Greg Boss, Executive Vice President

Legal and General Counsel, CSL

DIRECTORS' ROUNDTABLE

September 16, 2016

CSL Overview

- Founded in 1916
- Headquartered in Melbourne Australia
- Major operations in US, including King of Prussia, PA
- Privatized in 1994
- Today, >$6 billion, >60 countries, >16,000 people

Seqirus™
A CSL Company

- Second largest influenza vaccines provider in the world
- Provides influenza vaccines to both the Northern and Southern hemispheres
- Operates one of the world's largest network of influenza vaccine manufacturing facilities

CSL Behring
Biotherapies for Life™

- Based in King of Prussia, US
- Broad range of quality products to treat serious medical conditions
  - Primary immune deficiencies
  - Hemophilia
  - Von Willebrand disease
  - Alpha1, and
  - HAE

CSL Purpose and Values

Our Purpose

The people and science of CSL save lives around the world. We develop and deliver innovative specialty biotherapies, helping people with life-threatening conditions live full lives. Our Values guide us in creating sustainable value for our stakeholders.

Customer Focus:
We are passionate about meeting the needs of our customers

Innovation:
We seek better ways of doing things

Integrity:
We are ethical and honest at all times

Collaboration:
We work together to achieve better results

Superior Performance:
We strive to be the best at what we do

Innovation for Success

1,100+ R&D experts worldwide

>$600M R&D spend this fiscal year

85% of filings approved on 1st submission

CSL's Biotherapeutics continue to have tremendous potential for a wide range of serious and life-threatening diseases.

Medicines are a small part of healthcare spend

Every dollar spent on healthcare is broken down as follows, according to the Pharmaceutical Research and Manufacturers of America:

- $.07 – government administration and net cost of private health insurance
- $.08 – home health and nursing home care
- $.09 – prescription drugs
- $.21 – physician and clinical services
- $.23 – other
- $.32 – hospital care

VIDEO

Best practice for ensuring employee compliance in a global market

- Know what you're committed to.
- Ensure everyone you work with shares this commitment.
- Know where you can win without ever compromising your values.

Driven by Our Promise

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DIRECTORS ROUNDTABLE

Modern E-Discovery For U.S. Multinational Companies

Gregory Boss, Executive Vice President, Group General Counsel, CSL Behring
Robert Baron, Partner, Ballard Spahr

Also authored by Philip N. Yannella, Partner, Ballard Spahr

September 16, 2016

Overview

- E-Discovery 101
- Best E-Discovery Practices for Large Organizations
- December 2015 E-Discovery Amendments to Federal Rules of Civil Procedure
- Ethics & E-Discovery
- Cross-Border Discovery

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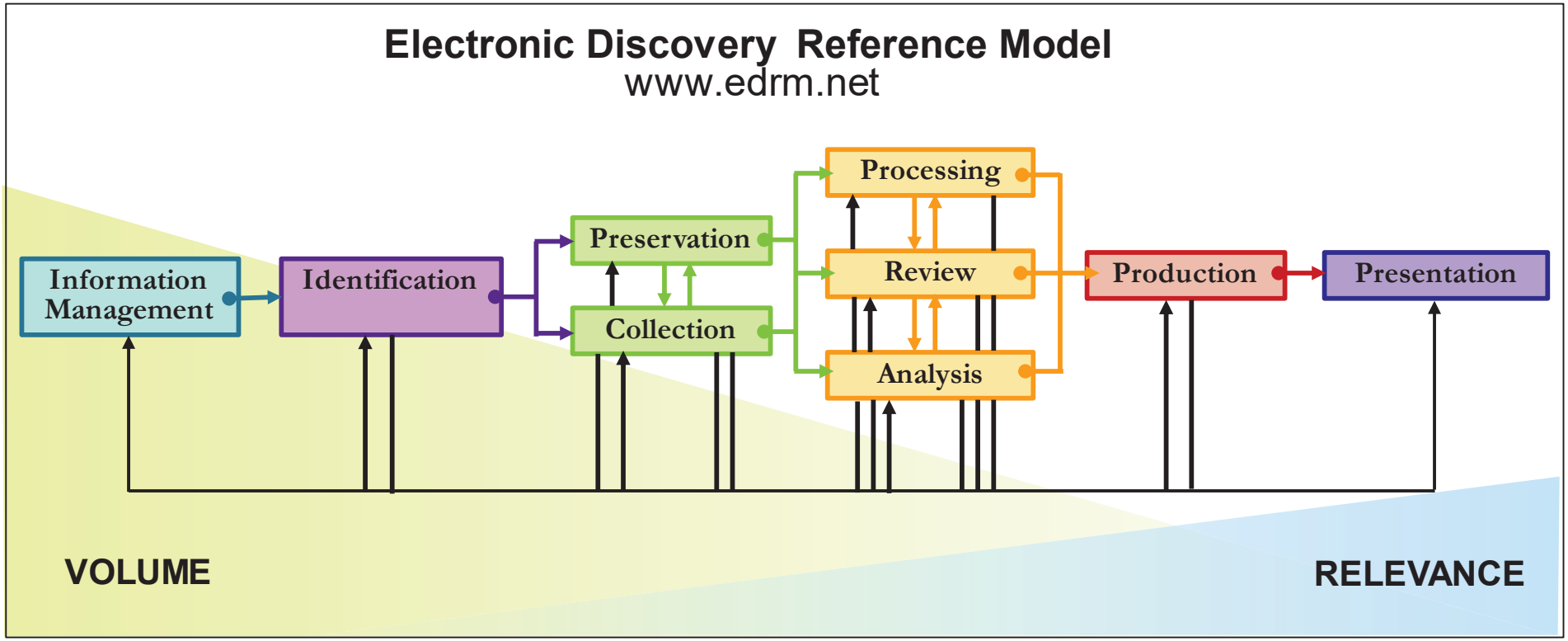
E-Discovery 101

What is E-Discovery and Why Does it Matter?

What is E-Discovery?

- Discovery of electronic information
  - 97 % of information in litigation is electronic
  - So, really, Discovery = E-Discovery

The E-Discovery Timeline



Why is E-Discovery Important?

- Legal and ethical standards mandate that counsel actively manage all discovery operations
  - Preservation
  - Collection
  - Document review and production
- Must balance duty of advocacy with duty to court

Why is E-Discovery Important?

- Failure to manage E-Discovery properly can result in significant legal sanctions

Costs of E-Discovery Are Significant

- According to a recent FTI study the *average* cost of E-Discovery in complex litigation is $1.2 mm
- According to RAND study, costs of E-Discovery for 1 GB is $15,000-$18,000
  - Average employee maintains **10 GB** of email in Outlook
- Recent Patent Case shows one party spent $2,829,349 in discovery
  - *Gabriel Techs., Corp. v. Qualcomm, Inc.* (S.D. Cal. 2013)

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Best E-Discovery Practices For Large Organizations

Best E-Discovery Practices For Large Companies

- Coordination Among Knowledge Stakeholders
  - Legal, IT, HR, Business Units, including from relevant Territories
  - Create Standard Operating Procedures to serve as "blueprint" for implementing a Legal Hold
- Understand Where Relevant Data is Located
- Common Preservation Issues:
  - Laptops/data for former employees
  - Making sure IT applies hold and stops auto-delete to all applicable data, not just some
  - Updating legal hold memos to include new employees
  - Discovery of personal email or social media accounts for employees
  - Applying legal hold to data held in cloud
  - EU Privacy issues

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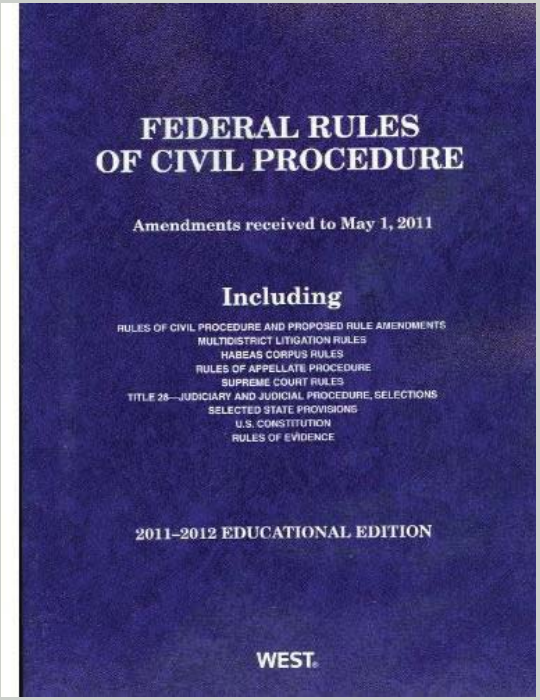
December 2015 Amendments to the Federal Rules of Civil Procedure



Since Rules Were Last Amended in 2006

- Many Disputes Regarding Preservation and Production
- Different Courts Resolving Disputes Differently
- Complexity of discovery has increased:
  - New devices (*e.g.*, smartphones, tablets)
  - New platforms (*e.g.*, social networks)
  - Unlimited virtual warehouse at little to no cost

