THIRD ANNUAL PHARMA LAW CONFERENCE NEW YORK

TROUTMAN SANDERS LLP • 875 Third Avenue, New York, NY

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April 27, 2017

8:30 AM – 5:00 PM

Reception to follow

Co-Sponsored By

HURON

NYC MedTech
NYC Medical Technology Forum

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THE SCHOOL OF LAW
Compliance Affinity Group

NEW YORK STATE BAR ASSOCIATION
NYSBA INTERNATIONAL SECTION
Corporate Compliance Committee

C L G
Corporate Lawyering Group

WELCOME

Thank you for joining us for our Third Annual Pharma Law Conference. We look forward to discussing the current legal and policy issues facing pharmaceutical companies, from start-ups to Fortune 100 entities.

Our speakers will discuss the latest legal and business developments, as well as tactics for dealing with the high-stakes challenges affecting the pharmaceutical industry today.

Should you need a private space for a phone call or meeting, please ask our receptionists to direct you to a conference room that has been set aside for this purpose.

We are also happy to provide wireless Internet service:

Wireless Network: TSvisitor
Password: troutmanlaw

If there is anything else that you need while you are here today, please do not hesitate to ask.

Again, thank you for joining us! We look forward to a productive day.

Sincerely,

Aurora Cassirer and Joe Robinson
Program Chairs

AGENDA • April 27, 2017

TIME	TOPIC	PRESENTERS
8:30 – 9:30 am	**Breakfast**	
9:30 – 9:35 am	Welcome & Introduction by Program Chairs	Aurora Cassirer and Joe Robinson, Troutman Sanders
9:35 – 10:55 am	**Session 1 – Pharma Under Attack**	Moderator: Aurora Cassirer, Troutman Sanders
	New Developments in Securities Litigation	Alistaire Bambach, SEC Aurora Cassirer, Troutman Sanders
	Lessons Learned in Valuation Dispute Litigation Cases	John Levitske, Huron Peter Wollmeringer, Huron
	Hot Topics in Product Liability	Eric Rumanek, Troutman Sanders
	Trade Secrets	Joe Robinson, Troutman Sanders
10:55 – 11:00 am	Break	
11:00 am – 12:15 pm	**Session 2 – Economics, Business & Law in the Trump Era**	Moderator: Aurora Cassirer, Troutman Sanders
	Deregulating the FDA & Dismantling ObamaCare	Lindsay Austin, Troutman Sanders Strategies Rob Browne, Troutman Sanders
	Bringing the Cash Home: Corporate Income Tax Reduction & Repatriation of Cash at Discounted Rate – End of Inversions with Lower US Tax Rates	Robert Friedman, Troutman Sanders
	A Second Chance: Real Life Experiences with Distressed Pharma Companies	Steve Mermelstein, Huron Jim Lukenda, Huron Hugh McDonald, Troutman Sanders
12:15 – 1:15 pm	**Networking Lunch**	

1:15 – 3:00 pm	**Session 3 – Regulatory & Investigations Part I**	Moderator: Joe Robinson, Troutman Sanders
	Digital Health Privacy & Cybersecurity Risks	Steve Gravely, Troutman Sanders Ondrej Krehel, LIFARS LLC
	New Regulations & Risks: Hazardous Pharmaceutical Waste	Gregory Blount, Troutman Sanders Karlie Webb, Troutman Sanders
	Value-Based Contracting Trends & Its Implications	Marc Tomassi, Huron Kenneth Beers, Huron Chris Cobourn, Huron
3:00 – 3:10 pm	Break	
3:10 – 4:45 pm	**Session 4 – Regulatory & Investigations Part II**	Moderator: Joe Robinson, Troutman Sanders
	The Changing Perceptions of Patient Assistance Programs & the Responses to Audit Takeaways	Savaria Harris, Johnson & Johnson
	Patient Assistance Programs & Charitable Foundation Audit Sensitivities	Mark DeWyngaert, Huron
	The Criminalization of Drug Pricing Strategies	John West, Troutman Sanders Bill Hurd, Troutman Sanders
	A Summation: Current Regulatory & Litigation Responses to the Changing Legal Landscape	Aurora Cassirer, Troutman Sanders Joe Robinson, Troutman Sanders
4:45 PM	**Cocktail Reception**	

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Program Chairs

Aurora Cassirer, Troutman Sanders

Aurora is a Business Litigation partner at Troutman Sanders, whose leadership roles have included several terms on the firm's Executive Committee and service as New York office managing partner. An experienced trial lawyer, Aurora has had substantial experience in securities fraud class actions, breach of contract, qui tam, fraud, and privacy actions. She has counseled pharmaceutical companies, cyber security firms, private equity funds, start-ups, medical technology companies and various financial institutions on compliance, FCPA, privacy, and whistleblower issues. In the area of professional liability, she has defended professional liability claims against actuaries, attorneys, and consultants. Among her international clients, she has represented clients based in Israel, Korea, India, and China in disputes before U.S. courts or in arbitrations. She has frequently lectured and written on cyber security issues, securities litigation against pharma and medical device companies, whistle-blower claims, internal investigations and attorney-client privilege issues.

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Joe Robinson, Troutman Sanders

Joe Robinson has 30 years of experience in all aspects of intellectual property law. Joe focuses his practice in the pharmaceutical, life sciences, biotechnology, and medical device fields. His practice encompasses litigation, including Hatch-Waxman litigation; licensing; counseling; due diligence; and patent and trademark prosecution. He has served as intellectual property counsel in over $100 billion of pharma transactions and has served as litigation counsel in a variety of patent and trademark disputes in many different jurisdictions, and has also served as appellate counsel before the Court of Appeals for the Federal Circuit. Joe has counseled on or litigated Hatch-Waxman issues involving numerous different drug products. His litigation experience also includes other pharmaceutical, biologicals, industrial enzyme, biofuel production, molecular biology, recombinant technology, protein expression, immunology, drug formulation, drug delivery systems, microelectrodes, licensing, complicated mechanical device, charitable organization trademark and unfair competition, trade dress, product liability, and diversion of goods cases.

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Session 1 • Pharma Under Attack

Alistaire Bambach, U.S. Securities and Exchange Commission

Alistaire Bambach has been an Assistant Regional Director and Chief Bankruptcy Counsel to the Division of Enforcement since 2001. She was previously a Senior Trial Counsel in the Division of Enforcement. Ms. Bambach obtained a B.S. in Industrial and Labor Relations from Cornell University in 1983 and a J.D. in 1986 from the University of Houston Law Center. From 1986-1987, she was a law clerk for the Hon. Carl O. Bue, Jr., United States District Judge, Southern District of Texas. Since 1995, Ms. Bambach has worked at the United States Securities and Exchange Commission.

In her current position, Ms. Bambach is counsel to the SEC's Enforcement Division on all bankruptcy and insolvency matters, and has oversight over the SEC's receivership program. Ms. Bambach is also responsible for investigating and litigating complex financial fraud cases which result in corporate insolvencies. These cases include Enron, WorldCom, Adelphia, Lehman, Madoff, and MF Global, among others.

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John Levitske, Huron

John has more than 30 years of experience in business valuation and forensic accounting. He focuses on complex business valuation, economic damages, and forensic accounting matters, and the resolution of valuation and accounting disputes arising from M&A transactions, commercial and shareholder litigation, business divorce, and private company controversies. John serves as a consultant, expert witness or neutral arbitrator in domestic and international dispute matters.

Prior to joining Huron, John served in senior positions with international financial advisory and Big Four accounting firms where he provided expert consulting and testimony in the U.S. and Europe in depositions and court trials, plus in ICC, SCC, AAA, JAMS, FINRA and ad hoc arbitrations. He also served as the arbitrator/neutral accountant or appraiser in which he conducted the dispute resolution process and rendered binding decisions.

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Session 1 • Pharma Under Attack

Peter Wollmeringer, Huron

Mr. Wollmeringer has 25 years of diverse professional experience in advising and consulting with clients on the valuation of things (VoT). From business valuations to business combinations to strategic value and disputes, Peter has served a broad range of clients in many industries. As part of the Valuation & Dispute team and head of the New York Valuation practice, Peter teams with Huron colleagues to deliver collaborative solutions to clients to address their pressing financial and economic issues

Prior to joining Huron, Peter enjoyed 25 years working with Big 4 accounting firms and independent firms. He joined Huron after working for Alvarez & Marsal, where he served clients and was the Risk & Quality leader. Peter had the unique experience as the valuation resource at KPMG's Department of Professional Practice. In that role he provided technical valuation consulting to other members of the firm and its clients, partner and manager training, and contribution to publications. Peter has also contributed to the profession through voluntary efforts such as teaching courses at the University of Massachusetts and the Practising Law Institute, co-writing an advisory publication for the Appraisal Foundation, presentations at ASA conferences and VALCON, and judging an AIRA sponsored MBA corporate restructuring competition.

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Eric Rumanek, Troutman Sanders

Eric Rumanek is a partner in the firm's product liability and business litigation practices. Eric specializes in representing pharmaceutical and medical device companies in complex mass tort, personal injury, and wrongful death actions concerning specialized and technical areas of science and medicine. Over the last several years, Eric has served as national counsel for Sanofi-Aventis in defending litigation claims involving a cosmetic injectible medical device. Additionally, Eric is heavily involved on the national defense team representing Johnson & Johnson in pelvic mesh litigation. In that role, he is responsible for taking fact and expert depositions, drafting and responding to dispositive motions and Daubert motions, and defending sales representative depositions. Eric serves on a select team of attorneys chosen by the client to work directly with expert witnesses. As part of the expert team, Eric is responsible for expert reports in more than 50 cases, preparing expert witnesses for depositions, and defending expert depositions.

In addition to his pharmaceutical product liability work, Eric has advised clients on issues related to product labeling/warnings and litigation response protocols. He has represented the manufacturer of electronic cigarettes in product liability litigation and successfully defended Georgia's largest electric utility company in numerous tort and personal injury claims.

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Session 2 • Economics, Business & Law in the Trump Era

Lindsay Austin, Troutman Sanders Strategies

Lindsay Austin is Director of Federal Affairs in the Washington, D.C. office of Troutman Sanders Strategies.

Lindsay brings to the firm over a decade of congressional and legislative experience as well as experience as a Washington government relations representative to corporations, organizations, and universities. Lindsay has managed multiple clients, with an emphasis on healthcare, health information technology, food safety, agriculture, education, and appropriations advocacy. Lindsay has years of experience in Government Affairs where she combines her political and policy know-how with her Washington and Georgia network to build strategy for clients at the federal level.

Currently, Lindsay represents clients in Washington by providing a wide range of tailored services including but not limited to: Advocacy and Federal Representation; Coalition Building; Reputation Management; Federal Funding and Appropriations; Federal Opportunities; Political Intelligence; Fundraising and PAC (Political Action Committee); and Communications, Event Planning and Media Strategy.

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Rob Browne, Troutman Sanders

Rob Browne's practice focuses on life sciences and complex litigation. His life sciences practice involves all facets of the industry, including biotechnology, food, medical device, and pharmaceuticals as well as the representation of clients involved in the tobacco industry. Rob's experience includes federal regulatory advice, assistance with compliance and related litigation, including product liability.

He has counseled clients on a wide variety of matters involving the FDA, FTC, and USDA, including regulatory submissions, product promotion and labeling, compliance with good manufacturing practices, agency inspections and investigations, licensing agreements, and due diligence.

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Session 2 • Economics, Business & Law in the Trump Era

Robert Friedman, Troutman Sanders

Robert Friedman is a partner in the New York office of Troutman Sanders LLP and is a member of the firm's Tax practice. He advises clients on all aspects of corporate and partnership tax matters, with a particular emphasis on the tax aspects of private and public mergers, acquisitions, joint ventures, divestitures, private equity fund formation, financial products and electric and gas utility tax issues.

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Steve Mermelstein, Huron

Steve has more than 25 years' experience providing strategic and corporate finance advisory to managements and boards of directors across a variety of industries and product areas. Since 2003, he has worked exclusively with clients in the life science tools and diagnostics, therapeutics and medical device sectors, where he has successfully executed a broad range of corporate transactions, including M&A, growth equity investments, recapitalizations, out-licensing and joint ventures. Steve joined Huron in 2016 to head up Huron Transaction Advisory LLC's life sciences investment banking practice, with a primary focus on M&A and equity financings.

Prior to joining Huron, Steve was at Covington Associates LLC, where he worked with life sciences companies and institutional investors, primarily on sell-side M&A and equity financings. Prior to that he held senior positions at Ferghana Partners, Asanté Partners, Wasserstein Perella & Co., and JPMorgan Chase.

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Session 2 • Economics, Business & Law in the Trump Era

Jim Lukenda, Huron

Jim provides assistance to clients with troubled debt restructurings, mergers, acquisitions and dispositions, litigation and claims analysis, fraud investigations, and other financial consulting and bankruptcy assignments.

His experience spans numerous industries including heavy manufacturing, retailing, electronics, consumer products and distribution, construction and contracting, communications and publishing, real estate, and hospitality.

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Hugh McDonald, Troutman Sanders

Hugh McDonald focuses his practice on all aspects of restructuring including workouts, bankruptcy and related issues, bankruptcy-related and general commercial litigation and has represented secured and unsecured creditors, banks, bondholders, debtors and creditor committees.

He is also experienced with asset sales in bankruptcy cases, debtor-in-possession financing, derivatives, repos, the liquidation of estates and cross-border cases.

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Session 3 • Regulatory & Investigations Part I

Steve Gravely, Troutman Sanders

Steve Gravely leads the Healthcare Practice for the firm. With over 40 years of experience in healthcare, both as a hospital administrator and lawyer, Steve advises clients on a wide range of strategic and legal issues. This includes digital health, data privacy, cyber-security, emerging companies and medical devices. He has advised the federal government on legal issues related to disaster preparedness and emergency response arising from terrorism and natural disasters that affect the US Critical Infrastructure. Steve is certified by the International Association of Privacy Professionals (IAPP) as a Certified Information Privacy Professional in the United States (CIPP/US).

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Ondrej Krehel, LIFARS

Ondrej Krehel is the CEO and Founder of LIFARS LLC, an international cybersecurity and digital forensics firm. He's the former Chief Information Security Officer of Identity Theft 911, the nation's premier identity theft recovery and data breach management service. He previously conducted forensics investigations and managed the cyber security department at Stroz Friedberg and the Loews Corporation. With two decades of experience in computer security and digital forensics, he has launched investigations into a broad range of IT security matters—from hacker attacks to data breaches to intellectual property theft. His work has received attention from CNN, Reuters, The Wall Street Journal and The New York Times, among many others.

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Session 3 • Regulatory & Investigations Part I

Gregory Blount, Troutman Sanders

Greg Blount is a partner in the Environmental and Natural Resources practice at Troutman Sanders LLP. His work with pharmaceutical waste issues includes work in many bellwether states, particularly California, regarding their approach to regulating and legislating the management of hazardous pharmaceutical waste. Greg continues to work on behalf of clients before U.S. EPA regarding its new rules and policies to protect both the nation's drug supply chain and the environment. His experience includes work serving as national environmental counsel for a Fortune Top 10 company during extensive negotiations in California, Connecticut, Florida, Illinois, Kansas, and New Jersey regarding the proper disposal of pharmaceutical waste.

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Karlie Clemons Webb, Troutman Sanders

Karlie Webb is an associate in the Environmental and Natural Resources practice at Troutman Sanders LLP. Karlie has a national practice, focusing on representing corporations, industry groups, and individuals in all aspects of environmental law, including regulatory compliance, rulemaking, permitting, particularly under RCRA, CERCLA, and EPCRA, defending federal and state environmental enforcement actions, and environmental litigation.

Karlie commonly represents chain grocers and pharmacies on retail and pharmaceutical hazardous waste issues, including advising on compliance with applicable federal and state regulatory schemes, permitting, and extensive negotiations with state environmental regulators to settle compliance claims.

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Session 3 • Regulatory & Investigations Part I

Marc Tomassi, Huron

Marc brings 25 years' experience in the healthcare and life sciences sectors to Huron. Prior to joining Huron in 2014, Marc spent 18 years with Frankel Group, initially as a Consultant. His work spans the industry value chain, encompassing early research & technology strategy, portfolio management, clinical development planning and commercial strategy. Industry clients include major global pharma, biotech, specialty pharma, med tech, generics, life science services and healthcare informatics. Investment community clients include private equity and banking firms engaged in equity & debt financing at venture and commercial stages.

Over the years, Marc has leveraged his payer background focused on market analytics and strategic planning acquired through previous work in the managed care sector. He also has worked extensively in life science transactions, assisting clients in LM&A planning, forecasting/valuation, and execution.

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Kenneth Beers, Huron

Ken serves life sciences clients across a variety of strategic issues, with emphasis on new therapy commercialization, brand and portfolio strategy, and market access. After years of management consulting to life sciences companies and a prior career in scientific research, Ken bridges the commercial, clinical, and regulatory complexities facing the industry. His clients span large pharmaceutical and early-stage biotechnology companies, and include not only manufacturers but also distributors, specialty pharmacies, and service providers.

Ken is active in multiple therapeutic areas including oncology, neurology, immunology, infectious disease, cardiology, hematology, respiratory, nephrology, psychiatry, pain management, and genetic rare diseases. Ken has experience in commercializing a wide variety of generic and branded small molecules, biologics, cellular, and gene therapies. Ken's global experience includes the US, EMEA, Asia Pacific, and Latin America.

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Session 3 • Regulatory & Investigations Part I

Chris Cobourn, Huron

Chris is an industry thought leader offering compliance consulting services and outsource operations services to pharmaceutical, biotech, and medical device companies. Focused on areas of regulatory compliance within commercial programs and pricing, sales and marketing, government programs (Medicaid, Medicare, PHS), and federal contracting, Chris has over 16 years in the industry. He has extensive experience in government programs and pricing which includes working with manufacturers of all types and sizes in areas such as policy and methodology, assessment and audit, recalculations and restatements, class of trade (COT) analysis, PHS membership, bona fide service fees, and recalculations as well as strategic business process outsourcing for statutory pricing calculations, chargebacks, and rebates processing.

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Session 4 • Regulatory & Investigations Part II

Savaria Harris, Johnson & Johnson

Senior Lawyer, Regulatory Law at Johnson & Johnson (New Brunswick, NJ)

Savaria Harris is a senior lawyer in Johnson & Johnson's Regulatory Health Care Compliance Group. In this role, she advises client groups in the pharmaceutical, medical device and consumer sectors on U.S. Health Care Fraud and Abuse Laws, including the Federal Anti-Kickback Statute, False Claims Act, and related health care legal obligations as well as the Foreign Corrupt Practices Act and equivalent anti-bribery laws and regulations outside the United States. Her additional responsibilities include advising the Global J&J Health Care Compliance organization on policy development, risk assessment, training, and monitoring.

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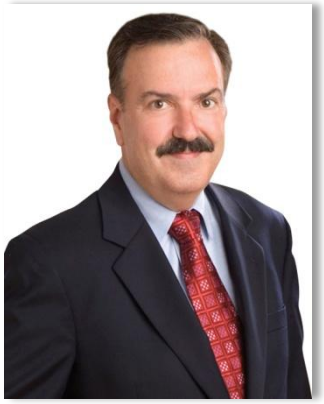

Mark DeWyngaert, Huron

Mark DeWyngaert, Managing Director, has provided operational, clinical, managerial, consulting, and litigation services to various segments of the health care industry. Mark trained as a molecular biologist and has been actively involved in both research and business development roles at the executive level for over 25 years. He specializes in assisting medical device, pharmaceutical and biotechnology manufacturers with identifying and mitigating regulatory risks and valuation of services and intellectual property.

Mark regularly leads teams in the assessment of promotional practices and medical /clinical development activities and assists companies in the redesign of business practices to comply with applicable regulations and standards. He also serves clients and their legal counsel in fraud investigations, compliance inquiries, litigation strategy issues, and acting as an expert witness.

He holds an MBA from New York University; plus a Ph.D. in Molecular Biology, an M.A. in Biology and a B.A. in Neurochemistry from University of Rochester.

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Session 4 • Regulatory & Investigations Part II

John West, Troutman Sanders

John West's practice focuses on representing individuals and corporations across the country in all phases of regulatory, civil and criminal litigation. He has extensive experience in the defense of DOJ investigations, SEC enforcement actions, federal and state grand jury proceedings, and internal investigations for companies and individuals across many industries. He has handled matters involving government contracting fraud, embezzlement, environmental crimes, healthcare fraud, securities fraud, tax and bank fraud, insider trading, money laundering, the Foreign Corrupt Practices Act, and the False Claims Act.

