formed the core of its approach to boosting Subsys sales: bonus structures for sales representatives that rewarded high-dosage prescriptions, accountability for representatives who failed to generate sufficient scripts, and the leveraging of personal relationships between physicians and representatives. Uniting these efforts, as an Insys national sales director wrote in 2013, was a simple idea: 'What drives us all? COMPENSATION.'

Josh Hawley Defeats Claire McCaskill in Missouri Senate Race

The New York Times

Nov. 7, 2018
3. Core Theories: Opioid Litigation
3. Core Theories: HHS-OIG Sr. Counsel Mary Riordan Slides from PCF (Nov. 7, 2018)

Lessons/Suggestions

- Think broadly about compliance risk areas—established and emerging
  - Risks under the Federal anti-kickback statute
  - Risks associated with failure to comply with FDA requirements
  - Risks associated with the Medicaid drug rebate program
  - Risks associated with HIPAA issues

- Maintain a focus on kickback issues
  - Kickbacks are a continued area of focus in cases
  - Think broadly about arrangements with a variety of individuals and entities
  - Risk areas to watch:
    - Arrangements with health care providers
    - Arrangements involving patient assistance programs
“Your Honor, we feel the trial failed to deliver on its pretrial publicity.”
3. Core Theories: FCPA Remains an Active Enforcement Area

Medical-Device Firm Settles Foreign-Bribery Case

Medical-device firm Stryker Corp. agreed to pay $7.8 million to resolve allegations of violating U.S. anti-bribery laws, marking the second time the company paid to settle such violations.

The Securities and Exchange Commission alleged that the Kalamazoo, Michigan-based company’s internal accounting controls were insufficient to detect the risk of improper payments of the company’s products in India, China and Kuwait. The company’s unit in India also failed to maintain accurate books and records, the SEC has alleged.

Stryker violated the internal controls and accounting provisions of the Foreign Corrupt Practices Act, the SEC said. The failures are “unacceptable,” especially because “this is not the first time” Stryker has been charged for these violations, said Marc Berger, director of the SEC’s New York office, in a statement.

Fresenius's FCPA penalty increases as settlement talks advance

The healthcare company said in a securities filing on 17 October that it has increased the $245 million it reserved for an upcoming Foreign Corrupt Practices Act settlement by $86 million (€75 million). It means the total cost of Fresenius’s FCPA case could be around $330 million.
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4. Emergent Theories: Drug Pricing: Executive Focus on Manufacturers?

How the Trump Administration Is Browbeating Big Pharma on Drug Prices
[Link to The New York Times]

Trump Eyeing ‘Disruptive’ Changes to Drug Pricing, Health Secretary Says
[Link to Bloomberg]

“I am not blaming pharmacy-benefit managers for the position we are in around drug pricing or the dynamic of rebates,” he said. “The pharmacy-benefit managers do an incredible job negotiating discounts, rebates in our system. In fact, a major part of the president’s plan is that we’re further empowering pharmacy-benefit managers,” referencing Medicare drug programs for the elderly.

Trump Proposes to Lower Drug Prices by Basing Them on Other Countries’ Costs
[Link to The New York Times]

King & Spalding
4. Emergent Theories: Drug Pricing: Executive and Congressional Focus

Just talked with Pfizer CEO and @SecAzar on our drug pricing blueprint. Pfizer is rolling back price hikes, so American patients don’t pay more. We applaud Pfizer for this decision and hope other companies do the same. Great news for the American people!

@POTUS has made clear that it’s time for drug companies to put American Patients First — Novartis halting its prescription drug increases is a step in the right direction and a win for American patients.

Thank you to Novartis for not increasing your prices on prescription drugs. Likewise to Pfizer. We are making a big push to actually reduce the prices, maybe substantially, on prescription drugs.

Great to see the Senate working on solutions to end the secrecy around ridiculously high drug prices, something I called for in my drug pricing Blueprint. Will now work with the House to help American patients! #AmericanPatientsFirst
"You’re in luck—you have a preexisting condition. It preexists Congress taking away your insurance."
4. Emergent Theories: Pricing: Outside Agitators Also Wield Influence

A Billionaire Pledges to Fight High Drug Prices, and the Industry Is Rattled

The Wall Street Journal
Oct. 21, 2018

Growing Strategy
John Arnold argues that drugmakers’ copay offset programs, which cover part of the higher copays patients must pay for certain drugs, promote the use of pricier brands. Drugmakers say copay coupons help defray patients’ out-of-pocket costs.

Antidepressants prescribed in similar cases, 30-day supply

<table>
<thead>
<tr>
<th>Antidepressant</th>
<th>Total Cost</th>
<th>Savings Card</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERTRALINE (generic)</td>
<td>$378</td>
<td>Covers up to $65 of a $75 copay</td>
</tr>
</tbody>
</table>

Manufacturer spending on copay offset programs

Mr. Arnold is the biggest single spender on his side of the battle. He made his money placing bets on price swings in the natural-gas market, first as an energy trader at Enron, then at his own hedge fund after Enron’s collapse. Now retired, the 44-year-old Texan with an estimated $3.3 billion in assets is dedicating himself to the topic of the U.S.’s ballooning health care costs.
4. Emergent Theories: Know Your Customer’s Customer

The government’s struggle to hold opioid manufacturers accountable

It was the first time the DEA had targeted a manufacturer of opioids for alleged violations of laws designed to prevent diversion of legal narcotics to the black market. And it would become the largest prescription-drug case the agency has pursued.