2015 Amendments – Key Changes

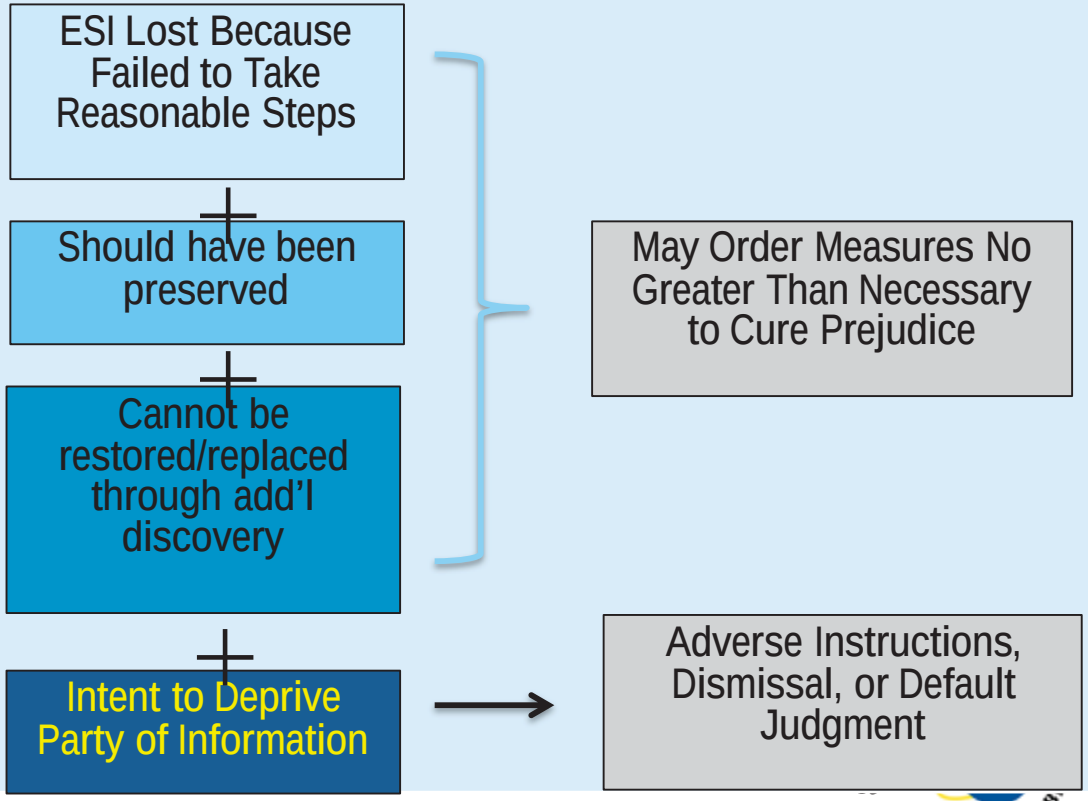
- Tightened Scope of Discovery
- New Standard for Imposition of Sanctions Arising from Spoliation

Rule 26(b)(1): Tightening the Scope of Discovery

"Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense ~~...[or] reasonably calculated to lead to the discovery of admissible evidence~~ and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope need not be admissible in evidence to be discoverable"

Amended 37(e) – Failure to Preserve ESI

FORMER RULE	AMENDED RULE
(e) Failure to Provide Electronically Stored Information "Absent exceptional circumstances," no sanctions for ESI lost as a result of the "***routine, good-faith operation*** of an electronic information system."	**(e) Failure to Preserve Electronically Stored Information**



Amended Rule 37(e)

37(e) FAILURE TO PRESERVE ELECTRONICALLY STORED INFORMATION.

If ESI that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve the information, and the information cannot be restored or replaced through additional discovery, the court may:

(1) Upon a finding of prejudice to another party from loss of the information, order measures no greater than necessary to cure the prejudice;

(2) **Only upon a finding that the party acted with the intent to deprive** another party of the information's use in the litigation,

(a) presume that the lost information was unfavorable to the party;

(b) instruct the jury that it may or must presume the information was unfavorable to the party; or

(c) dismiss the action or enter a default judgment.

Spoliation Cases Since 2015 Amendments - Analysis

- No clear trend to date
- 16 reported cases since rules amendment addressing spoliation
  - Sanctions denied in 8 cases
  - Sanctions awarded in 7 cases
  - 1 case did not apply new rules

Range of Evidentiary Sanctions Imposed

- Courts have discretion to issue evidentiary sanctions under Rule 37(e)(1)
- Some sanctions can be nearly as damaging as an adverse inference
  - *CAT 3 LLC v. Black Lineage* (S.D.N.Y 2016)(plaintiff precluded from relying upon emails as sanction for alteration of emails)
  - *Matthew Enterprises v. Chrysler* (N.D. Cal. 2016)(Chrysler can use spoliation to undercut Plaintiff's allegations)

Courts Imposing Sanctions

Cases Where Sanctions Were Awarded		
Adverse Inference	Default Judgment	Evidentiary Sanction
5	1	1

Courts Declining to Impose Sanctions

Cases Where Sanctions Were Denied – Rationale			
No Duty to Preserve	No Loss of ESI	No Prejudice	No Intent
1	2	2	3

Other Important Changes

- Rule 1 amended to include duty to cooperate in discovery
- Shortened time to serve complaint and issue Rule 16 Order; as a result, discovery can begin earlier in a case
- Rule 26(b)(3) now grants judges authority to allocate discovery expenses in protective orders
- Parties permitted to serve discovery before Rule 26(f) conference (deemed to be served day of conference)
- Objections to document requests must be stated "with specificity" and indicate whether any responsive materials are being withheld on the basis of that objection
- Responses to document requests must indicate when rolling productions will begin and end

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Ethics & E-Discovery

Ethical Rules Governing eDiscovery

- ABA Model Rule 1.1
  - Duty of Competence
  - Comment to Rule 1.1:
    - To maintain the requisite knowledge and skill, a lawyer should keep abreast of changes in the law and its practice, ***including the benefits and risks associated with relevant technology***, engage in continuing study and education and comply with all continuing legal education requirements to which the lawyer is subject.
  - Lawyers must understand technology or consult with others with requisite technological background.
  - Adopted by Pennsylvania and other states

Duty of Confidentiality

- ABA Model Rule 1.3
- A lawyer shall not reveal information relating to the representation of a client:
  - unless the client gives informed consent,
  - the disclosure is impliedly authorized in order to carry out the representation
  - or the disclosure is otherwise permitted by the Rules
- Understanding how E-Discovery processes (*e.g.*, metadata, protective orders) can reveal client confidences is paramount.

Duty of Candor

- ABA Model Rule 3.3
- A lawyer shall not knowingly:
  - make a false statement of fact or law to a tribunal or fail to correct a false statement of material fact or law previously made to the tribunal by the lawyer
- *Brown v. Tellermate Holdings* (S.D. Ohio 2014) (granting adverse inference as sanction for defendant's discovery misrepresentations)

  "Counsel have a duty (perhaps even a heightened duty) to cooperate in the discovery process; to be transparent about what information exists, how it is maintained, whether and how it can be retrieved, and above all to exercise sufficient diligence...***to ensure that all representations made to opposing parties and the Court are truthful***[.]" (emphasis added)

Duty of Fairness

- ABA Model Rule 3.4
  - An attorney shall not unlawfully obstruct another party' s access to evidence or unlawfully alter, destroy or conceal a document or other material having potential evidentiary value. A lawyer shall not counsel or assist another person to do any such act;
  - In pretrial procedure, make a frivolous discovery request or fail to make reasonably diligent effort to comply with a legally proper discovery request by an opposing party;
- Counsel must manage and oversee all phases of E-Discovery—cannot delegate to custodians

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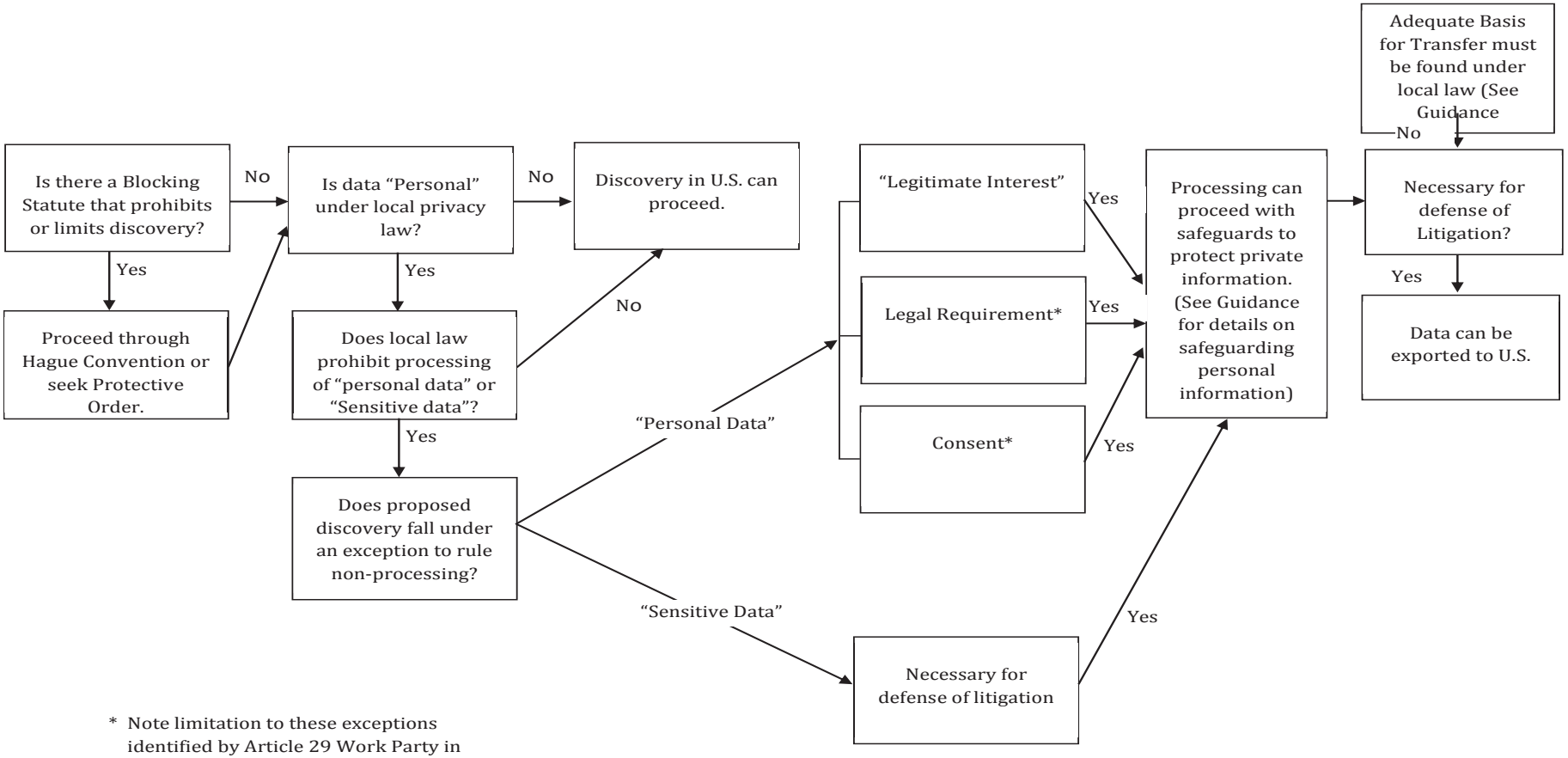
Cross-Border Discovery