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Bill Hurd, Troutman Sanders

Bill Hurd is a partner in the Richmond office of Troutman Sanders and focused on his firm's Appellate practice. He previously served as the first Solicitor General of Virginia (1999 – 2004). In the United States Supreme Court, Bill has appeared on brief (both party and amicus) in more than 30 cases, serving as principal author in more than 25 cases and personally arguing three cases before the Court. Altogether he has appeared on brief in more than 130 appellate cases and has argued more than 50 times before federal and state appellate courts.

Bill served as lead counsel in the statewide election recounts for Attorney General of Virginia in 2005 and 2013, and served as legal counsel to the 2011 Independent Bi-partisan Advisory Commission on Redistricting.

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Session 1 • Pharma Under Attack

Moderator: Aurora Cassirer, Troutman Sanders

New Developments in Securities Litigation
Alistaire Bambach, SEC
Aurora Cassirer, Troutman Sanders

Lessons Learned in Valuation Dispute Litigation Cases
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Hot Topics in Product Liability
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Trade Secrets
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LESSONS LEARNED IN VALUATION DISPUTE LITIGATION FROM THE FINANCIAL EXPERTS' PERSPECTIVE:
CURRENT VALUATION LITIGATION NEWS AND IMPLICATIONS FOR PHARMA & LIFE SCIENCES COMPANIES ENGAGED IN MERGER & ACQUISITION AND CAPITAL TRANSACTIONS
HURON
TROUTMAN SANDERS
PHARMA LAW CONFERENCE:
APRIL 27, 2017
NEW YORK CITY
John Levitske and Peter Wollmeringer, Huron
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LESSONS LEARNED
Increase in appraisal rights litigation over merger prices
Implications for Pharma & Life Sciences industry
Public companies
Private companies
Common considerations
Standard of value matters
Informed judgment matters
In the detailed analysis, relevance and reliability matters
Some of the detailed areas of potential judicial review include:
Forecasts
Selection of methodology
Company specific risk and size risk premia
Embedded discounts
Different jurisdictions may handle valuation matters differently
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1.1 VALUATION DISPUTE LITIGATION CURRENT NEWS

Delaware Chancery Court, Appraisal Actions

Dealmakers Eye Safeguards Amid Rising Valuation Challenges (*BNA Corporate Law & Accountability Report*, April 18, 2017)

> *"An increase in Delaware litigation over merger prices ….. 22 appraisal lawsuits filed so far this year [2017], challenging 11 deals, according to Bloomberg Law data. There were 77 appraisal lawsuits filed in 2016 challenging 48 deals, compared to 51 lawsuits in 2015 challenging 33 deals."*

Appraisal Actions May Be The Next Frontier For PE Shops (*Law360*, Portfolio Media, Inc., April 21, 2017)

> *"Delaware's Supreme Court will soon decide if lower courts properly determined that both Dell Inc.'s $24.9 billion management-led buyout and DFC Global Corp.'s $1.3 billion buyout were priced too low, potentially leading more companies to try appraisal litigation as an investment strategy.*
>
> *In the Dell case, the state's Chancery Court had added roughly $7 billion to founder Michael Dell and private equity firm Silver Lake Partners' purchase price, while the DFC case saw the court add about $100 million to Lone Star Fund VIII's purchase price."*

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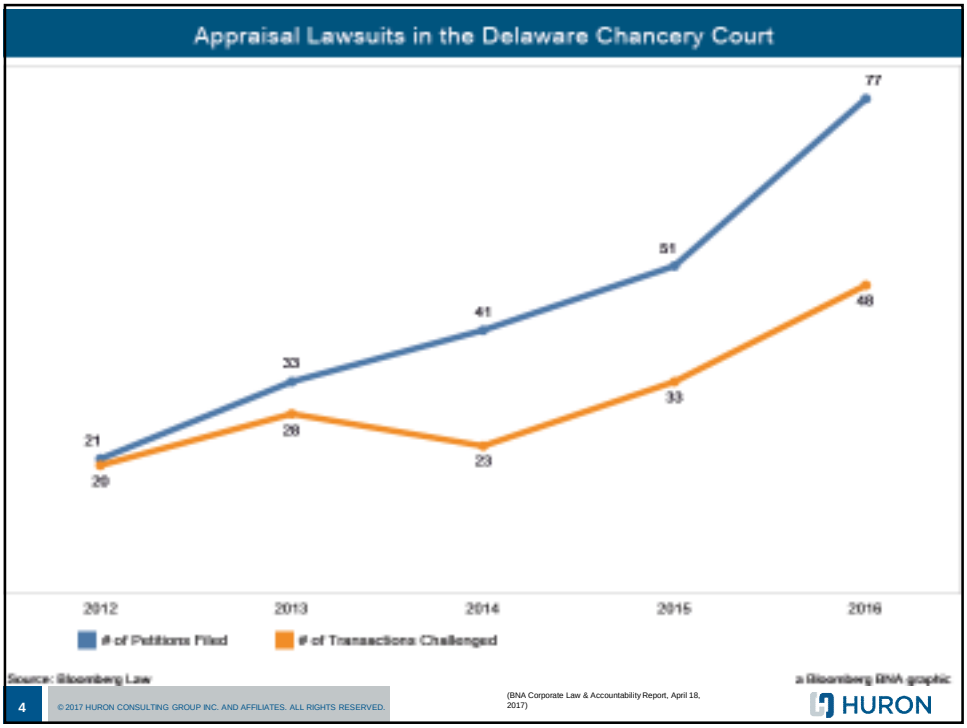

(BNA Corporate Law & Accountability Report, April 18, 2017)

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1.2 VALUATION DISPUTE LITIGATION
CURRENT NEWS CONTINUED

Delaware Chancery Court, Appraisal Actions, continued

In re Appraisal of Dell Inc. (2016 Del. Ch. LEXIS 81, May 31, 2016)

- Not a breach of fiduciary action.
- Query is *"Did the stockholders get fair value for their shares in the merger?"*
- *"Sales process functioned imperfectly as a price discovery tool."*
- Impossible to quantify the *"sales process mispricing."*
- Fair value is different than the merger price.
- Selected DCF analysis as measure of fair value.
- No weight given by Court to merger price.

In re DFC Global Corp. (2016 Del. Ch. LEXIS 103, July 8, 2016)

- Cited Dell decision *"the existence of drastic differences between experts' valuations is not an uncommon issue."*
- The *"tumultuous environment"* which the company experienced and issues about *"even its viability."*
  - *"Calls into question"* reliability of the company's forecasts.
- Raised doubts regarding the sales process.
- All of the valuation methods deemed *"imperfect techniques."*
- Weighted all three methodologies - DCF, Market Approach and deal price - equally.

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2.1 VALUATION DISPUTE LITIGATION
PHARMA & LIFE SCIENCES

Delaware Chancery Court, Appraisal Actions

In re Appraisal of Transkaryotic Therapies, Inc. (No. Civ.A. 1554-CC, 2007 WL 1378345 (Del. Ch. 2007))

- Transkaryotic Therapies ("TKT"), a biopharmaceutical public company focused on researching, developing, and commercializing treatments for rare diseases resulting from protein deficiencies, decided to sell itself to Shire Pharmaceuticals Group, a public company.
- *"The question presented in this case can be stated thusly: Must a beneficial shareholder who purchased shares after the record date but before the merger vote, prove, by documentation, that each newly acquired share (i.e., after the record date) is a share not voted in favor of the merger by the previous beneficial shareholder? The answer seems simple. No."*

In re Orchid Cellmark Inc. Shareholder Litigation C.A. (No. 6373-VCN 2011)

- Orchid Cellmark, a genetic testing public company, was acquired by Laboratory Corp. of America, a public company.
- The Court found that the Board acted reasonably in each claim and noted:
  - *"the question to be answered by the Court is whether the directors made a reasonable decision, not a perfect decision."*

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2.2 VALUATION DISPUTE LITIGATION PHARMA & LIFE SCIENCES CONTINUED

Delaware Chancery Court, Appraisal Actions, continued

CDX Holdings, Inc. (f/k/a Caris Life Sciences, Inc.) (C.A. No. 5233-VCP, (Del. Ch. 2012), App'l to Del. Supr. Ct. June 6, 2016))

+ Caris Life Sciences, a biotechnology private company, provides precision medicine information and molecular profiling platforms to help patients with cancer and other complex diseases.
+ Claim: failed to fairly value certain stock options in a Plan that were cancelled as part of a spinoff/merger transaction; the Plan required the Board, as the Plan's administrator, to determine the Fair Market Value.
+ Supreme Court upheld trial court's:
  - $16.3 million judgment in favor of the option holders.
  - Assessment that discredited valuation testimony as the product of *"hindsight bias."*

Zimmerman v. Crothall, et al. (C.A. No. 6001-VCP (Del. Ch., March 27, 2012))

+ In re Adhezion Biomedical LLC, an early-stage medical products private company engaged in the development and manufacture of adhesive and infection-prevention products for use in the closure and care of wounds in surgical and other medical applications.
+ Challenged transactions: Board caused the Company to issue preferred units, promissory notes, and warrants to certain company directors and investors to raise needed cash.
+ *"Because no expert valuation of the Company has been presented by either side, I cannot find conclusively that $7.05 was a fair price per share."*

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2.3 VALUATION DISPUTE LITIGATION PHARMA & LIFE SCIENCES CONTINUED

Utah Supreme Court, Appraisal Action

Hogle, et al, v. Zinetics Medical (Utah No. 20000470, 2002)

+ Zinetics, a private company, developed, brought to market and manufactured a specialized catheter designed for use in diagnostic equipment manufactured by others.
+ Minority shareholders of Zinetics dissenting from the *"forced purchase"* of their shares by the parent corporation, Medtronic, Inc., a public company.
+ Key issues in case:
  - Valuation methodology.
    - Court rejected guideline company methods used by both sides.
    - Court focused on investment value, or DCF and capitalization of earnings methods.
    - Forecasts were materially different.
      - Trial court used defendant's, while Supreme Court believed that the plaintiff's forecast was more realistic.
      - Supreme Court said that the Utah statute did not preclude hindsight to verify the value on the date of the merger (cited Oakridge Energy case).
  - Lack of marketability discount accepted by district court was ruled out by the Supreme Court.

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3.1 VALUATION DISPUTE LITIGATION HEALTHCARE

Delaware Chancery Court, Appraisal Actions

Gearreald Et al. v. Just Care, Inc. (C.A. No. 5233-VCP, (Del. Ch. 2012))

+ Healthcare detention private company, Just Care, acquired in cash acquisition by GEO Care, Inc., an affiliate of a public company.
+ Fair Value. Court evaluated:
  - DCF Methodology.
    - Cash flow projection selection.
    - Terminal value components.
    - WACC components.
      - Capital structure, consisting of debt and common equity.
      - After-tax cost of debt.
      - Risk-free rate.
      - Levered beta.
      - Supply side equity risk premium.
      - Size premium.

+ Reviewed the source of the size risk premium added into the cost of equity for the higher rate of return required by investors because of the greater risk associated with relatively smaller companies.
+ A liquidity discount, "*such a discount generally relates to the marketability of the company's shares and is therefore prohibited….. although a liquidity discount for marketability of a company's shares is prohibited, that does not mean that the use of any input that is correlated with a company's illiquidity is per se invalid.*"
+ However, petitioner's expert's *"methodologies for removing the liquidity effect from the size premium are novel and have not been peer reviewed."*

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APPENDIX

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A.1.1 REFRESHER: WHAT IS A VALUATION?

Valuation is a process for estimating an amount of value for a business, security, or an asset at a specific date and for a specific purpose

In general, there are three primary approaches used for estimating the value of a business or asset

- **Market approach** – Methods that use comparison to other similar businesses or assets as a basis to establish a value
- **Asset-based approach** – Methods that use adjustments to the balance sheet of a business to establish a value
- **Income approach** – Methods that use future cash flows of a business or asset as a basis to establish a value

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A.1.2 COMMON VALUATION PURPOSES

- ***Bankruptcy***
- ***Breach of fiduciary duty claims***
- Contract (e.g., buy-sell, executive employment, non-compete)
- Damages (e.g., lost profits, value diminution, benefit of the bargain)
- ***Dissenting shareholder and oppression claims***
- ESOP
- Estate & gift tax
- Federal and state tax
- Fraud claims
- Intellectual property
- ***Judicial dissolution (e.g., business divorce, buyout or withdrawal)***
- Marital dissolution
- Securities

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A.2.1 VALUATION DISPUTE LITIGATION HEALTHCARE

Delaware Chancery Court, Appraisal Actions

Delaware Open MRI Radiology Assoc., P.A. (Consolidated C.A. No. 275-N, April 26, 2006)

- Merger of private group of radiologists and private company which owned MRI scanning centers.
- In the Court's view, *"the key question is whether the minority stockholders ….. received fair value in a squeeze-out merger with an acquisition vehicle of the majority stockholders….. was the merger price fair and, if not, what was the extent of the underpayment to the minority stockholders?"*

- The Court evaluated:
  - *"(1) the reading and management fee dispute and (2) the expansion plans. The other major issue involves the proper way to address the reality that Delaware Radiology was an "S" corporation before the merger and that there was no likelihood that it would ever be other than an S corporation, irrespective of the merger. "*
  - What forecast to use in DCF, and selected non-litigation purpose forecasts prepared for financing.
  - Growth rate after discrete period forecast.
  - Terminal value components.
  - WACC.

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A.2.2 VALUATION DISPUTE LITIGATION HEALTHCARE

U.S. Bankruptcy Court

Med Diversified, Inc. (Bankr. E.D.N.Y. 2005, 2006)

+ Home healthcare public company (home healthcare and alternate site healthcare, skilled nursing, and pharmacy management and distribution services).
+ Fraudulent transfer solvency issue, Fair Market Value.
+ Court evaluated:
  - Qualifications as an expert witness on valuation.
  - Reliability.
    - Weight accorded to various valuation methodologies.
      - DCF v. market approaches.
    - Methodologies applied in other jurisdictions may not be deemed probative.
+ Benchmarking analysis.
+ Cash flow projections.
  - Revenue projections.
  - Costs of sales and expense projections.
+ Discount rate.
+ Terminal period.
+ Control premium.
+ Discount for lack of marketability.
+ Market approaches.
  - Guideline company approach.
  - Comparable transactions approach.

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A.2.3 VALUATION DISPUTE LITIGATION NUTRITIONAL PRODUCTS

U.S. Bankruptcy Court, continued

Nellson Nutraceutical, Debtor (Bankr., Del. 2006)

+ Chapter 11 Bankruptcy, Debtor's enterprise value, Fair Market Value.
+ Nutrition bars, nutritional powders, and healthy snacks manufacturing company, a private company.
+ Court evaluated:
  - Reliability.
    - Whether a theory or technique can be, and has been, tested.
    - Whether the theory or technique has been subjected to peer review and publication.
    - A technique's known or potential rate of error and the existence and maintenance of standards controlling the techniques operation.
    - Whether a particular technique or theory has gained general acceptance in the relevant scientific community.
    - The degree to which the expert testifying Is qualified.
    - The relationship of a technique to more established modes of scientific analysis.
    - The non-judicial uses to which the scientific techniques are put.
  - Relevance.
    - Reliance on management's business plan.
  - Weight accorded to various valuation methodologies.
    - DCF v. market approaches.
  - DCF methodology
    - Terminal value components

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PHARMA LAW CONFERENCE 2017

Litigation Tourism

Evaluating General and Specific Jurisdiction in an Age of Big Verdicts

Eric Rumanek, Partner – Troutman Sanders

TROUTMAN SANDERS

PHARMA LAW CONFERENCE 2017

Recent Large Verdicts Against Pharmaceutical Companies

- "Pfizer Jury Said to Award $75 Million Prempro Verdict to Woman" (2009)
  - Illinois Plaintiff – Philadelphia Court
- "J&J Wants to Move Talc Cases after $195 Million in 8 Months" (2016, St. Louis)
  - February 2016 -$72 million
  - May 2016 - $55 million
  - October 2016 - $70 million

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The Rise of Litigation Tourism

- Plaintiffs flock to jurisdictions known as "plaintiff friendly" with a history of large plaintiff verdicts
- Plaintiffs and the claims they are asserting have virtually no direct contacts with the forum state
- Defendants' contacts with the forum are primarily that they are global companies that do business throughout the country

Law School Professor Reminder

- Civil Procedure Wins Cases!
- Jurisdictional Issues Have Returned to the Forefront
  - *Tyrrell v. BNSF*
  - *Bristol-Myers Squibb Co. v. Superior Court of California*
- Oral Argument – 2 days ago

Brief Review of Personal Jurisdiction

- Specific Jurisdiction – Nexus between plaintiff's claims and defendant's contact with the state
- General Jurisdiction – Jurisdiction over all claims because of defendant's "continuous and systematic" contacts with the forum
  - Always general jurisdiction – Corporation's state of incorporation and principal place of business

Goodyear and *Daimler:* Defining Continuous and Systematic Contacts

- *Goodyear* (2011): Courts only have general jurisdiction where a defendant's contacts render it "essentially at home" in the forum state
- *Daimler* (2014): "At home" for corporations is generally only place of incorporation or principal place of business
  - General Jurisdiction elsewhere will only arise in an "exceptional case"

Impact of *Goodyear* (2011) and *Daimler* (2014)

- Pharmaceutical companies have vigorously fought jurisdictional arguments in cases of Litigation Tourism…

. . . with mixed success

Recent Wins Rejecting Litigation Tourism

- *In re Plavix* – Illinois Circuit Court - 2014
- *Evans v. Johnson & Johnson* – S.D. Tex. 2014
- *Genuine Parts Co. v. Cepec* – Delaware Supreme Court – 2016
- Non-pharma case

The End of Litigation Tourism in Missouri?

- *State ex rel. Norfolk Southern Railway Co. v. Dolan* – Supreme Court of Missouri – 2017
- Holding: Norfolk not "at home" in Missouri
- Notable, considering pending SCOTUS decisions

Tyrrell v. BNSF (Montana 2016)

- Exercised General Jurisdiction over railroad company – FELA Claim:
  - BNSF was neither incorporated nor had its PPB in Montana
  - Plaintiff – North Dakota Resident who had *never worked or been injured in Montana*
- Opinion largely asserted *Daimler* did not change the law
  - Examined BNSF's "significant, substantial, and continues and systematic" activities in Montana

Bristol-Myers Squibb Co. v. Superior Court of California (California 2016)

- No general jurisdiction over 600 out-of-state plaintiffs
  - BMS not "at home" in California
- However, the court held it had specific jurisdiction over BMS…
  - BMS engaged in marketing and distribution, research and development, and employment of hundreds of California employees, arising from the same course of conduct as was being sued for by other California Plaintiffs

BMS Impact on Specific Jurisdiction

- Could be interpreted to imply that if a corporation is subject to suit by plaintiffs arising from conduct that occurred throughout the country (i.e. nationwide marketing of a drug/device), they should be subject to suit by out-of-state plaintiffs alleging violations of the same conduct that occurred in the state.
  - Focus of analysis is on the Defendant and Defendant's Conduct – not the residence of the Plaintiff and the state where Plaintiff's injuries occurred

Implications in Wake of Pending SCOTUS Rulings

- Pay close attention to SCOTUS rulings
  - They will likely have a significant impact on jurisdiction arguments going forward
- Pharmaceutical Companies: Work closely with in-house and outside counsel to develop appropriate challenges to jurisdiction in cases of Litigation Tourism

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PHARMA LAW CONFERENCE 2017

Multi-Plaintiff Consolidated Trials

Fighting Against Uncertainty in an Age of Big Verdicts

Eric Rumanek, Partner – Troutman Sanders

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Recent Large Consolidated Trial Plaintiff Verdicts

- "Johnson & Johnson hit with over $1 billion verdict on hip implants" (December 2016)
  - **Six Plaintiff Consolidated Trial**
- "Johnson & Johnson to pay $502 million for hip devices" (March 2016)
  - **Five Plaintiff Consolidated Trial**
- "Boston Scientific ordered to pay $26.7M in mesh case" (November 2014)
  - **Four Plaintiff Consolidated Trial**

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What Are Consolidated Trials?