Ultimately, the DEA and federal prosecutors would contend that the company ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012 — 66 percent of all oxycodone sold in the state. Government investigators alleged in internal documents that the company’s lack of due diligence could have resulted in nearly 44,000 federal violations and exposed it to $2.3 billion in fines, according to confidential government records and emails obtained by The Washington Post.

But six years later, after four investigations that spanned five states, the government has taken no legal action against Mallinckrodt. Instead, the company has reached a tentative settlement with federal prosecutors, according to sources familiar with the discussions.

Under the proposal, which remains confidential, Mallinckrodt would agree to pay a $33 million fine and admit no wrongdoing.

2 drug distributors to pay $36M to settle WV painkiller lawsuits

Monday’s announcement follows a Gazette-Mail investigative report, which found that drug wholesalers shipped 780 million hydrocodone and oxycodone pills to the state in just six years, a period when 1,728 West Virginians fatally overdosed on those two drugs.

Cardinal Health and AmerisourceBergen combined to ship nearly 40 percent of all hydrocodone and oxycodone pills to West Virginia, according to the newspaper’s analysis of U.S. Drug Enforcement Administration data. Several counties saw significant spikes in shipments while drug overdose deaths were climbing.

For instance, Cardinal Health’s sales of hydrocodone to Cabell and Logan counties increased six-fold between 2007 and 2010, and doubled in Kanawha County in just one year. AmerisourceBergen’s oxycodone sales in Greenbrier County nearly quadrupled over six years, DEA records show.

“Obviously, they had to know, with a state this size, and that many pills coming in, that something wasn’t right,” Tomblin said Monday.

In 2012, McGraw filed lawsuits against Cardinal Health, AmerisourceBergen and a dozen smaller drug distributors for their role in a drug supply chain that includes doctors who write prescriptions for nonmedical purposes and “pill mill” pharmacies that dispense excessive numbers of painkillers. Attorney General Patrick Morrisey inherited the case upon taking office in January 2013.
Update from the Office of Inspector General

19th Annual Pharmaceutical And Medical Device Compliance Congress
Mary E. Riordan, Senior Counsel
Office of Counsel to the Inspector General
November 7, 2018

OIG FY 2018 Work Plan

- Planned opioid-related work includes:
  - Review of prescription opioid drug abuse and misuse prevention – Prescription Drug Monitoring Programs
  - Review of FDA oversight of REMS to address prescription opioid abuse
  - Review of opioid use in Indian Health Service
  - Review of States’ oversight of opioids
4. Emergent Theories: Cal. Insurance: No Longer a Sidekick

California Sues AbbVie Over Alleged Arthritis Drug Kickbacks

September 18, 2018

Jones is intervening in a whistleblower complaint filed in California by a nurse who was employed as an AbbVie ambassador in Florida several years ago. The suit, filed in Alameda County Superior Court, seeks three times the amount of each claim made for Humira as a result of the alleged kickbacks. The lawsuit involves private insurance claims, said Nancy Kincaid, a spokeswoman for the California Department of Insurance.

Humira is one of the world’s biggest-selling medications. The drug brought in $18.4 billion in 2017, accounting for roughly two-thirds of North Chicago, Illinois-based AbbVie’s revenue. Private insurers have paid out $1.2 billion in Humira-related claims, according to Jones.

King & Spalding
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5. Strategies

“Staffers, try to contain him and keep your hands in his face. Aides, cut off the outlets. Advisors, watch out for that quick release. And, everyone, stay alert for fumbles.”
5. Strategies: DOJ Settlement Dynamics

- **Factual disputes** – “agreed to disagree”
- **Legal issues** – DOJ’s self-serving views of law
  - DOJ aversion to bad precedent
  - E.g., damages issues
- **Settlement Agreements**
  - Requirements for factual admissions
  - Obstacles to Denial-type language
  - Lack of sensitivity to collateral litigation
- **Publicity surrounding settlement**
  - Calculated to generate headlines
  - Revisions to Justice Manual prohibit negotiation
5. Strategies: Procedures Matter (at least good ones...)
5. Strategies: Compliance Strategy Key Points

Possible “Mitigating” Factors As A Shield

- Issue first addressed through internal compliance measures, including discipline
- Holistic consideration of amounts provided to HCPs (unified systems)
- Established pricing philosophy or statement (and transparency)
- Suspicious order monitoring / CSA precautions
- Compensation plans
- Call plans / qualifying questions
- Medical judgment (e.g., compendia)
- Charitable budgets and planning forecasts
- Patient-oriented/non-sales policies and procedures
5. Strategies: Compliance Strategy Key Points

Possible “Mitigating” Factors As A Lance

- Agency disclosure / engagement (e.g., CIA, Price Reporting, voluntary disclosure)
  Relevant to FCA materiality under Escobar
- Declaratory judgment action
- Embrace government statements / agency guidance (e.g., consistent communications FDA guidance)
- Legal and/or scientific review of complicated issues
- Truthfulness
- Acting through legitimate coalitions (e.g., trade groups, pricing)
- Proactive monitoring / auditing
5. Strategies

WHAT LEMMINGS BELIEVE
Tilting at Windmills?

Questions?

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November 13, 2018

King & Spalding Pharmaceutical University