Legal Framework for Cross-Border Discovery

- Discovery of electronic documents located outside U.S. implicates nexus of laws:
  - Federal Rules of Civil Procedure permit discovery of relevant documents within party's "possession, custody or control"
  - Hague Convention (providing formal mechanism for discovery of ex-US documents in U.S. litigation)
  - Blocking Statutes (certain European countries, *e.g*, France, Switzerland and Holland, have laws that seek to block discovery of certain kinds of documents for U.S. litigation)
  - Data Protection Laws (many countries have laws that limit "processing" of documents containing "personal" information for use outside of home country)

Flowchart for Compliance with E.U. Data Protection Laws

Flowchart for Compliance with European Union Protection Laws in U.S. Litigation



* Note limitation to these exceptions identified by Article 29 Work Party in WP 153 "[O]n pre-trial discovery for cross-border civil litigation.")

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DMEast 21776113

DIRECTORS ROUNDTABLE

Coming Attractions: E.U. Law is Changing

- E.U. Data Protection Act will be replaced by General Data Protection Regulation (GDPR)
  - Intended to strengthen privacy protections for E.U. citizens
  - Approved and adopted by European Parliament and Council in April 2016
    - Will be in force May 2018
  - **<u>Effect on cross-border discovery currently unclear</u>**

Legal Impact

- Will U.S. Courts deny cross-border discovery requests because of other nation's laws?
- Generally, NO
  - *Societe National Industrielle Aerospatiale v. United States District Court for Southern District of New York* (U.S. 1987) (country's local laws limiting discovery of nationals for use in U.S. litigation **does not** bar discovery in U.S. courts)
  - *Devon Robotics v. DeVeidma* (E.D. Pa 2010) (allowing discovery of data subject to Italian data protection laws); *Accessdata Corp. v. ALSTE Tech GMBH* (D. Ut. 2010) (ordering discovery of documents subject to French privacy law); *Bodner v. Paribas* (E.D. N.Y. 2000) (permitting discovery of French documents).

Legal Impact (Cont'd.) – Tide May be Changing?

- Enactment of GDPR (May 2018) may make it more difficult for U.S. companies to conduct cross-border discovery
- Increased enforcement of current E.U. privacy law may lead U.S. courts to lend greater weight to foreign privacy concerns
- Some U.S. courts limiting discovery in criminal cases that infringe on E.U. privacy interests
  - *Microsoft v. U.S.* (2nd Cir., July 2016) (privacy interests under Stored Communications Act turn on where data is stored, not where subpoena compliance occurs)

Cross-Border Discovery: Balancing Test

- U.S. Courts will apply balancing test, weighing importance of documents against burden to producing party. Considerations include:
  - Specificity of discovery request
  - Relevance of documents
  - Availability of information from other sources
  - Location of documents and difficulty in complying with local law
  - Whether documents contain sensitive personal information

Considerations for Cross-Border Discovery

- Is discovery legally required?
  - Review discovery request and consider whether to contest (mindful that U.S. courts generally allow cross-border discovery)
    - Is request relevant?
    - Is request specific and narrowly tailored?
    - How burdensome will collection be under local data privacy laws?

Issues to Consider (cont'd.)

- <u>If Court Is Likely to Order Discovery</u>:
  - Negotiate scope of discovery request
    - Limit number of custodians
    - Argue for discrete specific discovery (not "any and all documents")
  - Seek Protective Order Governing Confidentiality
    - Ensure that foreign documents have heightened level of confidentiality
    - Limit third-party access and use of documents subject to data privacy laws

Issues to Consider (cont'd.)

- Once Discovery Process Commences:
  - Obtain employee consent
  - Retain local vendor to conduct data collection in-country
  - Use data culling to eliminate irrelevant documents (should also be done in-country, if possible)
  - Consider redaction of personal information
  - Export documents using encryption
  - Document steps to comply with local privacy laws
  - Consult local privacy lawyers as needed

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Thank You!

Hogan Lovells

Current Pricing Issues Facing the Pharmaceutical Industry

Stuart Langbein

September 2016

Agenda

- Current issues facing the pharmaceutical industry
- Opportunities for messaging
- Potential policy priorities depending on election results

Current Issues Facing the Pharmaceutical Industry

Current Issues Facing Pharmaceutical Industry

Overview

- Drug prices are the among the biggest issues
  - Cost to Medicare and patients
  - Lack of transparency regarding overall drug costs
- Related issues include:
  - Shift from cost to value
  - Insurer cost shifting
  - Non-interference/transparency
  - Pathways to Food and Drug Administration (FDA) approval
- Critical to shift focus to value of medicines, innovation, and putting costs in context

Drug Prices

Current Climate

- According to *Modern Healthcare,* high drug prices pushed aside the never-ending wrangling over the Affordable Care Act (ACA) as healthcare's #1 political and policy issue in 2015
- Providers, insurers, patient advocates and politicians from both parties have called for strong measures to curb drug costs, which rose more than twice as fast as the rest of healthcare spending over the past 2 years
- The pharmaceutical industry has work to do on the messaging front, putting drug costs into context

Drug Costs

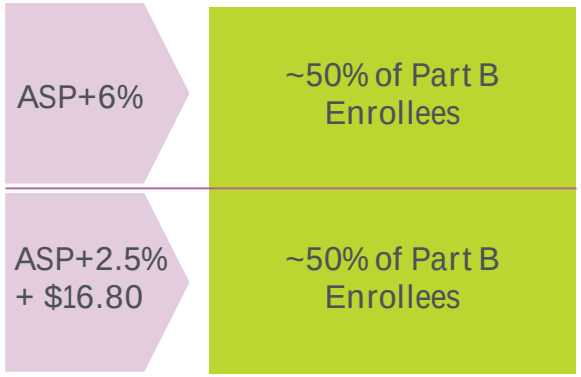
Medicare Part B

- Cost of drugs to Medicare and patients is a major focus of numerous legislative proposals on federal and state levels
- With respect to **Medicare Part B**: President's 2017 budget proposal would reduce payment for Part B drugs from average sales price (ASP)+6% to ASP+3%
- CMS proposal pending for demonstration to test alternative payment models

Part B Drug Payment Model Structure

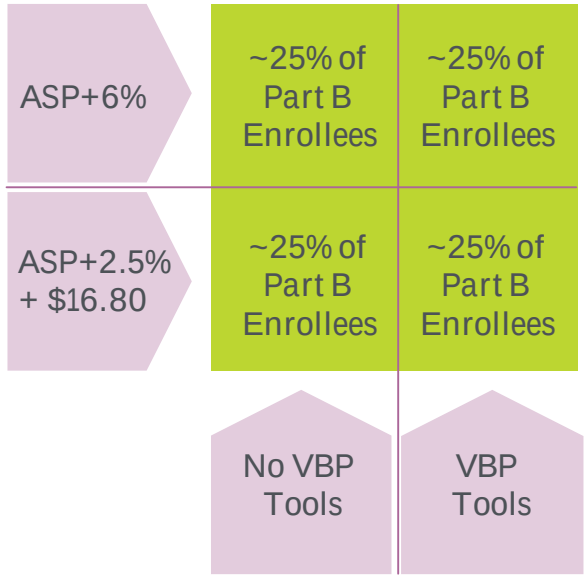
Phase I

- Implementation proposed as early as August 1, 2016
- Testing impact of new payment rate



Phase II

- Implementation as early as January 1, 2017
- Testing impact of new payment rate and value based purchasing (VBP) tools