- Procedural mechanism used by courts to adjudicate similar claims which "involve a common question of law or fact"
- Requirements to challenge:
  - Specific risks of prejudice and possible confusion outweigh
    - Risk of inconsistent adjudications
    - Burden on parties
    - Witness availability
    - Length of time required to adjudicate one vs. multiple trials
    - Relative expense of one vs. multiple trials

Standard for Granting Consolidated Trials

- Highly discretionary
  - Rooted in Federal Rule of Civil Procedure 42
- Not clear why any particular judge will decide that risks of prejudice outweigh judicial economy factors

Why Consolidated Trials Are Prejudicial to Defendants

- Juror Confusion
  - Large amounts of evidence
  - Difficult to differentiate between plaintiffs
- Impermissible Inference of Liability
- Evidentiary Issues
  - Related to juror confusion

Unique Issues in Drug/Device Cases: Inherently Individualized Inquiries

- Risk/Benefit Analysis
  - Drug/Device use requires physician prescription – given after balancing of risks and benefits for each plaintiff
- Learned Intermediary Doctrine
  - Physician is in the best position to understand risks/benefits of a drug/device
  - Each plaintiff had a separate physician
  - Each physician has separate knowledge of risks and different recommendations about product use

Unique Issues in Drug/Device Cases

- Causation
  - Each plaintiff has different symptoms, different complaints, different medical histories, and different risk factors for experiencing side effects
  - Each plaintiff had different informed consent processes with their respective physicians

Example of "Tailored" Consolidation: *Mullins v. Ethicon*

- Background of Pelvic Mesh MDLs:
  - As of the end of 2016, ~62,000 cases are consolidated in MDL for pre-trial proceedings against Ethicon, American Medical Systems, C.R. Bard, and Boston Scientific
- Judge Goodwin (S.D. W. Va.) consolidated 37 cases for trial:
  - Acknowledged trial would only be for "narrow and discrete" issues universal to plaintiffs concerning design defect
  - Planned for a second phase of trial for plaintiff-specific evidence if plaintiffs prevailed during first phase of trial

Impact of Consolidation

- Make forceful arguments for prejudice, especially in the context of drug/device litigation, knowing that the standard is highly discretionary
- Pharmaceutical Companies: Work closely with in-house and outside counsel to develop appropriate challenges to consolidation (including using recent verdicts as examples of prejudice faced by defendants in drug/device litigation)

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Litigation Tourism: Evaluating General and Specific Jurisdiction for Pharmaceutical Companies in an Age of Big Verdicts

S. Eric Rumanek and Shawn N. Skolky[1]

The concept of forum-shopping is far from novel – the practice whereby tort plaintiffs flock to jurisdictions with favorable laws/rulings in hopes of ensuring a positive result. However, forum-shopping has given rise to a more objectionable and perhaps unanticipated tactic of what has been referred to as "litigation tourism." In litigation tourism for personal injury product liability cases, the plaintiff's choices of venue has no connection to his/her alleged injuries or the causes of action asserted. Often, the plaintiff will never have even visited the state. In 2016, Bloomberg published an article on litigation tourism in St. Louis, noting that hundreds of plaintiffs with product liability claims against Johnson & Johnson, Bayer, and Pfizer had been filed, most with no connection to the state.[2] As of late 2016, approximately $195 million in verdicts had been handed down against J&J alone in Missouri courts regarding talc-based products, including a $72 million verdict in February, a $55 million verdict in May, and a $70 million verdict in October.[3] Missouri is not the only forum susceptible to litigation tourism. In 2010/2011, for example, Philadelphia was named the Number 1 "Judicial Hellhole" by The American Tort Reform Foundation for allowing litigation tourism to proliferate, resulting in

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[2] https://www.bloomberg.com/news/articles/2016-09-29/plaintiffs-lawyers-st-louis

[3] http://www.stltoday.com/business/local/after-million-in-talc-verdicts-in-st-louis-j-j/article_a6fd371c-d5da-5635-b2ce-d489fac629b9.html

multiple large verdicts, including an award of $75 million in punitive damages against Pfizer for its menopause treatment, Prempro.[4]

Given the magnitude of these large verdicts arising from litigation in jurisdictions that have reputations as being "plaintiff-friendly," it is important for all pharmaceutical companies and their defense counsel to understand the jurisdictional issues that will likely be on the front lines of litigation in many product liability cases in the near future. In particular, two cases currently before the Supreme Court raise the question of whether a court may properly exercise jurisdiction over litigation involving wholly out-of-state plaintiffs. How the Court deals with this issue is likely to have a long-term effect on the analysis of general and specific jurisdiction, and will have a lasting impact on the strategic litigation decisions made by pharmaceutical company defendants.

A Brief Review of Personal Jurisdiction

There are two types of personal jurisdiction – specific and general. "Specific jurisdiction . . . depends on an 'affiliation between the forum and the underlying controversy,' principally, activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation."[5] In determining whether specific jurisdiction, courts examine three factors: (1) whether the defendant has "'purposefully directed' its activities at the forum state; (2) whether the plaintiff's claims arise out of or are related to these forum-directed activities; and (3) whether the exercise of jurisdiction is reasonable and does not offend 'traditional notions of fair play and substantial justice.'"[6]

[4] Tort Reform Found., *Judicial Hellholes 2010/2011* JUD. HELLHOLES, 3-4 (Dec. 1, 2010), http://www.judicialhellholes.org/wp-content/uploads/2010/12/JH2010.pdf; https://www.law360.com/articles/132433/pfizer-prempro-verdict-rumored-to-be-75m

[5] *Goodyear Dunlop Tires Operations v. Brown*, 564 U.S. 915, 919 (2011)(internal citation omitted).

[6] *Asahi Metal Industry Co. v. Superior Court*, 480 U.S. 102, 113 (1987).

Conversely, "[w]hen a State exercises personal jurisdiction over a defendant in a suit not arising out of or related to the defendant's contacts with the forum, the State has been said to be exercising 'general jurisdiction' over the defendant."[7] It is axiomatic that a court may exercise general jurisdiction over a corporation in its state of incorporation or its principal place of business.[8] Additionally, courts have traditionally held that they have general jurisdiction over defendants where they had "continuous and systematic" contacts with the state.[9] The Supreme Court has addressed the importance and application of "continuous and systematic" contacts in recent years. Specifically, in *Goodyear Dunlop Tires Operations v. Brown*, 564 U.S. 915 (2011), the Supreme Court held that a court may only exercise general jurisdiction over a corporation where its contacts with the forum are *so continuous and systematic* as to render it "essentially at home in the forum state." Three years later, in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), the Supreme Court clarified the "at home" standard – noting that the traditional notion of continuous and systematic contacts with the forum is "unacceptably grasping" to confer general jurisdiction on a corporation.[10] Therefore, it held that a corporation is generally only "at home" in its place of incorporation and principal place of business. In fact, the Court seemingly acknowledged the rarity with which general jurisdiction should be conferred outside of a corporation's place of incorporation or principal place of business, noting that jurisdiction would only arise in "an exceptional case." Courts have applied *Daimler* to hold that this "exceptional case" is "extraordinarily unlikely" in situations where "a corporation is neither incorporated nor

[7] *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 415 n.9 (1984).

[8] *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915 (2011).

[9] *Int'l Shoe Co. v. Wash.*, 326 U.S. 310 (1945).

[10] *Daimler*, at 760-761.

maintains its principal place of business in a state[.]"[11] These rulings have provided guidance to courts on how and when to exercise general jurisdiction, yet their tenets have not been uniformly applied.

Pharmaceutical defendants have had mixed success in the application of *Daimler* to curtail litigation tourism.[12] However, while some courts have been faithfully applying *Daimler*, they have still allowed many cases to proceed based on specific jurisdiction – where the court has jurisdiction because the suit arises out of or relates to the defendant's contacts with the forum. Examination of recent rulings applying *Daimler* to reject litigation tourism is instructive for pharmaceutical company defense counsel. Notably, in light of these recent rulings, plaintiffs may begin to shift their focus from assertions of general jurisdiction, to broadening the traditional application of specific jurisdiction.

Decisions Precluding Litigation Tourism Under *Daimler*

A few recent holdings appear to be consistent with the Supreme Court's guidance in applying *Daimler*. In Illinois Plavix litigation, the Cook County Circuit Court, considered by many to be a very "plaintiff-friendly" venue, issued an order holding that allowing general jurisdiction over out-of-state defendants "would produce . . . that forbidden result: national general jurisdiction in every state in which Defendants are doing business and generating sales revenue. *Daimler* makes clear that such an approach to general jurisdiction does not comport

[11] *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 629 (2d Cir. 2016); *see also Weiss v. Nat'l Westminster Bank PLC*, 176 F. Supp. 3d 264 (E.D. N.Y. 2016).

[12] *See Eli Lilly & Co. v. Mylan Pharms., Inc.*, 96 F. Supp. 3d 824 (S.D. Ind. 2015) (holding Mylan was not "at home" in Indiana); *AstraZeneca AB v. Mylan Pharms.*, 72 F. Supp. 3d 549 (D. Del. 2014) (holding Mylan was not "at home" in Delaware); *Novotec Pharma LLC v. Glycobiosciences, Inc.*, 2016 US. Dist. LEXIS 452 (D.N.J. Jan. 5, 2016) (defendant was not "at home" in New Jersey); *Guillette v. PD-Rx Pharms., Inc.*, 2016 U.S. Dist. LEXIS 70988 (W.D. Okla. June 1, 2016) (defendants' manufacturing and marketing of pharmaceutical products, and conducting business in Oklahoma was insufficient to make pharmaceutical companies "at home"); *Mitchell v. Eli Lilly & Co.*, 159 F. Supp. 3d 967 (E.D. Mo. 2016) (the court did not have general jurisdiction over GlaxoSmithKline, as its principal place of business and place of incorporation were both Delaware); *In re Plavix Related Cases Applicable to All Cook County Cases*, 2014 Ill. Cir. LEXIS 1 (Ill. Cir. Ct. Aug. 11, 2014).

with due process."[13] Additionally, the Court held that it did not have specific jurisdiction over the plaintiff's claims because under Illinois law, courts only have specific jurisdiction over a claim which "directly arise[s] out of the contacts between the defendant and the forum." The Court took note to distinguish Illinois law's analysis of specific jurisdiction in comparison to California law's approach – which allows for specific jurisdiction based on a "substantial connection" between the plaintiff's claim and the defendant's contacts to the forum.

In *Evans v. Johnson & Johnson*, 2014 U.S. Dist. LEXIS 176598 (S.D. Tex. Dec. 23, 2014), a pelvic mesh case, the court declined to exercise general jurisdiction over J&J. In their briefing, Plaintiffs did not attempt to rebut J&J's arguments with respect to specific jurisdiction, instead attempting to focus on the breadth of J&J's contacts within the state for purposes of general jurisdiction. Without addressing specific jurisdiction at all, the Court held that because "[s]uch exorbitant exercises of . . . all-purpose jurisdiction would scarcely permit out-of-state defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." In discussing the degree of J&J's contacts with the forum, the Court noted that although plaintiffs alleged that J&J sold more pelvic mesh products in Texas than J&J's home state of New Jersey, such contacts were not sufficient under *Daimler* to render J&J "at home" in Texas.

Similarly in a non-pharmaceutical case from 2016, *Genuine Parts Co. v. Cepec*, 137 A.3d 123 (Del. 2016), the Delaware Supreme Court held that it did not have general jurisdiction over a Georgia corporation "over claims having nothing to do with its activities in Delaware."[14] In so holding, it emphasized *Daimler*'s rationale that even a corporation's continuous activity within a

[13] *In re Plavix Related Cases Applicable to All Cook County Cases*, 2014 Ill. Cir. LEXIS 1, *22 (Ill. Cir. Ct. Aug. 11, 2014).

[14] *Genuine Parts Co. v. Cepec*, 137 A.3d 123 (Del. 2016).

state "is not enough to support the demand that the corporation be amendable to suits unrelated to that activity."[15]

Missouri Supreme Court Decision Begs the Question: Is Litigation Tourism Coming to an End in Missouri?

A recent ruling from the Supreme Court of Missouri in *State ex rel. Norfolk Southern Railway Co. v. Dolan* has been celebrated by some of those within the defense bar, even going as far as decreeing that litigation tourism has "ended" in Missouri.[1617] This ruling is notable, considering the large verdicts that have come down from Missouri Courts.

In *Norfolk Southern*, a resident of Indiana alleged FELA claims in Missouri against Norfolk, a Virginia corporation with its principal place of business in Virginia. The plaintiff allegedly sustained injury during his years of employment with Norfolk in Indiana. Applying *Daimler*, the Court, while noting that conducting substantial and continuous business in a state is no longer sufficient to confer general jurisdiction, held that Norfolk was not "at home" in Missouri. Among the relevant facts analyzed was that Norfolk (1) generated only 2% of its revenues from Missouri activities; (2) generates greater revenue in 11 other states; (3) has more employees in 13 other states than it does in Missouri; and (4) most of the other 21 states in which Norfolk conducts business have at least as much contact with it as does Missouri. It therefore held that Missouri courts may not assert general jurisdiction over Norfolk, as the nature of Norfolk's activities in Missouri were "quite distinct from the 'nerve-center' of activities that the Supreme Court has said might be sufficient to make a 'home' state."

[15] *Goodyear*, 564 U.S. at 927.

[16] *State ex rel. Norfolk S. Ry. V. Dolan*, No. SC95514, 2017 Mo. LEXIS 66 (Fed. 28, 2017).

[17] https://www.druganddevicelawblog.com/2017/03/litigation-tourism-ended-in-missouri.html

The holding is even more interesting in light of two current cases pending in front of the Supreme Court. Pharmaceutical companies and their defense counsel are undoubtedly waiting for the Supreme Court's rulings in *Tyrrell v. BNSF Ry. Co* and *Bristol-Myers Squibb Co. v. Superior Court of California*. Both cases ask the Supreme Court to definitively rule on the reach and bounds of litigation tourism. These cases are scheduled for oral argument on April 25, 2017, two days before Troutman's Pharma Law Conference.

Pending Supreme Court Challenges to General Jurisdiction

In *Tyrrell v. BNSF Ry. Co.*,[18] the Montana Supreme Court held that it had general personal jurisdiction over BNSF, a railway company neither incorporated nor having its principal place of business in Montana. The Court acknowledged that it was irrelevant that a plaintiff's choice of forum is the result of forum shopping, even in cases such as this where the plaintiffs were not injured in Montana. The Court espoused its belief that *Daimler* "did not present novel law", and rather "emphasized prior holdings." It therefore applied prior rulings to affirm general jurisdiction over BNSF because it had a significant, substantial, and continuous and systematic business enterprise in Montana. Therefore, in the face of Supreme Court precedent, BNSF was determined to be "at home" in Montana. BNSF's briefing to the Supreme Court presents a compelling argument summarizing the issue from the company perspective:

> "Respondents here faced no injustice: They left their homes and the locations of all the witnesses and parties in the hope of gaining an advantageous forum in Montana's courts. Under *International Shoe* and *Daimler*, Respondents were not required to go to BNSF's place of habitation to litigate. Respondents were entitled to bring these cases wherever they arose (or, at Respondents' option, in Delaware or Texas). But the Due process Clause does not allow Respondents to bring these cases in the state courts of Montana, which lacks any connection whatsoever to the litigation. *Daimler*'s straightforward holding is directly applicable here and resolves these cases."

[18] *Tyrrell v. BNSF Ry. Co.*, 2016 MT 126 (2016).

The second case pending before the Supreme Court is *Bristol-Myers Squibb Co. v. Superior Court of California*.[19] The case revolves around 678 plaintiffs (86 California residents and 592 nonresidents) who allegedly suffered injuries as a result of their use of BMS' blood-thinner drug, Plavix. BMS sought dismissal of the non-California plaintiffs' claims, based on lack of jurisdiction. In its holding, the California Supreme Court affirmed the trial court's jurisdiction over the out-of-state plaintiffs. The Court noted that *Daimler* significantly narrowed the purview of general jurisdiction and found that there was no general jurisdiction over the claims asserted. However, while applying *Daimler* to reject general jurisdiction, it held that California had specific jurisdiction over BMS due to its marketing and distribution, research and development, and employment of hundreds of California employees, arising from the same course of conduct as was being sued for by other California plaintiffs.[20] Essentially, the Court held that since BMS was already subject to suits from multiple plaintiffs in California, and since BMS had engaged in a nation-wide practice of marketing and distributing Plavix, which did not differ from state-to-state in terms of the representations made with respect to the drug and/or the marketing materials used, jurisdiction over BMS was not "unreasonable." At base – since BMS is currently litigating in California and since the causes of action arose out of conduct that allegedly occurred throughout the country, exercise of jurisdiction is not unreasonable. Such a holding is problematic for defendants litigating cases in multiple jurisdictions that arise out of a coordinated national marketing and distribution of the product, but certainly for pharmaceutical manufacturers.

[19] *Bristol-Myers Squibb Co. v. Superior Court*, 1 Cal. 5th 783 (2016).

[20] Under California law, courts may exercise jurisdiction so long as its exercise of jurisdiction does not conflict with the United States Constitution. (Cal. Civ. Proc. Code § 410.10.)

Implications for Pharmaceutical Manufacturer Defendants in Products Liability Litigation

Pharmaceutical defendants and their counsel should be particularly aware of personal jurisdiction defenses and closely follow the Supreme Court's pending rulings on *Tyrrell* and *Bristol-Myers Squibb*. They must strongly assert the argument that courts do not have general jurisdiction over corporations just because they are registered to do business or place products into the stream of commerce in a state. They must be "at home" in the forum to be subject to general jurisdiction. And moreover, with respect to specific jurisdiction, it is irrelevant how often a product reaches a state – or how continuous a corporation's ties are to the state – *unless the injury is related to the corporation's actual contacts with the state*. The Supreme Court's ruling in *Bristol-Myers Squibb*, in particular, will likely provide significant direction on specific jurisdiction issues as they apply to global pharmaceutical companies that have a coordinated national marketing and distribution plan for promoting their products. As we have seen from many of the recent big verdicts against pharmaceutical companies, hundreds of millions or dollars, if not billions, are potentially at stake.

Fighting Against the Uncertainty of Multi-Plaintiff Consolidated Trials in an Age of Big Verdicts

S. Eric Rumanek and Shawn N. Skolky[1]

Multi-plaintiff trials are becoming more commonplace in products liability actions, as courts use them, in their view, to more efficiently utilize judicial resources and administer justice. Federal Rule of Civil Procedure 42(a)(2) and its state analogs specifically allow for courts to consolidate actions for trial, in their discretion, if they involve "a common question of law or fact." However, this procedure oftentimes disadvantages defendants, particularly in drug and medical device litigation. These disadvantages are clear on their face.

A 2015 Bates White Economic Consulting Report from 2015 showed that in consolidated asbestos trials in New York, consolidated verdicts result in 250% more per plaintiff than in individual trial settings, and 315% more per plaintiff than the national average award.[2]

In looking at recent verdicts in medical device cases, it is clear that these disparate outcomes are hardly limited to asbestos trials. In 2014, Boston Scientific was ordered to pay over $26.7 million (reduced to $14.3 million) to four plaintiffs stemming from their use of vaginal mesh.[3] In the Depuy Orthopaedics Pinnacle Hip Implant litigation, consolidated trials

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[2] Abelman, P., et al., The Consolidation Effect: New York City Asbestos Verdicts, Due Process and Judicial Efficiency, 14 Mealey's Asbestos Bankruptcy Report No. 9 (Apr. 2015); *See also Matter of New York City Asbestos Litig*., 2015 N.Y. Slip Op. 31358(U)(Sup. Ct. July 24, 2015) (Defendants presented statistics showing that of nine New York County trials with one plaintiff, there were six defense verdicts, with the plaintiff verdicts averaging $4.5 million per plaintiff. Of the ten consolidated trials, there was one defense verdict, with plaintiffs' verdicts of an average of $9 million per plaintiff).

[3] http://www.miamiherald.com/news/health-care/article3928147.html

have resulted in trial verdicts of $502 million (reduced to $151 million)[4] for six plaintiffs in one trial and $1.04 billion for another six plaintiffs in another trial.[5]

In *Depuy*, the Northern District of Texas addressed the issue of whether to consolidate multiple plaintiffs' cases for trial and held that, "any differences between the Plaintiffs can be easily explained to a jury, and any potential risks of prejudice or confusion may be avoided through the organized presentation of evidence and cautionary jury instructions." *In re Depuy Orthopaedics Pinnacle Hip Implant Prods. Liab. Litig.*, 2016 U.S. Dist. LEXIS 157502, *17 (N.D. Tex. Jan. 8, 2016). This finding seems to be increasingly common among courts addressing the issue, but is it right? Until the standards for consolidation change and/or become more concrete, which does not appear to be on the horizon, defense counsel are left with the question of how to effectively fight consolidation of multiple plaintiff's cases for trial, particularly in the context of drug/device mass tort litigation.

Legal Requirements for Granting Consolidated Trials

As noted above, Rule 42 of the Federal Rules of Civil Procedure permits consolidation for trial of any actions which involve a common question of law or fact.[6] Consolidation is entirely discretionary, and courts have wide authority to order consolidation to "avoid unnecessary costs or delay."[7] Challenging consolidation requires the challenging party to show that "the specific risks of prejudice and possible confusion" outweigh the risk of "inconsistent adjudications of common factual and legal issues, the burden on parties, witnesses and available

[4] http://www.reuters.com/article/us-johnson-johnson-verdict-hipimplants-idUSKBN13Q5XF

[5] https://www.nytimes.com/2016/12/01/business/johnson-johnson-must-pay-6-implant-patients-1-billion.html

[6] Fed. R. Civ. P. 42(a)(2).

[7] *In re Depuy Orthopaedics Pinnacle Hip Implant Prods. Liab. Litig.*, 2016 U.S. Dist. LEXIS 157502, *15 (N.D. Tex. Jan. 8, 2016)

judicial resources posed by multiple lawsuits, the length of time required to conclude multiple suits as against a single one, and the relative expense to all concerned of the single-trial, multiple-trial alternatives."[8] Often, courts hold that "any potential jury confusion and prejudice can be avoided if the evidence is presented in an organized manner and with proper jury instructions."[9]

The Argument Against Consolidation

The main argument against consolidated trials in drug/device litigation is that jurors are required to balance complex medical and scientific issues involved with prescription drugs and devices with unique patient-specific factors such as pre-existing medical conditions, alternative causation, the learned intermediary doctrine, and damages. Jurors are forced to attempt to separate the unique issues that are inherent in any drug/device product liability case, and the difficulty of this task cannot be overstated. Consolidated trials allow for multiple plaintiffs to present a jury with numerous instances of alleged injury which they contend are all caused by the same drug/device. This leads to the natural inference that if the drug/device is resulting in complications for the multiple plaintiffs in the courtroom, then something must be wrong with the product. Such an inference is particularly unfair for manufacturers of prescription drug/device products because those products necessarily carry the risk of adverse events and complications.

[8] *In re Mentor Copr. Obtate Transobturator Sling Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 18910, *7 (M.D. Ga. March 3, 2010), quoting *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1495 (11th Cir. 1985).

[9] *See, e.g., Frankum v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 80444, *9-10 (W.D.N.C. June 22, 2015); *see also In re Mentor*, at *3 ("While each of [p]laintiffs' specific medical conditions may be different, those differences and their significance can be explained to a jury and easily understood."); *Koch v. Breg, Inc.*, 2011 U.S. Dist. LEXIS 429755 (D.S.D. Apr. 20, 2011).

Defendants facing consolidation motions should make the argument that where individual issues predominate, consolidation is not appropriate, especially for trial.[10] Presentation of numerous plaintiffs' claims before a single jury will unfairly bolster the case against the defendants in an impermissibly prejudicial manner.

Additional Factors in Pharmaceutical Drug/Device Cases

As noted above, pharmaceutical drug/device cases present additional hurdles inherent in the nature of their use. There are two main causes of action asserted in drug/device litigation: (1) failure-to-warn, and (2) design defect.

To prevail on a failure-to-warn claim generally, a plaintiff must show that (1) the manufacturer had a duty to warn, (2) the defendant breached that duty, and (3) the breach proximately caused the plaintiff's injury. Administration of pharmaceutical products requires the intervention of a learned intermediary, a physician with knowledge of the product, who prescribes the treatment of choice based on each patient's unique presentation of symptoms and medical history. Each learned intermediary has a varied knowledge base of risks and preferences for particular treatments, as well as a different informed consent process by which they discuss whether any particular treatment is appropriate for the patient. Therefore, the vast majority of states apply what is known as the Learned Intermediary Doctrine, under which the manufacturer's duty to warn is solely to the physician who prescribes the product. "The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.[11]

[10] *Korren v. Eli Lilly & Co*., 150 Misc. 2d 429, 432, 568 N.Y.S.2d 670 (Sup. Ct. 1990) (In DES litigation, the court held that consolidation was "clearly unavailable.")

[11] *Restatement (Third) of Torts: Prods. Liab.* § 6(d)(1) cmt. b (1998)

In the context of a failure-to-warn claim, the necessity of the learned intermediary requires a case-by-case analysis that is improper for consolidated treatment. After all, each individual plaintiff had their own physician, each physician was aware of different risks at different periods of time, and each physician may or may not have decided to change his/her decision to prescribe the pharmaceutical product had a different warning been provided. These specific inquiries make it difficult to justify consolidated treatment of cases, where there are so many unique issues related to each case.

In the context of design defect claims, a plaintiff must prove that the product was defective, and it proximately caused its injury. Proximate cause requires a showing of both general and specific causation. Therefore, *even if* all plaintiffs in a consolidated trial were able to prove that a product was generally defective, the specific causation inquiry is highly individualized and necessarily involves an analysis of each plaintiffs' unique medical history, and proof that his/her specific injury was proximately caused by the defect in the specific product. Such an inquiry is unique to each individual plaintiff, and often requires expert medical testimony for each plaintiff.[12] It is because of this requirement that drug and device cases are so rarely heard in the class action context.[13]

Tailored Use of Consolidation: Reviewing *Mullins v. Ethicon*

Consolidated trials are not always objected to on all grounds. Recently, Judge Joseph Goodwin in the Southern District of West Virginia consolidated 37 pelvic mesh cases for trial

[12] For example, in Georgia, only experts may offer competent evidence of design defect, because it "is not an inference a jury can reasonably draw solely from human experience." *Meade v. Ford Motor Co.*, No. 1:09-CV-1833-TWT, 2011 U.S. Dist. LEXIS 106508, at *4-5 (N.D. Ga. Sept. 20, 2011).

[13] *See e.g., In re American Medical Sys.*, 75 F.3d 1069 (6th Cir. 1996) (granting motion to decertify class because products were different, each plaintiff had a unique complaint, and each received different information and assurances from his treating physician.)

(initially 26 cases, but expanded to 37).[14] After Judge Goodwin issued his Order consolidating the cases, both parties moved for clarification on the Order. Ethicon essentially conceded that it was prepared to proceed with trial on (1) whether defects actually existed in their TVT device; and (2) whether the conditions alleged to be "defects" actually had clinical consequences which could be avoided by a different and safer design. It argued that such issues would not require discovery relating to individual plaintiffs.

Offering clarification on his Order, Judge Goodwin noted that consolidated trial would only involve the "narrow and discrete issues" which were universal to all plaintiffs, concerning the design of the product and whether that design was reasonably safe.[15] Indeed, he noted that the consolidated trial would not be on design defect *liability*, but only on the existence of design defect generally – i.e., whether a defect existed at all in the product implanted in all plaintiffs, focusing on whether an alternative design to a defective product was feasible at the time of its manufacture. He further held that plaintiff-specific evidence would not be accepted, and such evidence would *only* be considered if plaintiffs were to prevail during the first phase of trial.

Judge Goodwin's tailored use of the consolidation mechanism is a bit of a compromise, allowing certain issues to be consolidated which do not directly speak to each individual plaintiff. It is not necessary for plaintiffs' counsel to put forth the same – or similar – evidence five or six times. Since the jury will only hear the evidence once, they can make a decision based on one set of facts, rather than cumulative, duplicative, and likely prejudicial sets of repetitive facts.

[14] Cases consolidated as *Mullins v. Ethicon, Inc.*, 2:12-cv-02952 (S.D. W.Va.).

[15] *Mullins v. Ethicon, Inc.*, 2:12-cv-02952, Dkt. 38 (S.D. W. Va. Aug. 4, 2015).

Discretion Often Leads to Consolidation

The law is not applied uniformly, and in seemingly similar scenarios, courts have come to differing conclusions.[16] For example, in *Rubio v. Monsanto Co.*, 181 F. Supp. 3d 746 (C.D. Cal. 2016), the Court held that trying two claims together was prejudicial because in order to state a claim, both plaintiffs were required to demonstrate that the defendant's product, Roundup, caused cancer in *each individual plaintiff*, rather than generally. It held that "[c]onsolidating the two claims may give rise to the easy, potentially prejudicial inference that if Roundup caused [one plaintiff's] cancer, it caused [the other plaintiff's] as well, or vice versa." Therefore, the Court severed the plaintiffs' claims.

Conversely, in *In re Mentor Corp. Obtate Transobturator Sling Products Liability Litigation*,[17] similar to the examples given earlier, the Middle District of Georgia allowed for consolidation of claims from four individual plaintiffs for trial. In consolidating, the Court held that "[w]hile each of Plaintiffs' specific medical conditions may be different, those differences and their significance can be explained to a jury and easily understood."

Many times there is seemingly no rhyme or reason for why any particular court will decide that one set of facts lends itself to consolidation, while others do not. It is therefore important to remember the discretionary nature of consolidation. Defense counsel must make their prejudice arguments as forcefully as possible with the knowledge that the ultimate decision is not that of black letter law, but of the judge him/herself. In fact, strong consideration should

[16] *See e.g., Hasman v. G.D. Searle & Co.*, 106 F.R.D. 459 (E.D. Mich. 1985) (holding that common issues of law and fact did not predominate in products liability action regarding intrauterine device because the cases "involve separate and unique medical social, and sexual histories peculiar to each woman and her sexual partners. Consolidation would make trial confusing, unmanageable and perhaps inequitable."); *see also Michael v. Wyeth, LLC*, 2011 U.S. Dist. LEXIS 42917 (S.D. W. Va. Apr. 20, 2011) (denying plaintiffs' motion to consolidate because the three plaintiffs' causes of action were "highly fact-specific").

[17] 2010 U.S. Dist. LEXIS 18910 (M.D. Ga. March 3, 2010).

be given to highlighting the recent verdicts discussed above as examples of the dangers and prejudice associated with consolidated multi-plaintiff trials in drug/device cases. The bottom line is that pharmaceutical defendants should work with their outside counsel to tailor the most effective strategies possible to defeat improper consolidation. While consolidation can be a useful tool for courts to conserve judicial resources, "[t]he systemic urge to aggregate litigation must not be allowed to trump our dedication to individual justice, and we must take care that each individual plaintiff's – and defendant's – cause not be lost in the shadow of a towering mass litigation."[18]

[18] *In re: New York City Asbestos Litig.*, No. 190411/13, 2015 N.Y. Misc. LEXIS 2634, at *9 (N.Y. Sup. Ct. July 24, 2015) (citation omitted) (unpublished).

PHARMA LAW CONFERENCE 2017

Trade Secrets

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- Pifizer v. Texas Health & Human Services Commi– 11/16 – Drug pricing and rebate protocol
- U.S. v. Scientists – 1/16 – Oncology research information
- U.S. v. Scientists – Eli Lilly targets for cardiovascular disease, diabetes, and oncology
- Former St. Jude VP – 2015 – St. Jude's research and marketing initiatives
- Alnylam v. Dicerna – 2015 – Conjugate technology
- Zimmer v. Howemedica – 2014 – Sales rep with confidential information

TROUTMAN SANDERS

What is a Trade Secret (TS)?

- Generally - any confidential business information which provides an enterprise a competitive edge
- Specifically - depends on the law in which TS is being defined
- Includes, but not limited to, formula, practice, process, design, instrument, pattern, commercial process, or compilation of information not generally known or reasonably ascertainable by others

What is a Trade Secret (TS)? (cont'd)

- Three key common factors
  - Information that is not generally known to the public
  - Information that confers some sort of economic benefit on its holder (where this benefit must derive *specifically from its not being publicly known, not just from the value of the information itself)*
  - *Information that is the subject of reasonable efforts to maintain its secrecy*

+ Trade Secret Advantages

- No government registration – not restricted to inventions or works
- Secret – including enforcement proceedings
- Immediate effect – no waiting
- Can encourage collaboration under confidentiality
- No term to expire
- Can be less expensive

+ Trade Secret Advantages (cont'd)

- Compatible with patents – improvements
- Avoids 35 U.S.C. §271(e)(1) safe harbor
- Inevitable disclosure doctrine - in rare circumstances an individual possesses such critical knowledge of a company's trade secrets he can be temporarily or even permanently banned from working in a specific job, because doing so would inevitably lead to disclosure of his former employer's trade secrets

Trade Secret Disadvantages

- Must be kept secret
- Employee turn-over
- Enforcement
- Inadvertent disclosure
- Publications
- Can discourage collaborations
- Cannot use for publicity, etc.
- Reverse engineering

Trade Secret Disadvantages (cont'd)

- Patenting by others
- Can be costly to maintain
- Independent creation by someone else
- Cannot unring the bell - if breached, it is public
- Cyber espionage and hacking
- Working remotely is dangerous

Trade Secret v. Patent

Trade Secrets	Patents
Valuable business information generally not known or readily ascertainable; no restriction on subject matter; not useful if reverse engineerable	Only certain subject matter
Reasonable efforts to preserve confidentiality	Not confidential – published
No exclusivity term limit	Limited exclusivity term
Enforceable through litigation	More readily enforceable
Cost of preserving secrecy	Costs associated with filing, prosecution and maintenance
Immediately effective	Not effective until granted (some exceptions)

Trade Secret Laws – U.S.

- *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974): states are free to develop their own trade secret laws
  - Nearly all states have adopted the Uniform Trade Secrets Act (UTSA) except MA, NY, NC
  - Laws are for actual and threatened misappropriation
- Economic Espionage Act (EEA) of 1996 (18 U.S.C. §§1831–1839)
  - Theft or misappropriation of trade secret to benefit foreign power or for commercial or economic purposes became federal crimes

Trade Secret Laws – U.S. (cont'd)

- Defend Trade Secrets Act of 2016 (DTSA) (18 U.S.C.§§1836 et seq.)
- Addition to EEA
- Created federal private and attorney general cause of action for trade secret misappropriation

Defend Trade Secrets Act ("DTSA") (18 U.S.C. §1836)

- Patterned on the Uniform Trade Secrets Act
- U.S. resident (even company) liable for ex-U.S. misappropriation
- Any person liable if an act in furtherance in U.S.
- Does **not** preempt state laws
  - Especially useful in NY, MA and NC which have not adopted UTSA
- Five year statute of limitations from the date of discovery

Defend Trade Secrets Act ("DTSA") (18 U.S.C. §1836) (cont'd)

- TS means "all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing, if –
  - the owner thereof has taken *reasonable measures* to keep such information secret; and
  - the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information." 18 U.S.C § 1839.

Defend Trade Secrets Act ("DTSA") (18 U.S.C. §1836) (cont'd)

- Punitive damages and attorney's fees available if bad faith claim or willful and malicious misappropriation
  - To take advantage of this, a company must advise its employees of the existence of whistleblower immunity

Defend Trade Secrets Act ("DTSA") (18 U.S.C. §1836) (cont'd)

- Equitable and monetary relief
  - Permanent injunction to prevent actual or threatened misappropriation.
    - But no "inevitable disclosure" doctrine
  - Preliminary ex parte seizure of property necessary to prevent the propagation or dissemination of the trade secret if other equitable relief is inadequate.
    - Extraordinary remedy - *OOO Brunswick Rail Mgmt v. Sultanov,* 2017 U.S. Dist. LEXIS 2343, *5, 2017 WL 67119 (N.D. Cal. Jan. 6, 2017) (No seizure if other means available, *i.e.* simply ordering return); Magnesita Refractories Co. v. Mishra, 2017 U.S. Dist. LEXIS 10204, 2017 WL 365619 (N.D. Ind. Jan. 25, 2017) (Temporary seizure for copying only)

Trade Secret Laws – New York

- Requires "continuous use" of a trade secret – actually being used in your business
- Common law based – No Uniform Act or statutes
- Usually filed as misappropriation
  - Consider tortious interference with contract, conversion, breach of contract, fraud, breach of fiduciary duty, and unfair competition claims
- Statute of Limitation – 3 years from accrual or discovery of cause of action N.Y.C.P.L.R §214.
- Injunctive and monetary remedies available
- Consider pendent/ancillary jurisdiction in Federal courts
- No attorney fee awards

Trade Secret Laws – New York

- Hesitant to apply the "inevitable disclosure" doctrine
  - Courts will generally enforce restrictive covenants, *i.e.*, non-compete provision, when the restraint is "(1) *no greater* than is required for the protection of the *legitimate interest* of the employer, (2) does not impose undue hardship on the employee, and (3) is not injurious to the public.'' *BDO Seidman v. Hirshberg*, 93 N.Y.2d 382, 388 (1999) (emphasis in original)
  - In other words, may be enforceable if it is reasonably limited temporally and geographically to protect against the misappropriation of a TS or competition from an employee whose services are unique or extraordinary. *Columbia Ribbon & Carbon Mfg. Co. v. A-1-A Corp*., 24 N.Y.2d 496, 499 (1977). *See also BDO Seidman,* 93 N.Y.2d 382 (1999) (18 mos.); *Albany Med. Coll. V. Lobel*, 745 N.Y.2d 250 (3d Dep't 2002).

Trade Secret Laws – EU

- EU (adopted 5/27/16) Directive on the Protection of Trade Secrets
  - EU members must "bring into force the laws, regulations and administrative provisions necessary to comply with this Directive" by May 2018
  - Trade secret holders will be entitled to apply for remedies for illegal appropriation of documents, objects, materials, substances or electronic files containing the trade secret or from which the trade secret can be deduced

What Are Reasonable Efforts

- Prioritize all company information – need to know, etc.
- Label it SECRET (*LeTeune v. Coin Acceptors, Inc.*, (Md. 2004))
- Compartmentalization (*Otis Elevator Co. v. Intelligent Sys., Inc.,* (Conn. Super. 1990))
- Restrict physical access (*VALCO Cincinnati, Inc. v. N & D Machining Serv., Inc.* (S. Ct. Ohio. May 21, 1986).)
- Restrict electronic access (*U.S. v. Aleynikov* (S.D.N.Y. Mar. 14, 2011))
- Constant monitoring (*Schalk v. State* (Tex. Crim. App. 1991))
- Use code names
- NDAs as part of employment agreement for employees and consultants (*Aetna, Inc. v. Fluegel* (Conn. Super. Feb. 7, 2008)

What Are Reasonable Efforts

- Diligent action against TS breaches (*Pre-Paid Legal Servs., Inc. v. Harrell* (E.D. Okla. Jan. 8, 2008); Alamar Biosciences, Inc. v. Difco Labs., Inc. (E.D. Cal. 1995))
- Education, *e.g.,* employee manuals, training sessions (*U.S. v. Chung*, (9th Cir. 2011))
- NDAs with third parties, e.g., CROs, supply chain (*Technicon Data Sys. Corp v. Curtis 1000, Inc.* (Del.Ch. 1984))
- Study employee turn-over reasons
- Review NDA at employee/contractor and obtain all TS at exit interview (*Agilent Techs v. Kirkland*, 2010 Del. Ch. LEXIS 34)

What Are Reasonable Efforts (cont'd)

- Adopt a global corporate policy regarding Proprietary Information Protection (PIP policy), acknowledgements and reminders, *Wyeth v Natural Biologics,* (D. Minn. 2003), aff'd 395 F. 3d 897 (Fed. Cir. 2005)
- Identify TS and develop an inventory or a registry (*Schalk v. State* (Tex. Crim. App. 1991))
- Information protection team/manager (*Materials Dev. Corp. v. Atlantic Adv. Metals, Inc.* (Mass. Super. Ct. 1971))
- NDA in settlement agreements involving TS
- No snowflakes, i.e., no exceptions

Trade Secret Protection Measures

	Materials Dev. v. Atl. Metals (1972)	Technicon v. Curtis (1984)	Valco v. DBA Superior (1986)	Otis v. Intelligent (1990)	Schalk v. Texas (1991)
Document destruction/return			X		
Employee CDAs	X	X	X	X	X
Employee IDs					
Employee sign-in					
Employee training					
Exit interviews					X
Limiting number of people w/access					X
Locked copiers					
Marking		X			
Need to know					
No past misappropriations					
Policy					X
Prior enforcement/firings				X	
Reminding employees					
Requiring employee confirmation					
Restricting physical access				X	X
Security measures		X	X		
Trade secret registry					X
3d party CDAs		X		X	
Tiered secrecy levels					
Video surveillance					