Products and Providers

- The model will include all Part B drugs and biologicals (including biosimilars) with Healthcare Common Procedure Coding System (HCPCS) codes except

Contractor-priced Drugs (but contractors would have option to include them)	**Influenza, Pneumococcal Pneumonia, and Hepatitis B Vaccines**	**Drugs Infused With Covered Durable Medical Equipment (DME) (excluded from Phase I)**
End-Stage Renal Disease (ESRD) drugs	**Blood and Blood Products**	**Drugs in Short Supply**

- All providers and suppliers in selected geographic areas are required to participate
- Payment rate is determined by model arm assignment based on Primary Care Service Area

Phase I: Proposed ASP Add-On Percentage for Part B Drugs

- CMS proposes to use the basic approach described in the June 2015 Medicare Payment Advisory Commission (MedPAC) report - a fixed percentage add-on and a flat fee
- Sequestration will continue to apply to payments made under the model effectively reducing the proposed payment rate to ASP + 0.86% + $16.53 per drug per day
- Phase I is expected to be budget neutral (i.e., the $16.80 add-on for all utilization will approximate the difference between ASP + 6% and ASP + 2.5%)
- The flat fee would be adjusted annually based on the Consumer Price Index (CPI) for medical care
- CMS anticipates using a HCPCS code (G-code) that providers and suppliers billers assigned to this approach would use to bill for the flat fee portion of the payment

CMS proposes a fixed percentage add-on of 2.5% and a flat fee of $16.80

Phase II: Value-Based Pricing (VBP) Strategies

- CMS proposes to deploy VBP reimbursement strategies and clinical decision support (CDS) tools, where appropriate, to realize programmatic cost savings
- CMS proposes that Phase II be implemented on a rolling basis starting as early as January 1, 2017
  - The goal is to have Phase II fully implemented for the final three years of the Model
- CMS intends to gather additional information on proposed tools, including which specific Part B drugs are candidates for the application of specific tools
- With a new Administration in place in January 2017, the future of Phase II is uncertain
- CMS would finalize the implementation of specific tools for the specific HCPCS codes after soliciting public input on each proposal with a 30-day public comment period and a minimum 45-day public notice before implementation, but would not use rulemaking

Phase II: Value-Based Pricing (VBP) Strategies

- CMS proposes value-based pricing strategies that include one or more of the following specific tools:

Reference Pricing	Standard payment for therapeutically similar products
Indications-Based Pricing	Varying payment for a drug based on its clinical effectiveness for different indications
Voluntary Risk-Sharing Agreements	Agreements with manufacturers to link health outcomes with payment
Discounting or Eliminating Patient Coinsurance	Amounts for services that are determined to be high in value in an attempt to tailor services

CMS proposes that VBP tools will be displayed on their website for 30 days for comment prior to implementation

Phase II: Clinical Decision Support (CDS) Tools

- CMS proposes the adoption of two-component online CDS tool to support clinical decisions concerning drugs and diagnoses typically encountered in Part B through:

Clinical Decision Support Tools	•	Education on best practices based on high quality, up to date scientific/medical evidence
	•	Feedback on prescribing patterns based on regularly updated drug utilization in Medicare claims

- The tool would be available to providers in the model's value-based pricing arms on a voluntary basis

Drug Costs

Medicare Part D

- With respect to **Medicare Part D**:
  - Under current law, beneficiaries receive a 50% discount on brand-name drugs while in the coverage gap; President's 2017 budget would increase manufacturer discounts to 75%
  - Budget proposal also would require manufacturers to provide Medicaid-level drug rebates for brand name and generic drugs provided to Medicare beneficiaries who receive Part D low-income subsidies, beginning in 2018

Drug Costs

Transparency

- Broad concern among stakeholders regarding the lack of transparency with respect to brand-name drug prices
- President's budget proposal would give Secretary of Health and Human Services (HHS) the authority to negotiate prices with manufacturers for high-cost drugs covered under Part D
  - As part of these negotiations, manufacturers would be required to supply HHS with all cost and clinical data, as well as other information necessary to come to an agreement on price
- Budget proposal also would establish transparency and reporting requirements in drug pricing
  - Currently, no law requires manufacturers to report on the costs driving their pricing decisions
  - President's proposal would require manufacturers to publically disclose production costs, including R&D investments and discounts to various payers for certain high-cost drugs
- States are jumping into the fray with bills requiring transparency (e.g. VT, CA)

Shift from Cost to Value

- Current trend is toward emphasizing payment for value – also discussed in terms of the shift from "volume to value"
- For example, with respect to Part B:
  - CMS is looking to implement value-based incentives for Part B
  - Part B Drug Demonstration rulemaking process to test how variations in ASP-based reimbursement will affect clinical value of care delivered
- And with respect to Part D:
  - President's budget would create a "coverage with evidence development" process under Part D for certain identified high-cost drugs
  - Would require manufacturers to undertake additional clinical trials and data collection to support use in the Medicare population and for any relevant subpopulations identified by the Centers for Medicare & Medicaid Services (CMS)
  - Goal is that Part D plans would be able to use this evidence to improve clinical treatment guidelines and in negotiations with manufacturers to help ensure that the coverage and use of new high-cost drugs are based on evidence of effectiveness for specific populations

Insurer Cost-Shifting

- Specialty drug spending is expected to increase by 361% from 2012-2020
  - Specialty drugs have gained regulatory approval at a faster rate than traditional drugs with the trend expected to continue
  - Six therapy areas account for approximately 2/3 of specialty drug spending in the USA: oncology, rheumatoid arthritis, multiple sclerosis, HIV/AIDS, intravenous immunoglobulin (IVIG), and inflammatory bowel disease (IBD)
- Given the rising costs of specialty drugs, patients are increasingly being asked to pay a percentage of the drug's cost, rather than a fixed co-pay amount, for non-preferred drugs outside the specialty tier
- Plans also are requiring patients to meet a deductible for medicines before anything at all is covered – the number of plans with a deductible for medicines doubled from 2012 to 2015
- Charging patients huge out-of-pocket payments for necessary medications simply shifts costs to the sick and vulnerable
- Such costs can present a significant barrier to patients having access to crucial medications

Non-Interference

- Part D's "noninterference" clause in effect means that the government can have no role in negotiating or setting drug prices in Medicare Part D
- Despite numerous claims from various stakeholders that repealing the non-interference provision would save money, the nonpartisan Congressional Budget Office (CBO) continues to say
  - private Part D plans effectively negotiate savings on Medicare drug costs and
  - striking the non-interference clause is unlikely to achieve any significant savings unless the government also restricts beneficiary access to drugs
- The President's proposed 2017 budget would allow HHS to negotiate prices for biologics and high-cost prescription drugs for Medicare beneficiaries

FDA Approval Pathways

- Ongoing push to facilitate drug and device approvals and simplify clinical trial requirements
  - Accelerated approval pathways can get a drug on the market faster, but Medicare can require additional studies to obtain coverage
  - FDA approval standards (safe and effective) are not the same as CMS coverage standards (reasonable and necessary)
- There is also an ongoing convergence of software, digital, mobile and medical technologies that affect the way health and disease are treated and managed
  - Digital technologies provide greater flexibility, connectivity and information to patients, providers and payers
  - Can lead to improved health outcomes
  - But they also present new legal/regulatory challenges from an approval and coverage standpoint

Opportunities for Messaging

Value over Costs

- Rather than allowing discussion to focus purely on cost and prices, message should involve what those dollars buy – in terms of benefits to patients, the health care system, and the economy
- **Benefits to patients:** Medicines are allowing millions to live longer, healthier lives and transforming the treatment of many difficult diseases
- **Benefits to the health care system:**
  - Providing incentives for manufacturers to develop new, innovative medicines helps put healthcare system on a more sustainable path
  - Medicines help patients avoid expensive hospitalizations and emergency department visits – the U.S. could save $213 billion annually if medicines were used properly
  - The health care system could save $367 billion annually if we develop a new medicine that delays the onset of Alzheimer's disease by just 5 years
- **Benefits to the economy**:
  - The biopharmaceutical industry supported 3.4 million jobs in 2011
  - The biopharmaceutical industry's sponsorship of clinical trials of medicines supports $25 billion in economic activity

Putting Cost in Context

- Spending on retail prescription medicines is roughly the same percentage of health care spending today as it was in 1960 – 10%
- Private insurers spent nearly as much on medicines as on administrative costs in 2013, and the U.S. will spend $13.5 trillion on hospital care over the next decade – *more than 3 times the total spending on prescription medicines*
- The prescription drug life cycle promotes innovation and affordability – improved health for patients and, over time, generic copies
- Cost containment is built into the drug pricing life cycle
- From 2014-2018, $115 billion of U.S. brand sales are projected to face generic competition; nearly 9 out of 10 U.S. prescriptions are filled with generics

Challenges of Innovation and Development

- From drug discovery through FDA approval, developing a new medicine on average takes at least 10 years and costs $2.6 billion
- Science is getting harder (more complex diseases) and more costly (higher regulatory hurdles; longer, more complex clinical trials; increased cost of R&D)
- Market is getting tougher
  - Slow uptake of new medicines and rapid uptake of generics;
  - Unprecedented scale of patent expirations; and
  - Increased patient cost-sharing and coverage restrictions.
    - On average, patients pay out of pocket nearly 20% of total drug costs, compared to 5% of hospital care costs
    - Share of commercial plans with an Rx deductible is increasing
    - Enrollment in high-deductible health plans is increasing

Potential Policy Priorities Depending on Election Results

Presidential Candidates Agree: Drug Prices Too High!