Trade Secret Protection Measures

	Aldamar v. Difco (1995)	Wyeth v. Natural Bio (2003)	LeJune v. Coin Acceptors (2004)	Pre-paid Legal v. Harrell (2008)	U.S. v. Chung (2011)
Document destruction/return		X			
Employee CDAs		X		X	X
Employee IDs		X			
Employee sign-in		X			
Employee training		X			X
Exit interviews					
Limiting number of people w/access		X			
Locked copiers		X			
Marking		X	X		X
Need to know		X			X
No past misappropriations		X			
Policy			X		
Prior enforcement/firings				X	
Reminding employees	X				X
Requiring employee confirmation					X
Restricting physical access		X		X	X
Security measures		X			X
Trade secret registry					
3d party CDAs		X	X		X
Tiered secrecy levels		X			
Video surveillance		X			

Pitfalls via Collaborations

***Eli Lilly and Co. v. Emisphere Tech. Inc.*, 408 F. Supp. 2d. 668 (S.D. Ind. 2006)**

- Parties collaborated to develop new chemical carrier compounds for oral delivery of parathyroid hormone (PTH)
- During collaboration, Eli Lilly filed a PCT for a carrier compound delivery of glucagon-like peptide 1 (GLP-1)
- Emisphere notified Eli Lilly of breach of contract and Eli Lilly filed a declaratory judgment action
  - Emisphere counterclaimed for breach of contract
  - Parties were attempting to negotiate a broader collaboration agreement, but failed and Emisphere tried to terminate collaboration

Pitfalls via Collaborations (cont'd)

***Eli Lilly and Co. v. Emisphere Tech. Inc.*, 408 F. Supp. 2d. 668 (S.D. Ind. 2006)**

- While still working with Emisphere, Eli Lilly created a separate, new team led by two doctors that worked on collaboration to conduct related research and allegedly filed patent applications using information from the collaboration
- Court found Eli Lilly breached the contract and terminated the collaboration agreement – Eli Lilly could not continue with the PTH or GLP-1 program

Pitfalls via Collaborations (cont'd)

***Tekmira Pharm. Corp. v. Alnylam Pharm., Inc.*, No. 11-1010-BLSZ (Mass. Bus. Lit. Sess. Mar. 16, 2011)**

- Parties entered into a collaboration on RNAi therapeutics where Alnylam would supply active molecule and Tekmira would provide delivery mechanism
- Interference was raised between a Tekmira and Alnylam patent application claiming the same RNAi

Pitfalls via Collaborations (cont'd)

***Tekmira Pharm. Corp. v. Alnylam Pharm., Inc.*, No. 11-1010-BLSZ (Mass. Bus. Lit. Sess. Mar. 16, 2011)**

- Tekmira asserted that Alnylam breached the NDA by misappropriating TS and conducting its own research and applying for patents
- Settled with payment to Tekmira for $65M, Alnylam relinquished its patent application to Tekmira, Tekmira cross-licensing RNAi technology to Alnylam, and restructuring of business relationship

FDA and Trade Secrets

- Food, Drug, and Cosmetics Act (FDCA) prohibits FDA employees from disclosing "any method or process which as a trade secret is entitled to protection" acquired through the FDA review process. 21 USC §331(j)
  - Disclosure of confidential commercial information is banned also. 21 USC §331(y)(2)

FDA and Trade Secrets (cont'd)

- "A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. *There must be a direct relationship between the trade secret and the productive process*." 21 C.F.R. § 20.61(a); *see also Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280 (D.C. Cir. 1983)
- FDA can be sued for disclosing TS – *Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1252 (D.C. Cir. 2005)

FDA, Trade Secrets, & FOIA

- FDA's current practice is to treat a substantial amount of the information that is submitted to FDA by companies and that does not fall under FDA's definition of trade secrets as confidential commercial information that is not publicly disclosed
- Public can request information from FDA via Freedom of Information Act (FOIA) (5 U.S.C § 552) unless information falls under one of the nine exemptions
  - Exemption 4 - "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. 552(b)(4) (2002)

FDA, Trade Secrets, & FOIA (cont'd)

- When a FOIA request is made, the FDA has an obligation to make "an independent determination" as to whether Exemption 4 applies.
- If requester is dissatisfied with the response, it can file suit against the FDA and submitter has the right to intervene. Appleton v. FDA, 310 F. Supp. 2d 194 (D.D.C. Mar. 24, 2004).

FDA, Trade Secrets, & FOIA (cont'd)

- Mitigate TS disclosure by:
  - Clearly designate what information in the FDA submission constitutes trade secret or other confidential information (also make it clear to a third party regulatory submitter)
  - Review, or preferably draft, documents to be publically disclosed by FDA, *e.g.*, Summary Basis of Approval
  - Monitoring FOIA docket to track relevant requests

EUROPE - EMA, FOI, & Trade Secret

- Trade secrets relating to a manufacturing process for a biologic are captured by the term "commercially confidential information" (CCI)
  - CCI - "*information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information*"
  - Generally, pharmaceutical development information is CCI

EUROPE - EMA, FOI, & Trade Secret (cont'd)

- Third parties can request information from the EMA regarding a complete marketing authorization (MA) application via a freedom-of-information (FOI) request
  - Requester would have to show why such information should be in the public domain, *i.e.* there would have to be an overriding public interest
  - EMA decides what information in a dossier is confidential, but holder can comment on the redacted documents
  - EMA's practice in relation to what it considers CCI has led to a number of law suits, but none of them have gone to a final decision because the parties settled the dispute before a final decision issued

AUSTRALIA - TGA, FOIA, & Trade Secret

- Third parties can request information from the Australian Therapeutic Goods Administration (TGA)
- The TGA **must** give the Owner an opportunity to make submissions explaining why any requested documents constitute "exempt documents" under the FOI Act and cannot be released
  - An "exempt document" relevantly includes one that contains:
    - a trade secret; or
    - any other information having a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed

AUSTRALIA - TGA, FOIA, & Trade Secret (cont'd)

- If the TGA rejects an Owner's submissions and decides to release the documents, the Owner can appeal or challenge that decision and the TGA cannot release the information until those avenues of appeal have been exhausted

CANADA – FOIA & Trade Secret

2014 BILL C-17 amends the Food and Drugs Act

- Section 21.1(2) The Minister may disclose confidential business information (CBI) about a therapeutic product without notifying the owner of the information or obtaining consent, if the Minister believes that the product may present a serious risk of injury to human health
  - Actual serious risk is not necessary, only the Minister's belief that there may be one

CANADA – FOIA & Trade Secret (cont'd)

2014 BILL C-17 amends the Food and Drugs Act

- (3) The Minister may disclose CBI about a therapeutic product without notifying the owner of the information or obtaining consent, if the purpose of the disclosure is related to the protection or promotion of human health or the safety of the public and the disclosure is to
  - (a) a government;
  - (b) a person from whom the Minister seeks advice; or
  - (c) a person who carries out functions relating to the protection or promotion of human health or the safety of the public

CHINA - CFDA, FOIA, & Trade Secret

- No procedure exists for third party requests for information from China Food and Drug Administration (CFDA)
- The State protects undisclosed drug study data and other independently acquired data for obtaining production or marketing approval of drugs that contain new chemical entities. No one may make unfair commercial use of the said data
  - However, drug regulatory department may disclose this data

    (1) for the need of public interests; or

    (2) where steps are taken to ensure that the data are protected against unfair commercial use.
- Disclosure of TS is rare
- CFDA would notify the applicant first

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Notes

Session 2 • Economics, Business & Law in the Trump Era

Moderator: Aurora Cassirer, Troutman Sanders

Deregulating the FDA & Dismantling ObamaCare
Lindsay Austin, Troutman Sanders Strategies
Rob Browne, Troutman Sanders

Bringing the Cash Home: Corporate Income Tax Reduction & Repatriation of Cash at Discounted Rate – End of Inversions with Lower US Tax Rates
Robert Friedman, Troutman Sanders

A Second Chance: Real Life Experiences with Distressed Pharma Companies
Steve Mermelstein, Huron
Jim Lukenda, Huron
Hugh McDonald, Troutman Sanders

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The Trump Era

Lindsay Austin, Director of Federal Affairs – Troutman Sanders Strategies

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Overview

- Washington: Lay of the Land
- Administration: Trump Focus
- FDA: Gottlieb
- Congress Activity

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Washington: Lay of the Land

- ACA Repeal & Replace
  - American Health Care Act (AHCA)
    - No final agreement since March (E&C/W&M), but HFC and MacArthur (co-chair Tuesday Group) negotiation
    - Amendment to AHCA, not a full repeal but claims to lower premiums
      - Amends to give states options to repeal parts of ACA
      - Provides waivers for states on essential benefits (ER visits, maternity care, etc), but requires risk-pools
      - Preserves pre-existing conditions but may allow higher pricing for patients if they don't maintain insurance
      - Still allows Medicaid expansion

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Washington: Lay of the Land

- ACA Repeal & Replace
  - Appealing to Voters
    - Two week recess, frustrated constituents
    - For House & Trump, must-pass but challenge in Senate
      - Byrd Rule, non-budget items may derail AHCA
    - Dynamics for use in 2018 elections
    - WH wants vote now , no whip count yet. No Dem support, moderates unsure.
    - House Leadership needs guarantee, may have HFC votes but Pence and Priebus key

*Pharmaceutical companies were not the focus in GOP repeal bill, but some impact from trickle down

Washington: Lay of the Land

- Budget & Appropriations
  - Current FY2017 funding expires Friday, April 28
    - Rules Cmte approved "martial law", same-day authority to vote
    - Stopgap bill introduced, still negotiating possible omnibus
      - Trump backed off border wall trade for funding for insurance subsidies, agreed to cover and not include in FY17
    - Dems ok with CSR payment deal but skeptical on riders
  - FY 2018 budget from the administration expected in May
    - Cuts across board, maybe some FDA changes

Washington: Lay of the Land

- Tax Reform
  - White House Tax outline released Wed. 4/26 after Treasury Secretary Steven Mnuchin and NEC Director Gary Cohn met with Leadership
    - Outline of principles for cuts (no pay-for):
      - Top rate of 35% for individual (3 levels), 15% for Corps. large and small
      - Child care tax credit, repeals AMT & Death
      - Individual deductions eliminated other than mortgage & charitable
      - Repatriation included, but no Border Adjustment Tax receiving, push-back from industry
  - Must-pass in 115th Congress, may require reconciliation
  - Will require House and Senate buy-in, end of year likely and may recoup ACA repeal $

Administration: Trump Focus

- First 100 Days, "Achievements"
  - Will emphasize Executive Orders, Foreign Policy, Supreme Court , and now Tax Plan
- On Drug Pricing
  - Made statements during campaign and at start of presidency about addressing concerns
  - Met with Pharma CEOs in January, positive meeting
  - Shown desire to work with Democrats
    - Met with Rep. Elijah Cummings (D-MD) at White House
    - Open to Medicare negotiating drug prices and drug importation (Republicans unsupportive)

Administration: Trump Focus

- On Regulations
  - Executive Order Instituted a "2-for-1" regulation rule
  - Targeting agency waste and spending through OMB (Mulvaney)
  - Additional Regulatory Reform expected, with support from Congress
- On Healthcare and ACA Repeal
  - Suggested moving forward before Tax and Infrastructure, may capture savings from repeal

FDA Commissioner: Dr. Scott Gottlieb, M.D.

- Background:
  - Private: T.R. Winston & Co (investment, current), venture partner New Enterprise Associates, assistant professor at NYU School of Medicine, adviser to GSK, AEI
  - Public: Position at FDA and worked at CMS during the Bush administration
  - Has testified before Congress as an American Enterprise Institute Fellow, known in Washington circuit

FDA Commissioner: Dr. Scott Gottlieb, M.D.

- Confirmation Status:
  - Senate HELP Committee vote on nomination Thursday, April 27 *along party lines*
    - Delay bc of 100s of pages of Q&A and had issues with FBI background
  - Likely confirmed in May
  - April 5 HELP hearing topics: *opioid epidemic, potential conflicts of interest, FDA workforce, bringing generic drugs to market, as well as drug and medical device regulation and approvals*
  - Latest recusal challenge: position on e-cig/vaping company board (Kure Corp.). Industry Rule under consideration at FDA

Gottlieb & FDA Policy

- Competition, innovation, pricing
  - May want FDA to adopt standards and regulatory tools to help drug companies
  - Has stated FDA should adjust standards for generic drugs
  - Aligned with Republicans, e.g. no new importation changes or Medicare negotiation of drug prices

Gottlieb & FDA Policy

- PDUFA/MDUFA
  - Agrees reauthorization is critical for FDA, fee agreements $2B of FDA $5B budget
  - If not reauthorized before August, could layoff more than 5,000 FDA employees
- 21st Century Cures
  - Will move FDA to increase flexibility in clinical trial development process
  - Has stated extensive clinical trial requirements may have a “chilling effect” on bringing new therapies to market
  - Concerns from members and Gottlieb about fulfilling Cures goals of hiring new talent, he was vocal in past

Gottlieb & FDA Policy

- Opioid Crisis
  - Priority, biggest challenge & concern facing FDA
  - Lawmakers suggest FDA approvals allow addictive drugs to reach the market too quickly
  - Price announced HHS $485 million in grants to help states and territories combat opioid addiction
- Patient & Consumer Engagement
  - FDA to more rigorously incorporate patient view and input in approval process

114th Congress

- Passed 21st Century Cures
  - Overall bill addressed drug innovation, development, and delivery
  - Provides $4.8 billion over 10 years for the Precision Medicine Initiative, the Cancer Moonshot Initiative, and other medical objectives
  - Requires the FDA to update standards in scientific areas pursued by pharma
  - Incorporates more patient input
  - Instructs use of "real world evidence" to support new drug applications, likely to move FDA in industry innovation-friendly direction
  - Implementation may occur after budget and Appropriations process or when PDUFA/MDUFA clears to ensure staff

115th Congress

- ACA Repeal Replace Effort (see slide 2)
  - Failed in March, negotiations with WH, Leadership, HFC, and Tuesday Group
  - 3 Phases continuing: Reconciliation, Legislative, Regulatory/Administrative
- User Fee Reauthorizations
  - 2012 PDUFA, MDUFA, GDUFA, BsUFA all must be updated and reauthorized by September 30 (or by end of July before August recess)
  - House/Senate initial hearings held in March and April
  - Released bipartisan draft April 14
    - Would give FDA the power to collect $2B in fees from FY18 through FY22
  - Could be push for controversial FDA policy changes, i.e. prescription drug pricing, opioid abuse and terminally ill patients rights to try experimental treatments

Other: *Debt Ceiling, Trade Deals, Tax Package, FY18 Approps/Budget, Immigration, Infrastructure, etc.*

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Deregulating the FDA

Robert E. Browne, Jr. , Partner – Troutman Sanders

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What Does the Future Hold?

- Initial Steps of the Trump Administration
  - Regulatory Freeze Pending Review
  - "One In, Two Out" Executive Order
  - "Enforcing the Regulatory Reform Agenda" Executive Order
  - CRA used to eliminate regulations issued in the final months of Obama administration
  - Nomination of Scott Gottlieb for FDA Commissioner

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Regulatory Freeze Pending Review

- Issued Memorandum for the Heads of Executive Departments and Agencies
  - No regulations to be sent to the Office of the Federal Register for publication until a presidential appointee or designee has reviewed and approved;
  - Any regulations that have already been sent to the Office of the Federal Register are to be immediately withdrawn, and then reviewed by a presidential appointee or designee;
  - Regulations that have been published in the Federal Register but have not taken effect are to have their effective dates postponed for 60 days

'One In, Two Out' Order

- Executive Order ("EO") which requires that two regulations be struck for every new regulation
- Agencies would have to submit suggested rule cuts to the White House to review in order to enact new legislation
- Additionally, each agency will have a set budget each year for new regulations

Enforcing the Regulatory Reform Agenda

- Executive Order which directs agencies to identify personnel to oversee implementation of the Administration's regulatory reform initiatives. Order does the following:
  - Creates the role of Regulatory Reform Officer ("RRO")
    - RRO is to "oversee the implementation of regulatory reform initiatives and policies to ensure the agencies effectively carry out regulatory reforms . . ."

Enforcing the Regulatory Reform Agenda (cont'd)

  - The establishment of a Regulatory Reform Task Force
    - Task Force is composed of RRO, the agency Regulatory Policy Officer and a representative from the agency's policy office
    - The Task Force is to "evaluate existing regulations . . . and make recommendations to the agency head regarding repeal, replacement, or modification consistent with applicable law"
    - Task Force must seek input and assistance from consumers, small business, and trade associations

CRA Used to Eliminate Regulations

- The Congressional Review Act ("CRA") has been used to eliminate certain regulations issued in the last months of the Obama Administration
  - Potential FDA targets for the CRA
    - Menu Labeling Rule
    - Expanded Tobacco Rules

Nomination of FDA Commissioner

- Trump nominated Dr. Scott Gottlieb for FDA Commissioner
  - Formerly deputy commissioner for medical and scientific affairs at the FDA during the George W. Bush administration
  - Dr. Gottlieb wrote that FDA "In so heavily prioritizing one of its obligations -- the protection of consumers -- the FDA has sometimes subordinated and neglected its other key obligation, which is to guide new medical innovations to market"
  - In a departure from the agency position that it has little control over drug costs, Dr. Gottlieb has also shown a willingness to take on high prices by making it easier for certain generic drugs to be approved

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Tax Reform… It Will Be Huge!

2017 Tax Reform for Economic Growth and American Jobs
The Biggest Individual And Business Tax Cut In American History
(Announced 4.26.2017)

Robert A. Friedman , Partner – Troutman Sanders

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2017 Tax Reform for Economic Growth and American Jobs

The Biggest Individual And Business Tax Cut In American History

Goals For Tax Reform

- Grow the economy and create millions of jobs
- Simplify our burdensome tax code
- Provide tax relief to American families-especially middle-income families
- Lower the business tax rate from one of the biggest in the world to one of the lowest

Individual Reform

- Tax relief for American families, especially middle-income families:
  - Reducing the 7 tax brackets to 3 tax brackets of 10%, 25% and 35%
  - Doubling the standard deduction
  - Providing tax relief for families with child and dependent care expenses
- Simplification:
  - Eliminate targeted tax breaks that mainly benefit the wealthiest taxpayers
  - Protect the home ownership and charitable gift tax deductions
  - Repeal the Alternative Minimum Tax
  - Repeal the death tax
- Repeal the 3.8% Obamacare tax that hits small businesses and investment income

Business Reform

- 15% business tax rate
- Territorial tax system to level the playing field for American companies
- One-time tax on trillions of dollars held overseas
- Eliminate tax breaks for special interests

Process

- Throughout the month of May, the Trump Administration will hold listening sessions with stakeholders to receive their input and will continue working with the House and Senate to develop the details of a plan that provides massive tax relief, creates jobs, and makes America more competitive – and can pass both chambers.

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Tax Reform… It Will Be Huge!

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The President's Tax Plan – 4.26.17

- The White House made its opening bid for what officials called the "biggest tax cut" in U.S. history—with cuts that would benefit businesses, the middle class and certain high-earning individuals—but left many unanswered questions including about whether the plan would be paid for, or how.
  - "This is going to be the biggest tax cut and the largest tax reform in the history of our country and we are committed to seeing this through" … "The president is determined to unleash economic growth for businesses." Treasury Secretary Steven Mnuchin

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The President's Tax Plan – 4.26.17

- Goals for Tax Reform
  - Grow the economy and create millions of jobs
    - Intending to get 3% or more annual GDP growth
  - Simplify our burdensome tax code
  - Provide tax relief to American families-especially middle-income families
  - Lower the business tax rate from one of the biggest in the world to one of the lowest

The President's Tax Plan – 4.26.17

- Business Reform
  - 15% corporate rate for corporations, small businesses and partnerships of all sizes
    - The move to tax partnerships, limited liability companies and other so-called "pass-throughs" at 15% would represent a major tax cut for many businesses (from mom-and-pop grocers to hedge funds). Under current law, those companies pass their earnings and deductions through to their owners, who then are taxed at their individual income tax rates.
  - Territorial tax system
  - One-time repatriation tax allowance
  - Eliminate tax breaks for special interests

The President's Tax Plan – 4.26.17

- Individual Reform - Tax relief for American families, especially middle-income families
  - Three tax brackets (currently there are seven brackets)
    - Top rate for individuals – 35% (currently 39.6%)
  - Double the standard Deduction
  - Protect mortgage interest and charitable contributions
    - Possibly eliminate itemized deductions
  - Repeal alternative minimum tax
  - Repeal 3.8% Obamacare tax on net investment income for individuals earning more than $200,000
  - Repeal estate tax (currently applies only to estates worth more than $5.49 million for individuals and $10.98 million for couples)

The President's Tax Plan – 4.26.17

- Process
  - Throughout the month of May, the Trump Administration will hold listening sessions with stakeholders to receive their input and will continue working with the House and Senate to develop the details of a plan that provides massive tax relief, creates jobs, and makes America more competitive-and can pass both chambers.

The President's Tax Plan – 4.26.17

- Legislative Prognosis
  - The President's goal of enacting a large tax cut faces daunting obstacles in Congress.
  - The Republican Party is divided on how and whether the plan should be paid for. And a Senate rule prevents any tax plan from adding to the federal deficit outside a 10-year window -- if it's enacted with a simple majority rather than 60 votes, a procedure known as budget reconciliation.

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The President's Tax Plan – 4.26.17

- Legislative Prognosis
  - A statement from Senate Majority Leader Mitch McConnell, R-Ky., House Speaker Paul Ryan, R-Wis., and other top GOP lawmakers said:
  - "The principles outlined by the Trump Administration today will serve as critical guideposts for Congress and the Administration as we work together to overhaul the American tax system and ensure middle-class families and job creators are better positioned for the 21st century economy."
  - "We want to look at every avenue, but we think reconciliation is the preferred process, we think that's the most logical process to bring tax reform through," Ryan said to reporters Wednesday.

The President's Tax Plan – 4.26.17

- Legislative Prognosis
  - Senator Chuck Schumer, the Democratic leader, promised opposition to a tax plan that gives breaks to the highest earners.
  - "If the president's plan is to give a massive tax break to the very wealthy in this country -- a plan that will mostly benefit people and businesses like President Trump's -- that won't pass muster with we Democrats," he said Wednesday morning on the Senate floor. "We don't need a tax plan that allows the very rich to use pass-throughs to reduce their rates to 15 percent while average Americans are paying much more."
  - Senate Finance Committee Ranking Member Ron Wyden, D-Ore., issued a statement calling it an "unprincipled tax plan that will result in cuts for the one percent, conflicts for the President, crippling debt for America and crumbs for the working people.

The President's Tax Plan – 4.26.17

- Legislative Prognosis
  - The White House proposal didn't specify whether a tax plan should be revenue-neutral -- if it isn't, the cuts would expire within a decade. It didn't take a position on revenue-raisers that House Republican leaders have proposed, including a border-adjusted tax on imports and domestic sales.
  - The White House proposal mirrors parts of the tax plan the President proposed during the campaign, which would cost the government $6.2 trillion in the first decade, and more than $20 trillion by 2036 after accounting for interest costs and macroeconomic factors, according to an analysis by the nonpartisan Tax Policy Center.

Other Elements of Tax Reform

- April 21, 2017 - Executive Order instituting an immediate review of “all significant tax regulations" since the beginning of 2016 and requiring Treasury to provide an interim report on its findings within 60 days.
  - The interim report will identify regulations that “impose an undue burden” on taxpayers, “add undue complexity” to the tax laws, or “exceed the statutory authority of the Internal Revenue Service.”
  - Second report (within 150 days) recommending specific actions to lessen the burden of the regulations identified in the interim report.
  - 385 Regs; estate tax valuation regs; certain partnership regs.

Other Elements of Tax Reform

- House Republican tax reform "Blueprint,“ released in June 2016.
  - Among other major reforms, the plan would reduce the corporate rate to 20 percent, shift to a destination-based cash flow tax that taxes imports and exempts exports, enact a deemed repatriation tax on deferred foreign-source income, and move the United States from a worldwide tax system to a territorial system.

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CASE STUDY
BFS MANUFACTURER

Blow-fill-seal (BFS) manufacturer of generic prescription and over-the-counter pharmaceutical products involving, primarily, nebulized inhalation solutions. BFS is a continuous line of machines that start with resin being used to blow a plastic vial, fill it and seal it. It then moves to a packaging line and ultimately shipped to customer.

There was a general management issue with a lack of cost controls, resulting in significant cost overruns in building a new production facility and ultimately requiring a refinancing.

Issues encountered

- The company faced the life cycle of the generics business where pricing decreases rapidly after generics enter the market.
- FDA approval of products and new facility caused significant liquidity issues. New product approval was nearly one year beyond forecast.
- FDA finding regarding the new facility resulted in production and revenue delays.
- The Trump administration is promising to reduce the regulatory burden of bringing products to market, but significant investment will continue to be required.

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CASE STUDY
BIOPHARMA COMPANY

Biopharmaceutical company that focuses on the discovery, development and commercialization of therapeutic products for patients with chronic diseases. Product adoption has not met expectations due to the novel nature.

Issues encountered

- The FDA approved product has not met anticipated adoption.
- The product is a novel delivery method of a chronic disease treatment. Adoption by prescribers and patients has been very difficult and the company continues to struggle.
- Given the nature of pharmaceutical product development significant funds have been spent, with very little revenue achieved.

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CASE STUDY
INTEGRATED DEVELOPMENT AND MANUFACTURING COMPANY

The company had a contract with the Department of Defense (DoD) to build a state of the art, single-use, multi-purpose-multi-product, biosafety containment level 3 (BSL-3) capable facility.

Issues encountered

- DoD was slow to pay its invoices, but the company paid its employees and vendors to keep the work flowing, resulting in severe liquidity issues.
- Ultimately, the company was able to complete the facility and sold certain assets to raise funds to pay down its debt.

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Notes

Session 3 • Regulatory & Investigations Part I

Moderator: Joe Robinson, Troutman Sanders

Digital Health Privacy & Cybersecurity Risks
Steve Gravely, Troutman Sanders
Ondrej Krehel, LIFARS LLC

New Regulations & Risks: Hazardous Pharmaceutical Waste
Gregory Blount, Troutman Sanders
Karlie Webb, Troutman Sanders

Value-Based Contracting Trends & Its Implications
Marc Tomassi, Huron
Kenneth Beers, Huron
Chris Cobourn, Huron

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Cybersecurity Threats to the Pharmaceutical and Healthcare Industries

Steve Gravely, Partner – Troutman Sanders
Ondrej Kehel, Founder and CEO – LIFARS

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Healthcare is Under Attack

- 90% of hospitals report at least 1 data breach during the past 2 years, 45% reported 5 or more
- 69% of healthcare organizations believe they are more vulnerable than other industries
- 47% of Covered Entities have little to no confidence in ability to detect loss or theft of patient data

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Healthcare is Under Attack

- Estimated cost of data breaches to healthcare is $6.2 billion
- Average cost of a data breach:
  - <10,000 records = $2.1 million
  - > 10,000 records = $6.0 million
  - "Average" Breach = $7.0 million

Hollywood Presbyterian Medical Center.

Hospital pays hackers $17,000 to unlock EHRs frozen in 'ransomware' attack

By Joseph Conn | February 17, 2016

Privacy & Security

MedStar attack found to be ransomware, hackers demand Bitcoin

Cybercriminals said they'll unlock the data for 45 Bitcoins, and they gave the hospital an option of paying 3 Bitcoins to unlock a single computer.

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3

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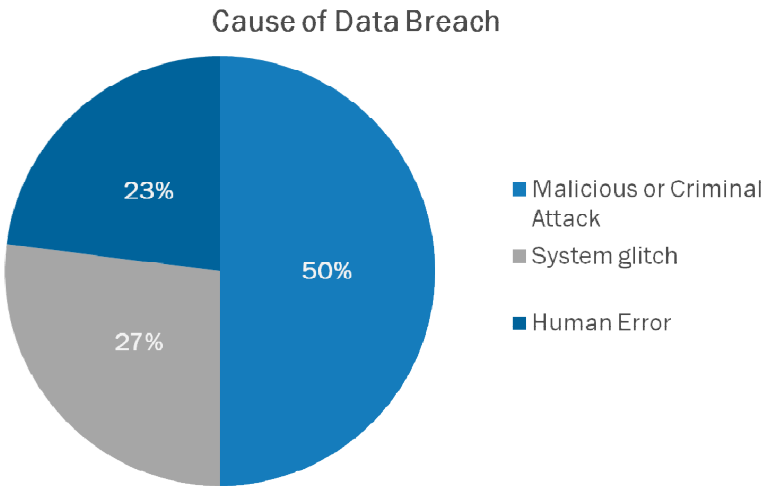
Healthcare is Under Attack



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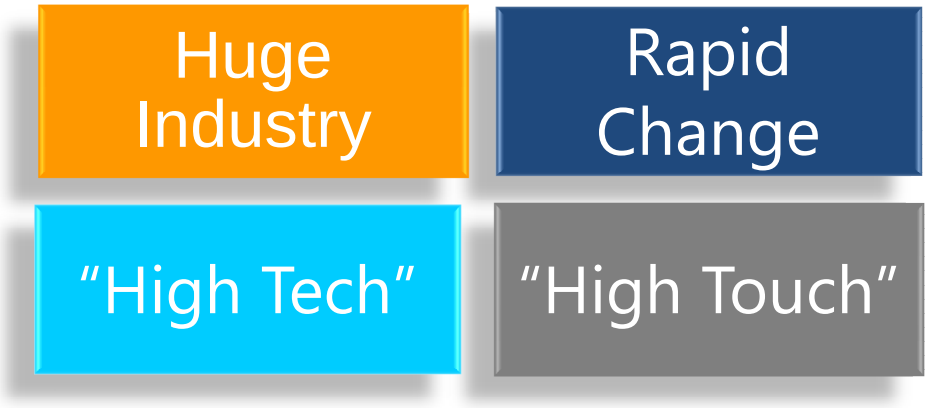
4

Why is Healthcare so Vulnerable?



Healthcare is a Huge Industry

- Healthcare = 20% of U.S. GDP
- 5,627 U.S. Hospitals (AHA 2016 Report)
- 34,878,887 hospital admissions per year and multiple times that many outpatient encounters at doctor offices, hospital outpatient departments, pharmacies, behavioral health centers, etc.
- 4 Billion prescriptions filled at retail pharmacies in 2016
- Medical apps are booming with hundreds of thousands now available
- Creating unprecedented amounts of data – "zettabyte"
  - This data is gold for analytics tools and other legitimate purposes, but it is also gold for cyber-criminals
  - Healthcare records are MANY times more valuable than credit card data on the black market
  - Patient ID, billing records, and clinical information to support billing is the most often targeted data

Healthcare is a Rapidly Changing Industry

- The only constant in healthcare is change!
- Pace of change has dramatically accelerated in recent years
- Rising costs, new technology and demands for greater access are all revolutionizing healthcare

- Unprecedented consolidation of healthcare systems, employment of physicians and data driven care

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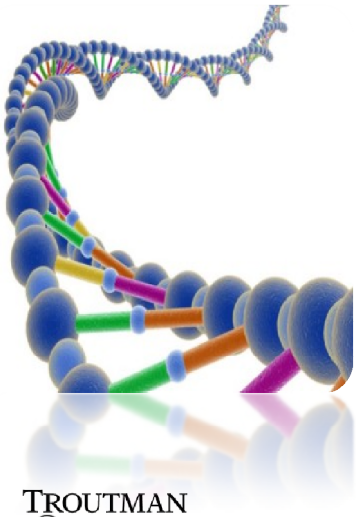
Healthcare is a Rapidly Changing Industry



- Genomics alone is transforming medicine
  - 1st genome cost $2.7 billion; 5 years ago it cost $100,000 and in 2016 it only cost $1,000
  - Genetic mapping of cancers is now routine; some health systems routinely conduct genetic testing on every newborn
  - Consumers have readily available genetic testing like “23 and Me”
  - Many physicians do not even know what to do with all this data
- President Obama’s Precision Medicine Initiative is driving innovation in medical devices and pharma

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Healthcare is "High Tech"

- Delivery of care requires sophisticated technology
  - The average number of connected devices in a modern hospital room is 15
    - Monitors record everything
    - "Alert Fatigue"
  - Drug delivery systems are vastly more sophisticated to target diseased tissue and better deliver medications
  - Robotics and remote monitoring becoming the norm
  - Point of Care systems at bedside
  - Implanted devices (pacemakers, pumps)
  - Virtual doctor visits

Healthcare is "High Tech"

- Digital health records have transformed industry
- Integrated delivery systems often include networks of "legacy" systems with varying levels of security
- Health Information Exchange is connecting health systems across the US to promote "interoperability"
- By 2020, there will be over six billion smart phones with extremely personal information and substantial amounts of medical information
- "Big Data" has arrived:
  - Needed to support analytics tools for care management and population health
  - We are adrift in an ocean of Protected Health Information (regulated under HIPAA) and Personally Identifiable Health Information (not really regulated at all)

Healthcare is "High Touch"

- Healthcare industry is staff intensive
- Most of these staff members have access to EHRs, financial systems and ancillary systems
- Many staff members work at multiple facilities, so they have digital credentials across multiple systems
- Large number of non-employed persons have access (i.e. medical staff)

Healthcare is a Target

- **Maintains large amounts of valuable electronic data, which is not required to be encrypted "at rest"**
- **Increased reliance on technology to deliver care, sometimes with limited human oversight**
- **Dependence on EHRs to document care provided which drives additional care, risk management and billing**

Top Security Challenges in Healthcare

Corporate Espionage

- High stakes intellectual property

Critical Infrastructure

- Supply chain production tampering

Insider

- Multiple FBI stories
- Espionage

Ransomware and Fraud

- Targeting the healthcare and pharma industries

Lack of Visibility

- Flat networks with open points

Third Parties

- Massive outsourcing of IT/ITSEC

Regulations around the Globe

- Challenges to operating in different countries

Security Funding Challenges

- Product budget
- Under staffing and dependence on third parties

Critical Infrastructure Protection (CIP)

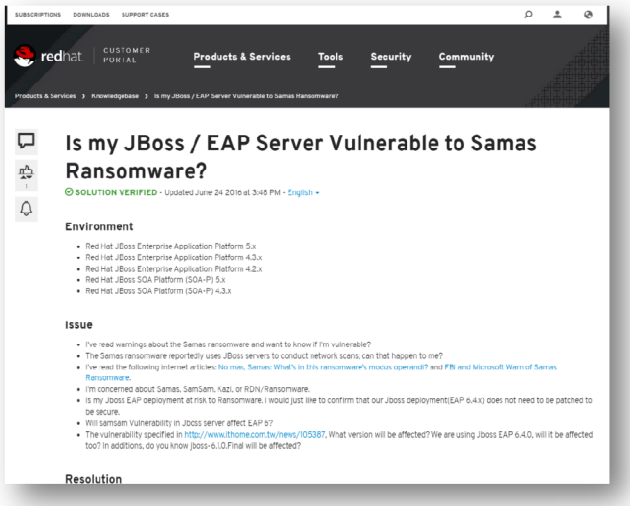
- Pharma manufacturing falls under Critical Infrastructure Protection – an effort made by various intelligence agencies around 10 years ago
- Massive disruption affecting production, formulas and supply chains
- Cases of intrusions and breaches are often not well documented
- Air gap systems affected
- 90% Victims are unaware about being compromised
- Lines are affected via industrial systems vulnerabilities

Corporate Espionage

- APT 10 and other heavily affected pharma companies
- Target is Intellectual Property (IP)
  - Victims experience "ghosts" being deployed into generally flat networks
  - Mainly Asian military groups, some from Eastern block
  - Implants are generally persistent
  - Webshell is deployed to back activities
- Massive regulatory and legal issues

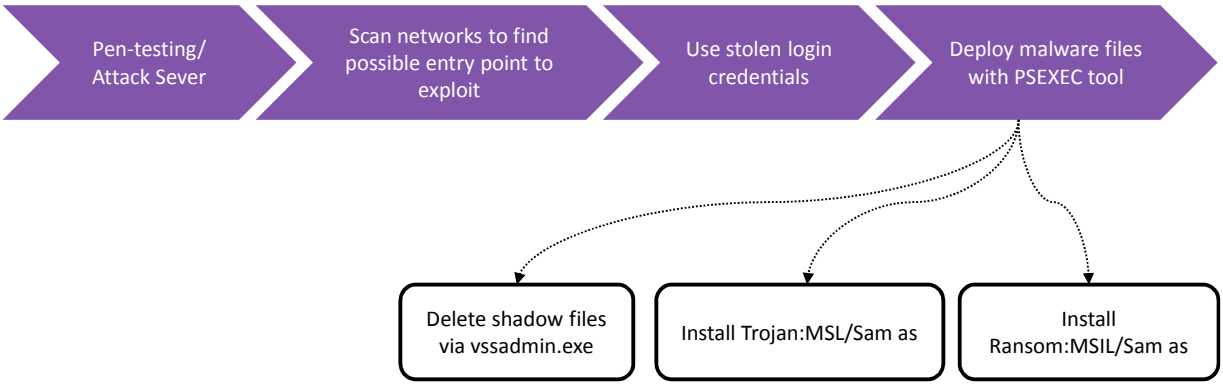
Ransomware

Reuters / May 28, 2016 - "FBI wants U.S. business to help as cyber extortion gains urgency"



Redhat / June 24, 2016 - "Is my JBoss / EAP Server Vulnerable to Samas Ransomware?"

SamSam Ransomware



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CASE - Secondary intrusion via Ransomware

- **The Situation**
  - A medical association of 15 employees could not access files
  - LIFARS responded and quickly discovered the server was encrypted
- **What was the damage?**
  - LIFARS methods recovered the credentials and restored files
  - However, the attacker had access to over 1500 social security numbers that had been forgotten about and left on the server
  - High ranking leaders in association were exposed
  - This led to legal action and notifications causing a loss of reputation and up to $1,000 in damages *per record* for identity protection

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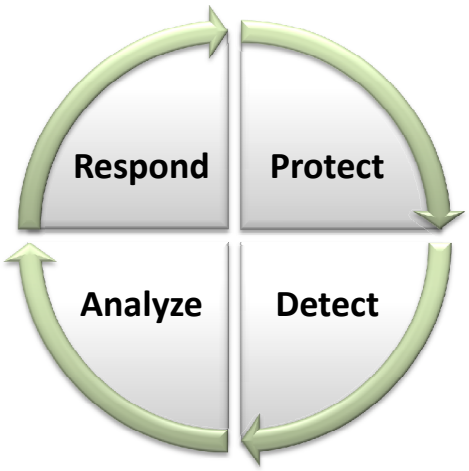
How to Start your Security Program

- Managed Incident Response
- Network and Passive Forensics
- Digital and Ransomware Forensics



- Tabletop and Red Team Exercises
- Procedures Creation
- Third Party Reviews
- Planning, Scoping and Budgeting

- Indicator of Compromise
- Initial Vector of Entry
- Penetration Test
- Access Controls Assessment

- Infrastructure and Endpoint Sensors
- Threat Intelligence
- Detection of APT, Phishing and Fraud

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Lots of Liability

- HIPAA
  - OCR continues aggressive investigations and settlements
    - Lost devices with unencrypted data lead the parade
    - CardioNet recently settled for $2.5 Million, Children's Hospital Dallas settled for $3.4 Million earlier this year
  - OCR 2016 guidance on non-HIPPA regulated entities collecting data
    - OCR cannot sanction them but can sanction the covered entities or business associates that share ePHI with them
  - OCR 2016 guidance on ransomware
    - Presumed to be a reportable breach unless you can prove that ePHI not accessed
    - Must document this and retain that documentation

HIPAA

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Lots of Liability

- FTC
  - Section 5 of the FTC Act-"unfair and deceptive trade practices"
  - Much broader reach than HIPAA
  - Long line of cases involving unauthorized use of customer data
  - Settlements are onerous – $$$ and 20 year compliance requirements
  - FTC moving toward a "strict liability" position whenever data is exposed
- Lawsuits
  - HIPAA does not provide a "private right of action"
  - State data breach laws often do allow affected persons to sue and allow state AGs to file suit
  - Emerging common law "standard of care" to protect privacy of ePHI using HIPAA as the legal standard

Lots of Liability

- Class Action lawsuits have become a significant legal and financial threat
  - Explosion in class action lawsuits related to data breach
  - US Chamber Institute for Legal Reform just released a report called "Engineered Liability"
    - Premise is that plaintiff's class action firms have discovered data breach and it is the new "asbestos"
    - 4 class action law firms dominate this space per report
    - Causes of action are routinely breach of contract, common law negligence and breach of fiduciary duty
    - Emerging causes of action include "intrusion on seclusion", conversion and unjust enrichment
    - Companies spent $1.5 Billion in 2015 on outside counsel to defend these cases, $1.67 Billion for 2016
  - Healthcare is generally held to a higher standard given the sensitivity of the information and the, perceived, vulnerability of the patient
  - The risk of class action lawsuits fundamentally changes the calculus for data privacy and security professionals in all business, especially healthcare

Liability Beyond Mere Data Loss

- Connected Devices are everywhere in healthcare
  - "…just think of the consequences if a hacker were able to remotely recalibrate a medical device…" Careful Connections, Building Security in the Internet of Things, FTC
- Summer of 2015 – FDA issued an industry alert to US healthcare providers to stop using the Symbiq IV infusion pump due to its serious vulnerability to being hacked
  - This was the first time that the FDA issued such an alert, it will not be the last
- January 2016 – FDA published its Postmarket Management of Cybersecurity in Medical Devices, Draft Guidance, to alert the medical device industry to the FDA expectations re: cybersecurity

PHARMA LAW CONFERENCE 2017

Liability Beyond Mere Data Loss

- August 2016 GAO issues Report to Senate HELP calling upon HHS to strengthen security and privacy guidance for ePHI
  - Healthcare part of the nation's critical infrastructure per Presidential Executive Order 13636 issued February 2013
  - GAO report emphasized importance of a comprehensive risk assessment – CardioNet
  - GAO urges HHS to adopt the 2014 NIST Framework for Improving Critical Infrastructure Cybersecurity
  - Urges ramped up Phase II audits by OCR

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The Latest on Hazardous Pharmaceutical Waste Regulation and Risk

Gregory W. Blount, Partner – Troutman Sanders
Karlie Clemons Webb, Associate – Troutman Sanders

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Roadmap

- New U.S. EPA hazardous waste rules, applicable to pharmaceutical manufacturers, effective May 30th
- Regulatory scrutiny on retailers and reverse distributors regarding manufacturer credit will put pressure on manufacturers and this system
- California focused on pharmaceuticals, including OTCs, going to landfills and ultimately into water supply will increase pressure on producer responsibility and other risks

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U.S. EPA Hazardous Waste Generator Improvements Rule

- Applies to all hazardous waste generators
  - Regardless of industry sector
  - Regardless of how much hazardous waste generated
- Effective May 30th
  - Immediately in Iowa and Alaska
  - Other states must adopt portions of new rule that are more stringent than existing federal rule
- On appeal to D.C. Circuit Court of Appeals by American Chemistry Council

U.S. EPA Hazardous Waste Generator Improvements Rule – Major Points

"Condition for Exemption" concept may subject generators to more stringent treatment/storage/disposal facility requirements.