Hillary Clinton	Donald Trump
"It is time to deal with skyrocketing out-of-pocket costs and runaway prescription drug prices that are going up..."	**"We don't negotiate the price of the drugs so we're spending perhaps $300 to 350 billion more buying drugs from our drug companies..."**

Big Picture

- Health care is an inevitable agenda item for any president, Democratic or Republican
- The fact that health care costs consume 1/6 of the American economy makes them a huge budgeting concern
- Health care reform is, in that sense, a non-partisan issue
- Prescription drug costs are one of the most central health care issues, if not the most central – plus they have been a campaign issue, so the topic isn't going anywhere

If a Republican Wins the White House…

- Donald Trump pledges to repeals the ACA and replace it with a new system, though he has not provided much detail on a replacement
- Conservative policy-makers agree on a number of key components of a new system, included in House Republican June 2016 proposal:
  - Refundable tax credits to the needy to purchase insurance
  - Giving the power to regulate insurance back to the states
  - Consumer freedom of choice among insurance plans and benefits
  - Modified Medicare and Medicaid system (e.g., modeling Medicare on the Part D competitive market model)
  - Fostering innovation and technology, particularly in drugs and devices
  - Allowing everyone to enroll in Health Savings Accounts, regardless of plan deductible, to take control of their own health spending
- Repeal of the ACA on Day 1 likely will be impossible for political reasons
- Focus on skyrocketing drug costs is inevitable

If a Democrat Wins the White House…

- Twin Democratic health care goals: improving quality of care while making it cheaper
- Full and continued implementation of the ACA
- Access to affordable, quality health insurance
- Democrats in Congress likely will work to strengthen Medicare by providing free preventive benefits and extending the solvency of the Medicare Trust Fund
- Lower drug costs are always a Democratic priority – Clinton and Sanders both campaigned on the issue
- Funding and support for medical research also likely to be a focus
- Important to note that if a Democrat wins the election, he or she potentially will be pressured to make some of the reforms discussed previously because of many Americans' unhappiness with the ACA

Hogan Lovells

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Simpson Thacher

Antitrust and the Pharmaceutical Industry

A Brief Enforcement Update

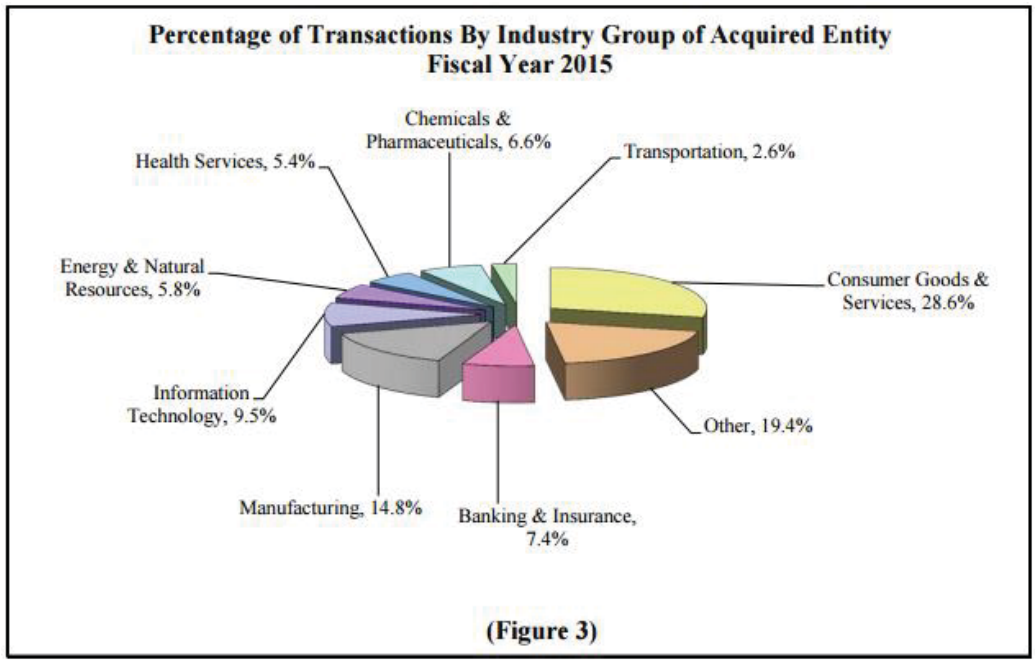
Kevin Arquit

September 16, 2016

Aggressive Antitrust Enforcement

We are in a time of aggressive antitrust enforcement by federal and state governments.

- Pharmaceutical mergers (6.6% of reportable mergers) resulted in 35% of the FTC's 2015 merger enforcement actions.
  - **55%** if medical device mergers are also included.



1. Source: FTC & DOJ, *Hart-Scott-Rodino Annual Report: Fiscal year 2015*, *available at* https://www.ftc.gov/policy/reports/policy-reports/annual-competition-reports.

Recent FTC Merger Enforcement

The FTC has investigated, required divestitures in, and even litigated many pharmaceutical, biotech, and medical device cases over the last year.

- In July 2016, the FTC issued its largest drug divestiture order ever, resolving allegations that the *Teva/Allergan* merger would substantially reduce competition in the markets for:
  - 79 different finished generic drugs based on horizontal product overlaps; and
  - the supply of active pharmaceutical ingredients (APIs) to competing drug manufacturers for use in 15 different FDA-approved, finished dosage products (requiring Teva/Allergan to give customers the option to enter into long-term API supply contracts).[1]
- The FTC recently required divestitures in cases such as *Mylan/Perrigo*, *Endo/Par*, and *Pfizer/Hospira* to resolve concerns regarding:
  - *Mylan/Perrigo*: direct horizontal overlaps in four different generic drug markets, and the elimination of likely future competition in three others;[2]
  - *Endo/Par*: direct horizontal overlaps in two different generic drug markets;[3] and
  - *Pfizer/Hospira*: direct horizontal overlaps in two different drug markets, and the elimination of likely future competition in two others.[4]

1. Decision and Order, *In the Matter of Teva Pharmaceutical Indus. Ltd.*, F.T.C. Case No. 151-0196, Docket No. C-4589 (July 27, 2016).
2. Decision and Order, *In the Matter of Mylan N.V.*, F.T.C. Case No. 151-0129, Docket No. C-4557 (Feb. 22, 2016).
3. Decision and Order, *In the Matter of Endo Int'l plc*, F.T.C. Case No. 151-0137, Docket No. C-4539 (Nov. 18, 2015).
4. Decision and Order, *In the Matter of Pfizer Inc.*, F.T.C. Case No. 151-0074, Docket No. C-4537 (Oct. 19, 2015).

Merger Enforcement Snapshot

Illustrating the antitrust agencies' aggression most vividly, the FTC recently litigated a "potential" competition case against two sterilization service providers, Steris and Synergy.

- Although the two companies were not *actual* competitors, the FTC alleged that Synergy had been *planning* to enter the U.S. market with an emerging technology that would compete with Steris' gamma sterilization process.
  - As a matter of law, the court assumed the validity of the FTC's "actual potential" competition theory, but ultimately found that the FTC had not proven—as a factual matter—that Synergy would have entered the U.S. market within a reasonable period of time.[1]

- Notwithstanding this loss, the FTC has expressed an intent to continue efforts to protect potential competition.

"In the end, the evidence unequivocally shows that the problems that plagued the development of x-ray sterilization . . . were the same problems that justified termination of the project in 2015: the failure to obtain customer commitments and the inability to lower capital costs."[2]

"[P]reservation of future competition is important and something I believe is likely to remain an active part of the Commission's merger enforcement agenda."[3]

1. *FTC v. Steris Corp.*, No. 1:15-cv-1080 , slip op. at 6, 27-28 (N.D. Ohio Sept. 24, 2015).
2. *Id.* at 40.
3. FTC Bureau Director's Report, Spring 2016 at 4, *available at* https://www.ftc.gov/system/files/documents/public_statements/944113/feinstein_-_spring_update_april_2016.pdf.

Recent Reverse Payments Enforcement

The FTC has also been active in "reverse payments" cases, especially since winning *Actavis* in the Supreme Court.

- The typical "reverse payment" agreement settles a patent dispute in which the brand company pays the generic company to delay bringing its generic drug to market for a certain amount of time.
  - Currently, in *FTC v. Endo Pharms.*, the FTC is arguing that a brand company's commitment not to market authorized generics during a generic's 180-day exclusivity period (*i.e.*, a "no-AG" commitment) as part of a patent dispute settlement is an unlawful reverse payment that deprives consumers of the benefits of competition.[1]
    - Previewing its theory, the FTC filed an amicus brief in a private reverse payments suit in 2012, asserting that "no-AG commitment[s] provide[] a convenient method for brand drug firms to pay generic patent challengers for agreeing to delay entry."[2]
- The relief sought in reverse payments cases may include not only injunctive relief, but also restitution or disgorgement.
  - In 2015, the FTC secured $1.2 billion in disgorgement by settling claims that Cephalon's reverse payment agreements had caused consumers to pay "billions of dollars more than they should have for Provigil, resulting in billions of dollars in ill-gotten profits for Cephalon."[3]

1. Compl. at 2-3, *FTC v. Endo Pharms.*, No. 2:16-cv-01440-PD (E.D.. Pa. March 30, 2016).
2. Brief for Amicus Curiae FTC Supporting Plaintiffs-Appellants at 2, *In re Effexor XR Antitrust Litigation*, No. 3:11-cv-05479 (N.D. NJ Aug. 10, 2012).
3. Stipulated Order for Perm. Inj. and Equitable Monetary Relif, *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (E.D. Pa. June 17, 2015); Plaintiff FTC's Mem. of Law in Supp. of Its Mot. for Preclusion of Patent Issues or, in the Alternative, Partial Summ. J. at 1, *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (E.D., Pa. Sept. 20, 2013).