EPA says: "The primary legal consequence of *not* complying with the condition for exemption is that the generator who accumulates waste on site can be charged with operating a non-exempt storage facility . . . ." 81 Fed. Reg. 85746.

U.S. EPA Hazardous Waste Generator Improvements Rule – Major Points

Allows for Episodic Generation:
A Very Small Quantity Generator or Small Quantity Generator may temporarily generate a hazardous waste quantity that would push them to a higher generator category, without complying with the more stringent requirements.

Subject to multiple conditions, such as:

- Only one episodic event per year, unless EPA (or State) grants request for a second, in which case there may be no more than one planned and one unplanned per year
- Must notify EPA (or State) within 72 hours of unplanned event or at least 30 days before a planned event

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U.S. EPA Hazardous Waste Generator Improvements Rule – Major Points

Modifies requirements related to closing a hazardous waste accumulation unit.

- Requirements are more onerous than prior regulations
- Specifically applies to “containers”
- If closure requirements are not satisfied, must close as a landfill, triggering post-closure care and permitting requirements

U.S. EPA Hazardous Waste Generator Improvements Rule – Major Points

Revised Labeling Requirements – must now label hazardous waste containers with indication of content hazards (e.g., characteristic)

U.S. EPA Hazardous Waste Generator Improvements Rule – Major Points

- In addition to full Contingency Plan, Large Quantity Generators must prepare and submit a "quick reference guide" to emergency responders
- Eliminates requirement to list home phone and address on Contingency Plan. Allows for "emergency telephone number"
- Allows LQGs to list a 24-hour position, rather than a specific person as the Emergency Coordinator

Regulatory Scrutiny on Retailers and Reverse Distributors Regarding Manufacturer Credit

- Issue: When is a hazardous pharmaceutical a waste?
- When does the intent to discard occur?
- CA, N.M., CO, MN, CT, and FL are all looking at issue differently from U.S. EPA
- If all hazardous pharmaceutical waste must be managed at the pharmacy or hospital, then how will credit arrangements need to be modified?

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Regulatory Scrutiny on Retailers and Reverse Distributors Regarding Manufacturer Credit

- How will drug integrity be assured at thousands of points of control?
- Most complicated in CA where state agency recently rejected using reverse distribution to defer point of waste generation, but this position further complicated by overlapping coverage under CA Medical Waste Management Act for certain pharmaceutical wastes

California Focused on Pharmaceuticals, Including OTCs, Going to Landfills and Ultimately into Water Supply

- Policy discussions in CA [AB 514] have also led to activist positioning regarding the fate and transport of pharmaceutical waste in the water supply
- Push for producer responsibility and take back programs also in play
- This positioning and stated fear has been extended to OTCs, including pain killers because of their uptake by organisms and the lack of treatment by sewer systems, even if landfilled

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California Focused on Pharmaceuticals, Including OTCs, Going to Landfills and Ultimately into Water Supply

Without natural background levels or an exemption from remedial statutes such as Superfund, the risk for addressing clean up of the nation's water supply is evident. E.g. rocket fuel and perchlorate or "Scotch Guard" and PFOA/PFOS

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TRADITIONAL U.S. CONTRACTING IS LIMITING IN ABILITY TO REWARD VALUE AND INNOVATION

Payer Contracting Today

- ~1-3 year cycles to set unit rebates and discounts
- Payers move from "open" to "closed" formularies and shift costs to patients
- Heighten competition for limited formulary positions – "1 of 2", "1 of 1" contracting and niche carve-out
- Question – privately and publicly – the value and evidence of novel therapies

Pain Points to Reward Value

1. Horizon limited to 3 years
2. Economics limited to benefits payers manage, risks they own
3. Economics unit-based, but units and value varies across indications and populations
4. Rebates negotiated on evidence available at launch
5. Primed to extract price concessions, not to incent evidence generation or to sustain innovation

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VALUE BASED CONTACTING IS ONE INNOVATIVE MODEL BEING EXPLORED

NEARLY HALF OF PAYERS SAY THEY HAVE OR SOON WILL ADOPT

Capitation

Indication-Level Pricing

Address inter-patient and cross-indication variations in dosing and incremental value

Installment Payments

Support therapies that deliver a lifetime of benefit but front-load the cost (e.g., genetic and cellular therapies)

Value Based Contracting

The Promise …

- Shift risk in translating trial efficacy to real world effectiveness to manufacturer, better positioned to assess/mitigate/assume it
- Align manufacturer and payer incentives to study and establish real world benefits
  - Payers direct spending to therapies that help them lower their overall costs while maintaining quality of care for patients
  - Manufacturers get return on investments to establish benefits, promoting an environment of sustainable innovation

… The Reality?

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Source: EMD Serono Specialty Digest

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ADOPTION HAS LAGGED EUROPE, REFLECTING A MORE SEGMENTED PAYER LANDSCAPE

Factors working for (√) and against (⊗) value-based contracts

Europe

- ✓ Single-payer system
- ✓ Formal HTAs and budget limits; willingness to deny
- ✓ Reference pricing

U.S.

- ⊗ Opaque, variable, and proprietary medical billing
- ⊗ Reference to appropriately-protected patient data
- ⊗ Split management of medical and pharmacy benefits
- ⊗ Historically-open medical benefit formularies
- ⊗ Concern over lowering CMS “best price” *(limits rebate)*
- ⊗ Uncertain future benefit and risk structure

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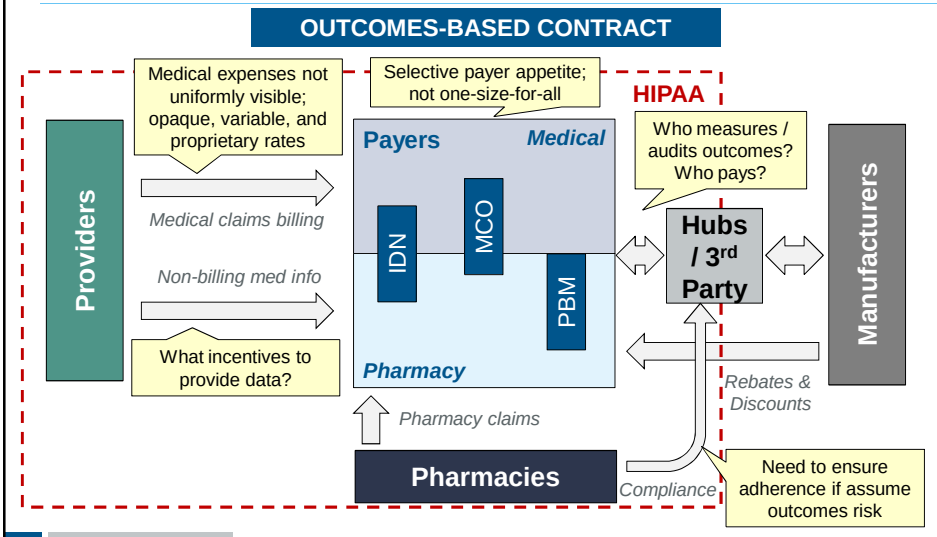
COMPLEXITY HAS LIMITED USE BEYOND THOSE TYING TO "EASY" MEASURES (e.g. COMPLIANCE)



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SELECTED EXAMPLES OF VALUE BASED CONTRACTS

Rebif™ *(EMD Serono : Cigna)*	*High-dose beta-interferon for relapsing remitting MS*	▪ Two years; Cigna tracks hospitalizations and ER visits, adherence (MPR) ▪ Discounts tied to adherence and event rates
Repatha™ *(Amgen : Harv. Pilg., Cigna)* **Praulent™** *(SA,Regeneron : Cigna)*	*PCSK9 inhibitor to lower LDL-C in patients with FH or ASCVD needing more lowering at max statin dose*	▪ If LDL-C lowered in real world similarly to clinical trial, negotiated rate holds, else discount is increased ▪ Exclusive option on "closed" formulary, coverage of both agents on "open" formularies
Harvoni™ *(Gilead : Catamaran, Cigna)*	*HCV combination therapy competing with AbbVie*	▪ Catamaran makes product exclusive in HCV through their Specialty Pharmacy ▪ Cigna makes Harvoni exclusive for GT1, with rebate tied to real-world SVR
Entresto™ *(AZ : Express Scripts)*	*Oral ARB/NI for CHF, superiority vs. ACEi in mortality, hospitalizations*	▪ Rebate varies with real-world hospitalization rate vs. trial data

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FOCUS HAS BEEN ON TYING REBATES TO "WARRANTY" THAT REAL-WORLD USE, AS LABELED, LIVES UP TO TRIAL DATA

Common Themes from Value Based Contracts Executed to Date

- ❖ The drugs involved often face significant competitive pressure for formulary position – e.g., the PCSK9 inhibitors, HCV therapies
- ❖ Contracts rely upon compliance or upon a readily-measured outcome directly tied to the drugs' intended use and end points from label

Observations from Engaging Payers on Value Based Contracts

- ➢ Limited appetite to explore outcomes not established in pivotal trials; rather focus in on "warranty" that real-world effectiveness match trials
- ➢ Little interest to support pricing by crediting offsetting medical savings
- ➢ Hesitancy to contract for more than ~3 years (no long term benefits)
- ➢ Reserve efforts for drugs with major budget impact, else not worth it

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A RANGE OF CONTRACT TYPES CAN BE PURSUED

Performance-Based Pricing

- Upside Model: up-front price with manufacturer sharing in any subsequent savings realized
- Downside Model: up-front price with manufacturer sharing in any subsequent losses realized
- Cohort Performance: price tied to patient population performance compared to control group
- Money-Back Guarantee: up-front price with refund where product not/less than effective
- Try-Before-You-Buy: free product up-front with price charged only where product effective

Course of Therapy Pricing

- Flat Pricing: single price per course of therapy regardless of amount of product needed
- Pricing Cap: per unit price up to certain volume with remainder free where additional product needed
- Interest is increasing, but difficult to implement

Indication-Based Pricing

- Same product has different pricing depending on indication for which it is used
- Increasing in use / exploration as more drugs are investigated across multiple indications

Annuity Pricing

- Product price/cost shared across payers that cover patient across his/her lifetime
- Nascent methodology

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AS USE EXPANDS, PREPARATION IS NEEDED TO MITIGATE RISKS AND CAPTURE OPPORTUNITIES

Payers' Goals with VBCs

- ❑ Increase predictability of pharmacy spend – stabilize margins & premiums
- ❑ Signal to customers that they pay only for drugs that work
- ❑ Differentiate on innovative models to balance quality of care and cost containment
- ❑ Off-load risk and extract concessions where they have power over manufacturers

Implications for Manufacturers

- ❑ Cost-of-entry in major competitive classes to gain formulary coverage
- ❑ Contracting economics become more complex than comparing rebates & discounts to volume loss from market access suppression
- ❑ Exposure to adherence risk and need to estimate real-world vs. trial outcomes at time of launch

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VALUE BASED CONTACTING

KEY CONSIDERATIONS FOR LIFE SCIENCES COMPANIES

Commercial Strategy	Evaluate your products and customers to prioritize where to focus your VBC efforts & resources
Research & Development	Consider the clinical development implications of a VBC and ensure those requirements are included in R&D planning discussions
Commercial Analytics & IT	Assess what technology platforms or partnerships are needed to support VBCs from a data collection & analytics standpoint
Compliance	Define regulatory sign post events needed to pave the way for VBCs at your organization, and build relationships with the appropriate stakeholders
Government Pricing	Map out the implications of a VBC on Government Pricing calculations, and anticipate potential statutory amendments addressing VBC arrangements

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HURON Whitepaper, 2016
David Gilman, Managing Director ● Ilina Sen, Senior Director ● Kirsten Kester, Manager
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A CONCERTED CORPORATE EFFORT IS NEEDED TO PREPARE

- Build analytics to evolve HEOR from value-messaging aid to a core valuation tool
- Define a framework of prototypical designs; identify and mitigate measurability, economic, executional challenges
- Obtain stakeholder consensus on the situations and objectives in which to pursue
- Work with new product and in-line brand teams to identify value-based contracting opportunities within this framework; and align to corporate/portfolio strategies
- Articulate the processes through which deals are modeled, designed, tested, and communicated to/through account managers; with supporting playbooks and training
- Engage payers to identify receptive parties and to foster mutual understanding of the uses and objectives of value based contracting
- Monitor evolution in health IT, benefit design, and other factors affecting the scope and structure of value based contracts, and adapt strategies/plans accordingly
- Articulate a corporate vision that promotes evolution of value based contracting into a tool that promotes sustainable innovation and translate to advocacy

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COMPLIANCE ENVIRONMENT

SIGNIFICANT UNCERTAINTY SURROUNDS VBC

Anti-Kickback Statute	• AKS prohibits offering or receiving remuneration (broadly defined) to induce or reward referrals for items or services paid for by federal HC programs. • Statutory and regulatory safe harbors protect certain arrangements from AKS liability, but it is unclear how enforcement agencies would apply these to value-based arrangements. • Because the AKS can be broadly interpreted, Congress and the OIG have specifically excluded other transactions from AKS liability, but no such clarity exists for value-based purchasing agreements.
Medicare Part D Requirements	• Off label communications or uses could implicate coverage itself under the Part D program, which does not cover certain off-label uses
Patient privacy	•HIPAA privacy laws may limit the exchange of personal health information for purposes of implementing value-based agreements, inhibiting the transfer of needed information between participants in the value-based data chain.
Off-Label Promotion/Unsubstantiated Claims	•Value measurement criteria and even communication of agreements that are a part of certain value-based arrangements could implicate FDA "pre-approval marketing" or "off label marketing" concerns.

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LIFTING THE BARRIERS TO ADOPTION OF VBC ARRANGEMENTS

VBC arrangements can be made more feasible by creating a policy environment conducive to allowing health plans and manufacturers to enter into VBC arrangements. This may include:

Creation of legislative/regulatory exceptions for Best Price and all other relevant government pricing calculations and requirements as they relate to products sold or transferred under value-based contracts

Additional safe harbors to the federal Anti-Kickback Statute (AKS) that protect value-based contracts from AKS liability.

The OIG could update guidance in order to explicitly protect VBC arrangements when certain criteria are met.

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GOVERNMENT PRICING

RECENT PERSPECTIVES AND/OR GUIDANCE FROM CMS

- On November 20, 2015, the US Department of Health and Human Services convened a Pharmaceutical Forum: “Innovation, Access, Affordability, and Better Health” to address value-based pricing.
- On March 8, 2016, the Centers for Medicare & Medicaid Services (CMS) released the proposed **“Part B Drug Payment Model rule** which plans to test a new Medicare Part B payment model for reimbursement of ASP products.
  - The objective of the proposed rule is to test whether an alternative payment structure and/or use of value-based purchasing tools can reduce Medicare spend and improve quality of care to Medicare beneficiaries.
- On July 14, 2016, **CMS issued Manufacturer Release #99 (State Release # 176) which provided minimal guidance on value based purchasing (VBP) arrangements.**
  - The release indicated that manufacturers should refer and adhere to existing regulations when determining which transactions are eligible for Best Price, which is not new guidance.
  - The guidance did, however, encourage manufacturers to consider VBP arrangements with state Medicaid agencies.
  - Encouraged any manufacturer that has these arrangements to submit any issues or questions to the CMCS Division of Pharmacy at RxDRUGPolicy@cms.hhs.gov.

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APPLYING CURRENT CMS VBC GUIDANCE TO CURRENT PRICING PRACTICES

No Changes From Current Guidance

Although CMS issued a manufacturer release addressing VBC arrangements, this guidance does not change how manufacturers should treat VBC related prices and discounts in their government price calculations

Reasonable Assumptions

Absent specific regulatory changes or guidance, manufacturers must make "reasonable assumptions" when including or excluding VBC prices and discount in price calculations

Include/Exclude Determinations

VBC prices and discounts are no different than other commercial prices and discounts and the same methodology should be applied when making include/exclude determinations

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GP IMPLICATIONS OF VBC
(1 OF 2)

Calculations

- At this time, VBC discounts would impact AMP, BP, ASP and NFAMP (for certain products) calculations
- Reduced prices and/or discounts would be included in government price calculations and could lower the aforementioned prices

Bona Fide Service Fees (BFSF) and Fair Market Value (FMV)

- If manufacturers pay fees in connection with VBC discounts (e.g., fees to the managed care entity for monitoring discounts), those fees would have to undergo a BFSF assessment and FMV evaluation
- This could prove to be challenging if the services and fees are structured in such a way that makes a cost-based analysis difficult and/or the service is so new there are no comparable for a market-based analysis

Bundled Arrangements

- Value-based contracts could easily create bundled arrangements that would have to be unbundled (i.e., discounts have to be allocated across products and/or time periods) and depending on how the arrangements are structured, the discount allocation could be difficult

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GP IMPLICATIONS OF VBC
(2 OF 2)

"Free Goods"

- Arrangements where manufacturers accept risk for treatment failure would not currently satisfy "free good" exclusion requirements
- If manufacturers and plans enter into VBCs where the manufacturers accepted risk for treatment failure (e.g., the health plans only pay for drugs with positive treatment outcomes), manufacturers would have to treat the sale as a zero dollar sale in their government price calculations
- This would drive down AMP/ASP values and would set $0.00 BPs

Lagged Price Concessions

- If VBC discounts are tied to patient outcomes, how lagged will those discounts be and are current smoothing methodologies sufficient to assess the true value over large periods of time
- For BP determinations, will manufacturers be able to tie VBC discounts back to an earned period?
- Non-unit based prices and/or discounts (e.g., basis is a course of therapy or treatment regimen) may be problematic because government prices are calculated on a per unit or per package basis

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VALUE BASED ARRANGEMENTS AS A "TEMPORAL BUNDLE" AND POTENTIAL MEDICAID/PHS IMPACTS
(1 OF 2)

Current Requirements	• Best Price (BP) is based upon Period Earned date • BP reporting is due thirty (30) days after the end of each quarter
Application to Value-Based Arrangements	• Because Value Based Arrangements may include a certain time period that must elapse before metrics can be calculated, each Arrangements would most likely be treated as a "Temporal Bundle" for Medicaid Best Price calculations and reporting
Temporal Bundle Treatment: Implications	• For BP, this will require (based upon a rolling quarterly process): ✓ Determination of what to report as an initial estimated BP ✓ Identification of the true up timeframe for a Temporal Bundle ✓ Creation of a True Up Allocation methodology • AMP would likely be based on transactions & adjustments in the quarter in which they occur; True Up Transactions would be included in the calculation for that quarter (within the 12 Month rolling average for price concessions)