Other Enforcement Actions

The federal agencies also investigate other issues in the pharmaceutical industry.

- The DOJ has an ongoing investigation regarding the generic drugs industry.
  - Several pharmaceutical manufacturers have recently disclosed DOJ grand jury subpoenas seeking information related to "corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products and certain other related matters." [1]

- The FTC sued Concordia Pharmaceuticals and Par Pharmaceutical for entering an unlawful non-compete agreement in the sale of generic drugs, which the parties settled.[2]
  - The FTC alleged that Concordia and Par were the only two firms permitted by the FDA to market generic Kapvay, a drug that treats Attention Deficit Hyperactivity Disorder.
  - Under the settlement agreement, Concordia and Par agreed:
    - not to enforce the anticompetitive provisions of their non-compete, and
    - not to agree with other entities to bar or delay entry of authorized generics after the patents covering the branded versions have expired.

1. Jeff Zalesin, *Sun Pharma Unit Supoenaed In DOJ Generics Antitrust Probe*, Law360.com (May 31, 2016), *available at* http://www.law360.com/articles/801869/sun-pharma-unit-supoenaed-in-doj-generics-antitrust-probe.
2. *In re Concordia Healthcare*, F.T.C. Case No. 1510030, Docket Nos. C-4553 and C-4554 (2015).

Other Enforcers

Recently, state attorneys general and private plaintiffs have been aggressive antitrust enforcers as well.

- For example, the New York Attorney General made waves when it won an injunction against Actavis in a product-hopping case.[1]
  - The New York Attorney General alleged, and the court found, that Actavis' announced plan to withdraw Namenda IR from the market would force patients to switch to Namenda XR, likely thwarting entry by generics.
- Unlike public enforcers, private antitrust litigation comes with the prospect of treble damages. Recent headline-grabbing private suits include:
  - *In re Cipro Cases I and II*: Bayer paid $74 million in 2003 to settle class action claims that its reverse payment agreement with generic producers unlawfully delayed entry of lower-cost versions of Cipro, and all but one of the generic producers agreed to settle for $100 million on August 15. The only remaining defendant, Barr Pharmaceutical, just lost its summary judgment motion.[2]
  - *In re Generic Digoxin and Doxycycline Antitrust Litigation*: Ten recently-filed putative class action complaints against five generic producers were just consolidated into one proceeding.[3] Plaintiffs seek treble damages, asserting that the generic producers colluded to fix the prices of two drugs.

1. *New York v. Actavis, PLC*, No. 14 CIV. 7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015), *cert. dismissed sub nom. Allergan PLC v. New York ex. rel. Schneiderman*, 136 S. Ct. 581, 193 L. Ed. 2d 421 (2015).
2. Dani Kass, *Cipro Buyers Want OK for $100M Pay-For-Delay Settlement*, Law360 (Aug. 15, 2016), *available at* http://www.law360.com/articles/828335/cipro-buyers-want-ok-for-100m-pay-for-delay-settlement.; Joshua Sisco, *Cipro Pay-For-Delay Case Hedaed to Trial After Barr Loses on Summary Judgment*, Mlex.com (Aug. 15, 2016), *available at* http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=821261&siteid=191&rdir=1.
3. Transfer Order, *In re: Generic Digoxin and Doxycycline Antitrust Litigation*, No. 2:16-md-02724-CMR (E.D. Pa Aug. 5, 2016).

Other Advocacy

Beyond enforcement, the antitrust agencies promote the antitrust laws through other means, such as speeches, testimony, reports, legislative advocacy, and amicus participation.

- The FTC has filed amicus briefs, such as one recently in a private suit arguing that product hopping can violate antitrust laws. [1]

- The FTC Chairwoman testified before Congress against legislation that would give it the same standard in merger enforcement as the DOJ. [2]

"[T]he very fact of product-hopping can itself be evidence of monopoly power."

"[The Smarter Act] is unwarranted and would remove a key tool the Commission has used successfully for many decades . . ."

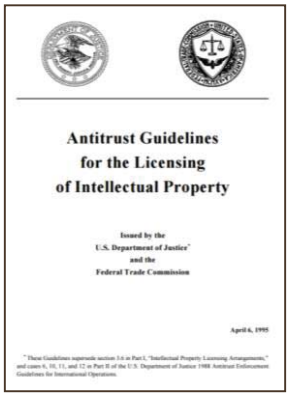
1. Brief for Amicus Curiae FTC Supporting Plaintiff-Appellant at 13, *Mylan Pharms. v. Warner-Chilcott PLC*, No. 15-2236 (3d Cir. September 20, 2015).
2. The Standard Merger and Acquisition Reviews Through Equal Rules Act of 2015: Hearing on S. 2102 Before the S. Subcomm. on Antitrust, Competition Policy and Consumer Rights, Comm. on the Judiciary, 114th Cong. 2 (2015) (statement of the FTC), *available at* https://www.ftc.gov/system/files/documents/public_statements/810871/151007smarteracttestimony.pdf.

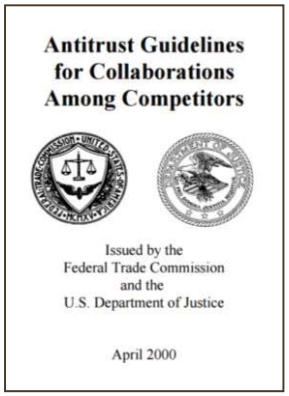
Guidelines Update

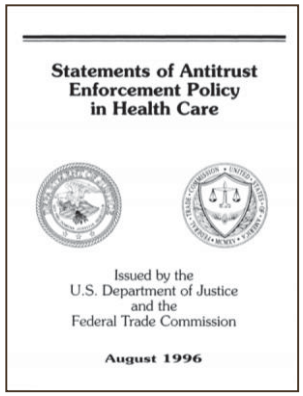
The FTC and DOJ just released proposed updated antitrust guidelines on IP licensing.

- Guidelines affect lawyers' counseling of clients and business practices around the country.
- IP guidelines update appears largely cosmetic, intended to put the agencies officially in line with recent court decisions, and are open for public comment through September 26.

The FTC/DOJ have not updated their healthcare guidelines since 1996 and their guidelines for dealings with competitors since 2000.







CUSHMAN & WAKEFIELD

A Cushman & Wakefield Strategic Consulting Publication

SO YOU THINK YOU HAVE A STRATEGY?

2016

WHAT IS "STRATEGY"?

A key ingredient of successful leadership is the ability to develop and communicate a strategy. Simply put, strategy is an integrated, externally-oriented plan that guides how a business will achieve its objectives. When properly developed, strategy sets enterprise objectives, reveals the actions required to achieve those objectives, and aligns employees and resources against those actions.

The best corporate leaders spend an inordinate amount of time on strategy since it ensures the execution of a particular vision. Without strategy, companies would:

- Waste time and money on the wrong activities
- Make decisions that do not align with the enterprise's core mission and goals (and potentially damage delivery against the mission and goals)
- Face difficulty motivating employees

In most industries, a core challenge is aligning the long-term nature of real estate assets with the short-term nature of business events. A real estate strategy is essential for getting this right. Unfortunately, actual strategies for managing corporate real estate are shockingly rare.

MOST COMPANIES DO NOT HAVE A REAL ESTATE STRATEGY

A company's corporate real estate portfolio requires a carefully developed strategy because it can make meaningful contributions to top corporate concerns including human capital, operational excellence, innovation, customer relationships, corporate brand and sustainability. When properly developed, a real estate strategy can also provide operating flexibility – a key requirement in the ever-shrinking business life cycle. Absence of a strategy will typically result in a quagmire of poorly-suited real estate commitments that can inhibit growth, create company-wide inefficiencies, jeopardize hiring, taint the company brand and ultimately hurt the bottom line.

After reading this, executives anxious about not having a real estate strategy may take some comfort in knowing they are not alone. When the Real Estate Executive Board surveyed a cross-section of companies on this topic, they found that only 18% possessed a long-term real estate strategic plan that aligned real estate with overall business goals. This misstep has resulted in unnecessary costs, operational inefficiencies and increased risk, all of which can harm other business initiatives.

Typically, the absence of a real estate strategy can be narrowed down to two root causes: thinking a strategy exists when it actually doesn't and a conscious choice not to create a strategy.

The biggest shortcoming of operating plans is that senior business executives are rarely integral to the process, ensuring a constant gap between company strategy and real estate execution.

ROOT CAUSE #1: YOUR "STRATEGY" ISN'T ACTUALLY A STRATEGY

In most instances, companies mistake an operating plan for real estate strategy. The same Real Estate Executive Board survey found 95% adoption of an operating plan that accommodates near- to medium-term real estate needs for timely space availability.