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VALUE BASED ARRANGEMENTS AS A "TEMPORAL BUNDLE" AND POTENTIAL MEDICAID/PHS IMPACTS
(2 OF 2)

Current Requirements	• Best Price (BP) is based upon Period Earned date • BP reporting is due thirty (30) days after the end of each quarter
Application to Value-Based Arrangements	• Because Value Based Arrangements may include a certain time period that must elapse before metrics can be calculated, each Arrangements would most likely be treated as a "Temporal Bundle" for Medicaid Best Price calculations and reporting
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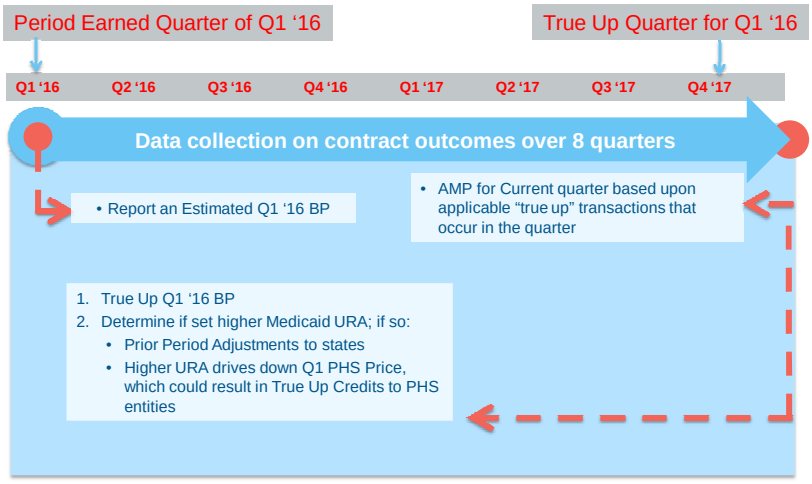
GP DATA COLLECTION & REPORTING TIMELINE



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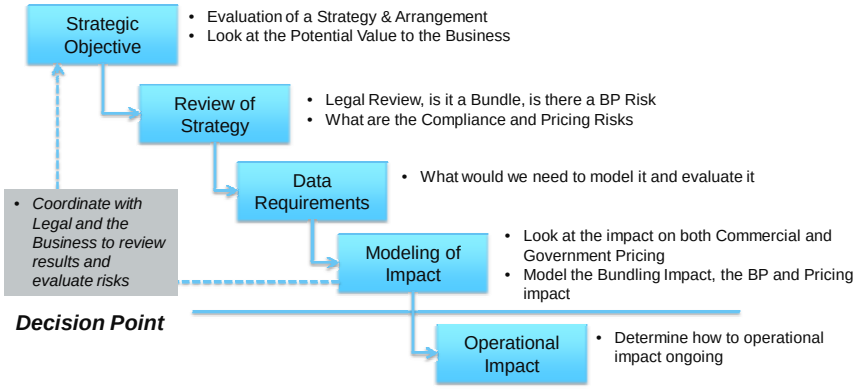
VBC IMPLEMENTATION CONTINUUM

BRIDGING STRATEGIC AND OPERATIONAL ELEMENTS



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Notes

Session 4 • Regulatory & Investigations Part II

Moderator: Joe Robinson, Troutman Sanders

The Changing Perceptions of Patient Assistance Programs & the Responses to Audit Takeaways
Savaria Harris, Johnson & Johnson

Patient Assistant Programs & Charitable Foundation Audit Sensitivities
Mark DeWyngaert, Huron

The Criminalization of Drug Pricing Strategies
John West, Troutman Sanders
Bill Hurd, Troutman Sanders

A Summation: Current Regulatory & Litigation Responses to the Changing Legal Landscape
Aurora Cassirer, Troutman Sanders
Joe Robinson, Troutman Sanders

HOW DRUG PRICING DEBATES CHANGED THE PERCEPTION OF PATIENT ASSISTANCE

Savaria Harris, Johnson & Johnson

THIRD ANNUAL PHARMA LAW CONFERENCE
APRIL 27, 2017

ELIZABETH WARREN AT VALEANT PHARMACEUTICALS HEARING ON BUSINESS PRACTICES

HISTORY OF PATIENT ASSISTANCE

How Did We Get Here?

- "Patient Assistance" began in the industry in the early 1990s.
  - Response to allegations by politicians, chiefly President Clinton, of industry "price gouging."
  - Idea to provide "no-or-low cost" prescription products to any patents who could not afford them.
    - Free for those without insurance.
    - Low cost for those who were under-insured.
- Relatively straightforward eligibility criteria based primarily on income relative to poverty limit and number of members in family.
- BUT! Economic challenges in 2002 and 2003 (US Recession) and 2007-2008 (Financial Crisis) increased the number of uninsured and "under-insured" populations.

INDUSTRY RESPONSE TO ECONOMIC CRISIS

- Industry responded with expanding the criteria to afford increased access to Patient Assistance to help those whose financial needs had grown during challenging economic times.
  - Expanded to individuals with basic health coverage if "functionally uninsured" due to the combination of the poor economy, high deductibles, and an income of $40,000 or less.
  - Expanded to include low income patients with inadequate insurance (e.g., no product coverage).
  - Even after Medicare Part D, PAPs began to help participants paying off the $3,700 annual copayments in the Medicare Part D coverage gap ("donut hole").

PATIENT ASSISTANCE EXPANDS TO MARKET ACCESS

- By 2013, manufacturers had begun to offer a variety of options beyond simply "low-or-no" cost drugs. These included:
  - Free Product
  - Copayment Assistance
  - Benefit Review
  - Education and Referral to Patient Advocacy Groups
  - One-on-One Counseling (advising patients on reimbursement options and the different market-access approaches available to them, including PAP-generated coinsurance and copay cards that help needy patients get access to specific therapies)

MODERN LANDSCAPE OF MANUFACTURER "PATIENT ASSISTANCE"

Manufacturer Patient Support Programs: Common Features

Type	Intended Population	Income Criteria	Typical Benefit	Distribution channel
Traditional PAP	Uninsured	Yes – manufacturer criteria	Free product	Limited distributor or retail benefit card
Institutional PAP	Uninsured	Yes – manufacturer criteria or stricter	Free product (inventory replacement)	Hospital
Independent foundation	Underinsured – government or private	Yes – established by foundation	Free product, cost-sharing assistance, or premium assistance	Retail
Medicare D PAP	Insured – Medicare Part D	Yes	Free product	Limited distributor or retail benefit card
Vouchers, coupons, and savings cards	Non-government insured or uninsured	No	Cost-sharing assistance	Retail

(RE)-ENTER THE DRUG PRICING DEBATES

SPECIAL CMTE REPORT CONCLUSIONS

"[S]elf-serving motives were often critical to understanding many patient assistance programs. ..Thus, what would seem to be a means to assist patients who are most in need was transfer instead into a mechanism to segment the market to allow the company to maximize profit from taxpayers."

"[T]here is reason to be concerned that companies may use copay assistance to steer patients toward higher price drugs, resulting in higher expenditures for federal health care programs and commercial providers."

"While copay coupons appear to help some patients, taxpayers and Medicare beneficiaries are absorbing the increasing costs of exorbitantly priced pharmaceuticals."

DEBATE GOES MAINSTREAM

"Drug companies aren't contributing hundreds of millions of dollars for altruistic reasons..."
– Bloomberg

"[The Access Programs] defense is becoming problematic in discussions about drug pricing....Some experts believe that, **in pricing drugs high, companies actually create the need for the patient assistance programs**.
- Medial Marketing & Media

*"The intent of these donations...is to 'deflect criticism of high drug prices. Meanwhile, they're **bankrupting the health-care system**.'"* - Bloomberg

"Experts warn that the coupons, increasingly being used by dozens of companies, are **sharply adding to the nation's medicine bill**. That cost is passed along to most Americans through higher insurance premiums and taxes needed to pay for government health programs." – LA Times

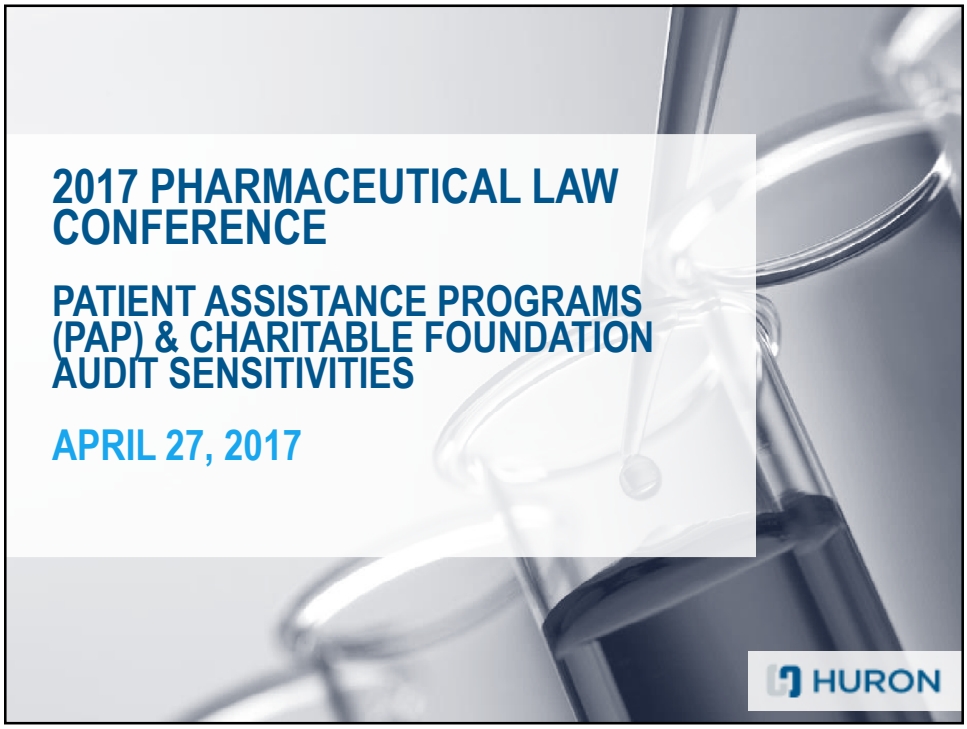
"They allow corporations to look like good corporate citizens,'...but are actually 'a thinly veiled program to drive up revenue.'" – LA Times

EXTERNAL RISKS ON THE HORIZON

- Bi-Partisan attacks on drug pricing to continue
- Continued regulator use of "patient assistance" as buzz word for "veiled manufacturer marketing strategies"
- Rejection of Expensive Drugs on Formularies by Pharmacy Benefit Managers
- Emerging litigation risks (domestically and abroad) under competition law theories attacking drug pricing.
- Emerging litigation under False Claims Act that discounts to cash paying patients should be incorporated into government reimbursement

KEY TAKE AWAYS

- "Patient Assistance" is **not** an absolute defense to allegations and/or the perception of high drug costs
- Be cognizant of regulatory climate when communicating about the patient assistance and support programs, especially the foundation. **Just because the program has been approved, does not mean you can discuss it without limitations**
- Consider that new patient assistance and/or support strategies may be seized upon by regulators and plaintiffs to argue that Janssen is seeking to disguise higher drug prices
- Remember that there is an emerging theory under the FCA that discounts to patients should be incorporated into government reimbursement
- Bi-partisan support for downward pressure on drug-pricing is likely to cause the model to be revisited for changes



PRESENTER

MARK DEWYNGAERT
Managing Director
Huron Consulting Group

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AGENDA

1 Recent Headlines & Enforcement Actions

2 Overview of Patient Assistance Programs

3 What Can You Do?

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RECENT HEADLINES & ENFORCEMENT ACTIONS

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RECENT HEADLINES

Bloomberg

May 19, 2016

How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes

USA Today

June 8, 2016

Drug Co-Pay Assistance Programs Facing Increasing State and Federal Scrutiny

LA Times

December 21, 2016

Drug Companies Rapidly Raised Prices on Life-Saving Drugs

Companies that donate to charitable patient assistance foundations have faced **an uptick in scrutiny by the media, the OIG, and states' attorneys** in the past two years; **the pace of subpoenas has increased significantly** – eight companies have publicly disclosed subpoenas in the past 12 months alone.

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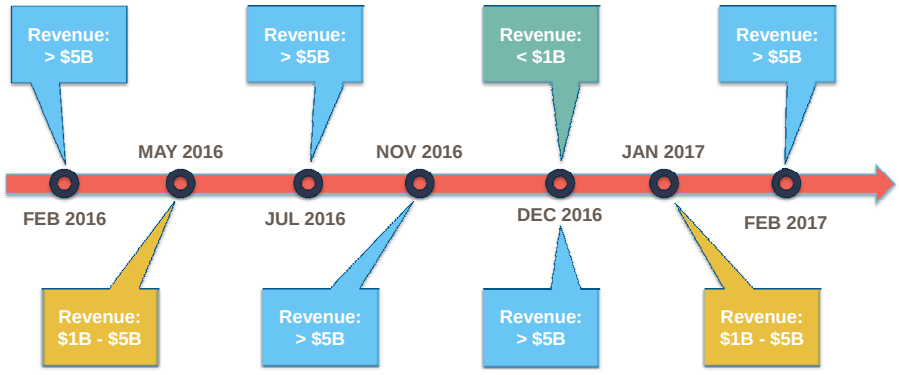
RECENT ENFORCEMENT ACTIONS

Over the past year, the DOJ and US Attorney's Office in Massachusetts have issued subpoenas to pharmaceutical companies of various sizes requesting information and documents about the company's relationships with charitable patient assistance programs.



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OVERVIEW OF PATIENT ASSISTANCE PROGRAMS

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PROGRAMS OPERATED BY MANUFACTURERS

"Pharmaceutical manufacturers may sponsor patient assistance programs that provide financial assistance or drug free product (through in-kind product donations) to low income individuals to augment any existing prescription drug coverage."

– Centers for Medicare & Medicaid Services

Typical patient eligibility requirements may include:

- Limited or no prescription drug coverage from private or public sources
- A demonstrated financial need based on set income and asset limitations
- Proof of US residence or citizenship

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PROGRAMS OPERATED BY CHARITABLE FOUNDATIONS

Third-party charitable foundations may offer patient assistance programs based on therapeutic area, disease type (e.g., chronic, life-threatening), patient population, etc.

Examples of charitable patient assistance foundations include:

NORD® National Organization for Rare Disorders

PAN Foundation

HealthWell Foundation®
When health insurance is not enough.®

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ADDITIONAL TYPES/SOURCES OF ASSISTANCE

Benefits Investigation	Prior Authorization Support	Appeals Assistance
Free Drug Programs	Insurance Gap Bridge Programs	Rapid Therapy Initiation Assistance
Sample Programs	Replacement Programs	Ancillary Services

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WHAT CAN YOU DO?

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KEY CONSIDERATIONS

The following slides provide key considerations for assessing your company's patient assistance programs and processes.

- Establish or update standard processes to justify activities and arrangements
- Understand the volume of therapeutic areas and products covered

- Review processes and charitable relationships
- Determine if controls are in place
- Determine if eligibility criteria is consistently applied
- Catalog programs and develop risk profiles
- Distinguish traditional PAPs vs. other patient support programs
- Identify third parties
- Confirm CMS definition

- Include PAP activities in auditing and monitoring program
- Require periodic performance reports and certifications
- Review and verify services performed by vendors and foundations
- Review trends, outliers, and program metrics

- Develop a vision
- Identify areas for improved support
- Develop summary of qualifications by vendor and foundation
- Assess approach to optimize operations and compliance

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KEY CONSIDERATIONS

Justify the Need

- Do you have standard processes to help ensure that each activity and arrangement can be appropriately justified?
- Do you understand the volume of therapeutic areas and products covered by any patient assistance charity with which the company might want to enter into an agreement?

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KEY CONSIDERATIONS

Conduct Independent Risk Assessment

- Does your annual risk assessment include a review of our PAP processes and charitable relationships?
- Are controls in place to ensure assistance is provided only to patients that meet the appropriate criteria?
- Is eligibility criteria consistently applied?
- Have you cataloged the different types of PAP arrangements your company has in place and developed a risk profile for each arrangement?
- Do you distinguish between traditional PAPs for poverty level vs. other patient support programs (e.g., coupon programs)?
- Have you identified the different third parties and charitable organizations with which your company does business?
- Have you confirmed that all PAPs meet the CMS definition for government pricing exclusions?

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KEY CONSIDERATIONS

Audit & Monitor

- Are PAP activities and services (full range of products, customers, vendors, foundations) included in your company's auditing and monitoring program?
- Do you require PAP vendors and charitable foundations to provide periodic performance reports, including certifications that they are applying the applicable eligibility criteria and/or complying with OIG requirements?
- Have you developed and implemented a process to review and verify the services performed by PAP vendors and charitable foundations?
- Do you periodically review monitoring trends, outliers, and certain program metrics (e.g., the number of applications approved/denied)?

Note: When conducting auditing and monitoring activities, companies must pay strict attention to OIG guidelines that prohibit the disclosure of certain information between charitable foundations and their corporate pharmaceutical donors.

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KEY CONSIDERATIONS

Refresh & Refine Patient Support Approach

- Have you developed a plan for what your company wants to achieve broadly with its patient support programs as well as specific plans for each brand?
- Have you identified current and potential areas for improved support (e.g., fulfilment, adherence)?
- Have you developed a summary of qualifications by vendor and foundation?
- Have you assessed your approach to optimize operations and compliance?

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THANK YOU
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Please contact me if you have any additional questions or would like to discuss this presentation.
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PHARMA LAW CONFERENCE 2017

THE FEDS AND THE STATES: A ONE-TWO PUNCH IN DRUG PRICE-FIXING INVESTIGATIONS

John S. West , Partner – Troutman Sanders
William H. Hurd, Partner – Troutman Sanders

TROUTMAN SANDERS

PHARMA LAW CONFERENCE 2017

Heightened Scrutiny

- Significant increase in investigations and litigation regarding generic drug pricing
- Heightened public concern over price increases led to harsh criticism of drug-makers pricing practices by US law makers
- Investigations initiated at the federal and state level

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DOJ's Criminal Investigation

- Two year investigation into the industry
- In December 2016: felony charges filed against two former executives of Heritage Pharmaceuticals Inc (alleging violations of the Sherman Act (15 U.S.C. § 1)
- Guilty pleas entered in January 2017
- Investigation is ongoing; at least 10 other companies and at least two dozen other drugs

What is the DOJ focused on?

- The entire industry – similar to recent prosecutions of companies and individuals in the auto industry
- Punishing - through criminal penalties and incarceration – of those that violated federal antitrust law
- Particular focus on holding individuals responsible
- Protecting development of criminal case by intervention in *Aurobindo*

DOJ's Investigative Powers

- Investigators from multiple agencies
- Grand jury subpoenas issued to companies for documents
- Grand jury subpoenas issued to individuals for documents and testimony
- Target letters issued to individuals
- Leverage

Connecticut, et al. v. Aurobindo Pharma USA Inc. (D. Conn.)

- Non-public investigation initiated by the State of Connecticut
- 20 states filed a civil complaint against six generic manufacturers (alleging state law and Sherman Act violations)
- Six companies and their executives alleged to have fixed prices and divided up the market (doxyclycline and glyburide)
- DOJ has intervened - common question of fact; protecting integrity of criminal investigation
- Amended Complaint filed; 40 states listed as Plaintiffs in the litigation

What are the States focused on?

- Drug-pricing: a long-standing concern
  - NAAG Presidential Initiatives
  - Previous suits and settlements
- Over 40 Attorneys General as Plaintiffs: How did they come together?
  - The origins of multistate cooperation
  - On-going coordination among States
  - Multistate investigations and lawsuits

What are the States focused on?

- Attorney General investigative powers: How did they gather those facts?
  - Civil Investigative Demands
  - Investigators
  - Interstate information sharing

What are the States focused on?

- Roles of the State Attorneys General: Who are they representing here?
  - State Agencies
  - Medicaid fraud control units
  - Consumers
  - *Parens Patriae*
  - Other

What are the States focused on?

- Enforcing the laws or making policy: What is the goal here?
  - Sherman Anti-trust Act
  - State Anti-trust Laws
  - State Consumer Protection Laws
  - Other State Laws

How to Respond if the Feds or the States Come Calling

- The Feds:
  - What is the Company's status?
  - What individuals are at risk
  - Balancing responses to criminal and civil inquiries
- The State AGs:
  - Common mistakes
  - Confidentiality Agreements
  - Forms of Resolution

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Notes