Operating plans have significant merits, but they ultimately fall short in creating an effective roadmap due to a piecemeal approach in addressing a company's real estate needs. Operating plans are typically reviewed annually with quarterly check-ins by the corporate real estate ("CRE") department and upcoming real estate decisions are made accordingly. As a result, CRE teams are continuously facing fire drill situations in which the company's physical space must somehow accommodate changing headcount projections, departmental shuffling or new corporate mandates. The biggest shortcoming of operating plans is that senior business executives are rarely integral to the process, ensuring a constant gap between company strategy and real estate execution.

Broad goals are also sometimes mistaken for strategy. Clearly, a strategy isn't the same thing as "keep real estate costs low" or "have an office in all fast-growing U.S. markets". These are broad, feel-good statements that may convince leadership that all is well. However, they don't drive real results because they only identify an ideal future state without any of the details of how to get there. Broad goals without an underlying roadmap for action are always insufficient.

ROOT CAUSE #2: A STRATEGY DOESN'T EXIST, AND WE'RE AWARE OF IT

Some CRE teams occupy the other camp: they know that they don't have a real estate strategy, and they haven't tried to build one. This decision can often be traced to three key challenges commonly faced by CRE departments. The first challenge is the perception of ability, or lack thereof. The notion of a holistic strategy that aligns real estate with the rest of the company is viewed as a monumental task. They don't believe they have the right attributes for success, including influence with senior corporate leaders, depth and breadth of data and the correct frameworks to develop a strategy.

The second challenge is having the right resources in place. Unfortunately, the CRE department is often operating on a different plane than their partner business units which are relied upon regularly for data and feedback. While the real estate department plans around long-term assets, other business units are moving quarter to quarter, reacting to immediate concerns like changing headcount growth projections and shifting customer preferences. Furthermore, CRE leadership is often buried deep in a corporation's organizational chart, tasked with putting out fires and only being noticed when real estate fails to perform. This lack of structure to regularly inform the CRE department of business unit needs is at odds with the basic inputs required to develop strategy. Frequently, CRE is set up to fail from the start.

Finally, whether they have already tried or have yet to start, many in CRE lack the will to develop a strategy. Both new and seasoned professionals aspire to have a strategy but feel discouraged, often due to lack of knowing where to start or how to align against disparate and diverse company objectives. Others have resigned themselves to a Band-Aid approach to real estate after trying to develop and execute a strategy, but ultimately failing.

WHY A REAL ESTATE STRATEGY IS ESSENTIAL FOR BUSINESS SUCCESS

The gap between corporate objectives and real estate strategy can result in at best, missed savings opportunities and at worst, a real estate portfolio that limits company growth. The solution for overcoming this gap is to change the mindset from "nice to have" to "essential for business" by highlighting the substantial benefits:

Transform real estate from an inhibitor of change into an enabler of growth.

Enable a quicker decision-making process that incorporates established company strategy in real estate decisions.

Reduce real estate cost and prevent poor space utilization by evaluating ongoing business unit requests against the strategy.

Expedite comprehensive planning of financial expenditures by location and department.

Optimize the performance of each facility against stated company space utilization, business enablement or revenue goals.

Improve talent attraction and retention through a strategy-led workplace that encourages employee wellness, enables collaboration and promotes company brand.

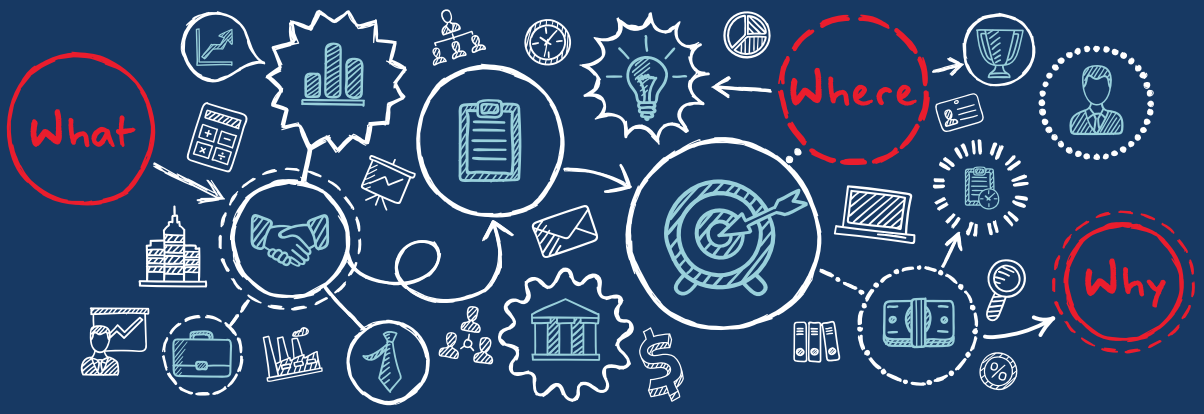
Promote regular realignment of the real estate portfolio during contractual lease renewals and resizing opportunities.

Improve flexibility in the real estate portfolio to meet the occasional bumps in the road.

Enhance risk mitigation through thoughtful capital placement on justifiable matters.

CASE STUDY

Several of these benefits are demonstrated in a recent Cushman & Wakefield study for an education technology company. By adopting a real estate strategy, the company realized transformative change after years of acquisition resulted in a bloated and inefficient portfolio. The company launched the strategy on the concept of realigning their portfolio around core employee hubs to insert strategic objectives on driving performance, enhancing culture, enabling growth and using space efficiently. The company adopted a center of excellence model to rationalize a portfolio of redundant operations. The model was used to evaluate the footprint for labor skill requirements, targeted demographics and access to target customers. The result of the realigned portfolio was an annual savings of 40% over the base case scenario and reengaged employees from new amenities, improved collaboration, enhanced culture and renewed energy.



COMPONENTS OF A REAL ESTATE STRATEGY

Development of a true real estate strategy requires executive leadership and CRE management to think through a wide range of complex and nuanced details, arranged into three key components - What, Where and Why.

WHAT

First and most broadly, a strategy must have a What which is what the company plans to achieve and what specifically the real estate will do to help the company achieve its vision. This includes the tools that will be used, the staging or phasing needed to smooth the impact to both customer and employees, and what the real estate will do to differentiate the company from its competitors. A common What in a competitive labor market is to create a workplace that promotes employee health and wellness as a way to retain and attract the best employees. The path for achieving this is a comprehensive workplace strategy that measures how employees actually work in the space, understands peer best practices and recommends high-impact solutions like improved access to natural light, healthy food and an environment that promotes movement.

WHERE

The next critical component is the Where, the geographic or departmental scope of real estate strategy. Unfortunately the Where is one of the most overlooked areas of strategy as business leaders frequently miss the nuances of market variation. Consider a manufacturing company planning an expansion or consolidation. Regardless of market share or growth plans, it is paramount in today's globalized economy that the Where is carefully considered and the finalist sites are in the right geographic region. Mistakes here can drastically affect significant P&L line items such as wages, energy cost, raw materials, and freight resulting in unfavorable cost structures. This diminishes competitiveness, pulls resources and limits the ability to continuously innovate. Where must also include an exit strategy for all assets to minimize cost and risk as the business evolves.

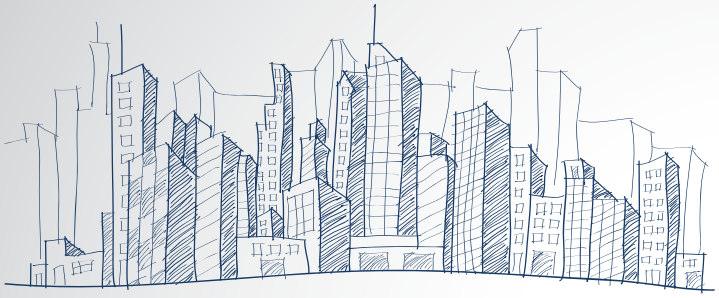
The Where challenge is equally important in the retail and service-based industries. These businesses thrive by locating in a geographic area that does not just have a large population, but more importantly has a large population of existing and potential customers. Many retailers spend millions to build out a location in a hip new area of the city only to shutter their doors after a few years of consistent underperformance. With location being such a heavy contributor to retail success, performing basic due diligence with attention to target customers can help avoid unfortunate losses from short term holds.

WHY

Why is the motivation for the company to undertake the strategy, since it identifies the return on investment. It is the economic logic that in the purest possible way justifies why the company should change course. This component requires a good amount of due diligence and data driven analysis to prove the strategy is tied to fundamental goals and is the correct path to head down in the long term. Why is necessary because significant strategic changes can disrupt employees who have done the same job the same way for years. It also creates substantial expense in new tools, processes, technology and the relocation of facilities.

HOW TO BUILD A REAL ESTATE STRATEGY

In order to build a real estate strategy, CRE leadership should enact a process that systematically aligns company goals and real estate criteria to develop a repeatable framework for decision making. Cushman & Wakefield suggests the following four steps when building a strategy:

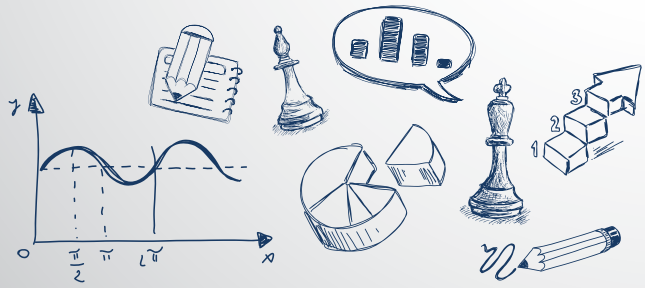


1 Mission & Goal Alignment

During the first step, key CRE stakeholders need to define the company's mission and the goals required to achieve that mission. It is essential that CRE stakeholders push their thinking and ensure that the full potential of the company today and in the future is included in the stated goals.

2 Real Estate Solution Criteria

The second step is to take the goals and translate them into specific real estate criteria that will enable the company to evaluate future decisions based on measurable data points. Criteria may include cost, access to labor, client access, brand and visibility, risk, transportation infrastructure, departmental organization, and workplace design standards.

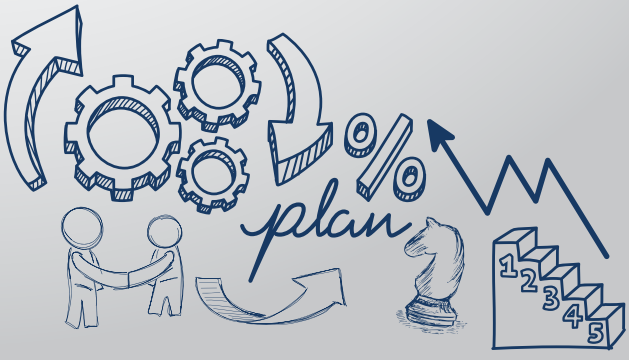


3 Criteria Weighting

Following criteria creation, leadership must weigh each of the criteria according to relative importance. This ensures current and future real estate options are evaluated and compared according to what matters most to the company's mission and are not subject to bias and preconceptions.

4 Strategic Scorecard Creation

In the final step, the company should be able to construct an interactive, weighted scorecard to compare different locations and ultimately make a decision based on a transparent quantitative and qualitative analysis. The relative merits of any real estate scenario, both portfolio-wide and individual properties, can be examined using a comprehensive and endorsed set of criteria.



While the four steps to building a real estate strategy appear straightforward, a successful strategy will also have several distinct attributes to address and overcome the two major root causes for lacking a strategy. The process of bringing the strategy to life begins with consistent data reporting (which is rarely aggregated and analyzed in one place) to understand the current state. Location, asset value and space utilization are significant cost and operational baseline data points for any company with a real estate portfolio consisting of multiple departments across wide-ranging geographies. The missed opportunity of understanding even basic performance is demonstrated in a survey conducted by the Real Estate Executive Board - only 14% of CRE departments knew how their current real estate spaces were being utilized!

After data consistency, multiple company departments need to be regularly engaged to share any relevant plans or issues that could affect the real estate strategic plan. Whether departmental or company-wide, issues like growth forecast variation and management change can quickly modify the current strategic objectives of the company and derail the real estate strategy. Lack of engagement and accessibility dooms CRE management to make the same mistakes leading to unnecessary costs and failure to the link real estate requirements to company-wide goals. Executive sponsorship of the strategy helps to drive cooperation among business units if it did not exist before. CRE management can also proactively meet with department leads to help them understand the real estate decision making process and the importance of lead time and regular check-ins.

An effective real estate strategy must adapt to changing internal and external forces. Internally, transformative events like a merger, new senior leadership, and departmental restructuring can introduce a series of challenges to the strategy's framework and established success criteria. Externally, the strategic value of a company's offices, warehouses and customer-facing centers can evolve based on changing factors such as employee demographics, supply chain cost and consumer tastes. A properly developed strategy ensures its survival by allowing new criteria to be evaluated using the same goal and criteria weighting framework. The strength of the strategy in the face of potentially sensitive and contentious matters is its defensible, informed, and data-supported decision-making process.

The strength of the strategy in the face of potentially sensitive and contentious matters is its defensible, informed, and data-supported decision-making process.

For those that think they have a strategy but don't, comparing the current plan to the essential What, Where, Why components is the ideal stress test. Simple but direct questions like "what do we plan to achieve?" or "how will we obtain our returns?" will lay bare any deficiencies in the current solution. For those that don't think they have the skill, resources or will to build a strategy, the steps above are designed to base all decisions on the ultimate core objective of the company, drive alignment across stakeholders, and remove bias and preconceived ideas from clouding the decision process. This process-driven approach puts CRE at the center of strategy development – increasing visibility and connecting business units.

WHAT SUCCESS LOOKS LIKE

Companies frequently use the What, Where, Why strategy components to enact change across the organization. In one recent example at a major health insurer in New York, company leadership used a real estate strategy as a strategic differentiator – that is, letting the real estate be a contributor to organizational success. Initially, the portfolio of more than 30 offices lacked the flexibility, attractiveness to talent and efficiency needed to realize corporate objectives.

Cushman & Wakefield developed a strategy starting with the What, which was to align the portfolio with existing long-term goals to better support work activities while realizing cost savings from efficiencies in increased space utilization. The Where focused on tactical, location-based suggestions including consolidation, relocation and placement of hard-to-fill occupations in growth markets. The solution was to identify functional redundancies, separate client-facing functions from support and reallocate critical operations to markets of high value. Lastly, Cushman & Wakefield provided the Why by quantifying the investment and identifying each recommendation's opportunity to affect positive change.

The real estate strategy was aligned with healthcare industry changes and relied upon internal resources that would ensure the plan was implementable. The approved recommendations resulted in productivity improvements, better deployment of employees allowing for growth in customer-facing clinical space, and access to target labor markets. The client's long-term benefit is expected to yield increased market share from maximizing accessibility to potential patients, thereby increasing overall revenue goals.

CASE STUDY: 1

CASE STUDY: 2

In another example, a major utility faced the challenge of providing consistent, reliable electric service to markets with varying levels of demand. Being part of a highly-regulated sector, the company also faced aging infrastructure that was unable to provide critical service to its customers every day. Company leadership recognized that they needed a strategy to realign their portfolio to provide better customer service and attract the best up-and-coming talent to their industry.

Cushman & Wakefield helped the company formulate how to think long term about their real estate portfolio of almost 500 properties (more than 5.1 million square feet) ranging from office parks to unimproved land. A strategy was developed in the form of a playbook that laid the groundwork for how capital should be allocated over 10 years to achieve operational performance, employee experience and talent attraction goals.

At the core of the playbook is the What built on the foundational questions of "What does the best possible workplace look like for our employees?" and "Where and how many workplaces should there be?" Research included leadership interviews, an employee survey and a space utilization study. The collected data was then compared against benchmarks and established industry best practices from leading peer companies.

The Where question asked where to operate certain business groups and where to locate both critical and service center facilities. C&W carefully considered which business groups could and could not be mixed together and conducted network optimization modeling to analyze current day frequency and quantity of service tickets to test service center locations for the optimal customer support.

The playbook ends with a discussion on economic logic - the Why - to support the recommendations. The answer for the company was an updated footprint that reduced wasted dollars on inefficient or redundant locations, improved the employee experience, and attracted and retained the best talent in the industry. These three major achievements also had a trickle-down effect contributing to the goal of providing great customer service.

IN SUMMARY

The influence of real estate on a company's success is often underestimated and misunderstood. However, an incredible opportunity exists to recast real estate as an important foundation of a company's success by instituting a strategy with the essential What, Where, Why components. These three elements form a coherent roadmap to let real estate help the company achieve its objectives and eliminate the frequent practice of piecemeal, disparate activities.

The good news for CRE leadership is that strategy is completely achievable if the prescribed goal, criteria, and scorecard development steps are followed. Strategy creates a huge opportunity to connect good data, input of business partners and a clear understanding of business objectives to make real estate a driver of company success instead of an impediment. Remarkably, few have seized the opportunity to adopt a true real estate strategy addressing how real estate inertia and constantly shifting external forces hinder the ability to compete and survive. Companies investing the upfront time and energy along with the property framework will result in immediate cost savings, an improved employee experience and the long-term ability to better compete, adapt and ultimately thrive.

METHOD CASE STUDY

Eco-friendly cleaning supply company Method is known for pushing the envelope in the business community for activities like making products from recycled Pacific Ocean plastic litter and promoting a work culture of "imagination plus execution". The strategy to embody positive impacts in everything they do resulted in the first LEED platinum factory certification for Method's first U.S. manufacturing plant on Chicago's south side. The chosen location allowed Method to positively influence the impoverished neighborhood by creating jobs for local residents. Sustainability also drove the site selection process to a former brownfield site which now includes a refurbished wind turbine and a solar array to generate about half of the plant's annual electricity. The factory is covered in a green roof and provides fruits and vegetables for local businesses and the community. The factory is truly clean in production and energy – the perfect complement to their "people against dirty" marketing campaign.

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ABOUT CUSHMAN & WAKEFIELD

Cushman & Wakefield is a global leader in commercial real estate services, helping clients transform the way people work, shop, and live. The firm's 43,000 employees in more than 60 countries provides deep local and global insights that create significant value for occupiers and investors around the world. Cushman & Wakefield is among the largest commercial real estate services firms in the world with revenues of $5 billion across core services of agency leasing, asset services, capital markets, facilities services (branded C&W Services), global occupier services, investment management (branded DTZ Investors), tenant representation and valuations & advisory. To learn more, visit www.cushmanwakefield.com or follow @Cushwake on Twitter.