

# Disclosure of Third Party Data: Compliance and Beyond

10<sup>th</sup> Annual Pharmaceutical and Compliance Congress  
November 11, 2009



**Howard L. Dorfman**  
Ropes & Gray LLP  
howard.dorfman@ropesgray.com  
(212) 596-9114

# Background of Third Party Data Legislation and Litigation

## State Prescriber Data Laws

- New Hampshire
- Vermont
- Maine
- Massachusetts

## Recent Litigation of Prescriber Data Laws

- Litigation of the NH, VT, and ME prescriber data laws
- Arguments Employed Against Prescriber Data Laws
- Courts' Reasoning In Upholding Prescriber Data Laws

# Summary of State Prescriber Data Laws

Prescriber data laws are currently effective in three states:

- New Hampshire
- Vermont
- Massachusetts

Maine's prescriber data law is currently subject to a preliminary injunction

Prescriber data legislation is being considered in approximately 24 additional jurisdictions

# New Hampshire's Prescriber Data Law

N.H. REV. STAT. § 318:47-f (2006)

Bans the use of prescriber data

Limited applicability with respect to public health and research

Enforcement

- Attorney General may file actions in superior court for an injunction and civil penalties

# Vermont's Prescriber Data Law

VT. STAT. tit. 18, § 4631 (2007)

Allows physicians to opt-in to drugmaker access to their data

Requires physicians to disclose to patients:

- Information on benefits and risks
- Range of drug treatment options
- Costs of treatment options

Entities using prescriber data must monitor the list of consenting providers every six months

## Vermont's Prescriber Data Law (cont.)

### Enforcement

- Attorney General may file an action in superior court
- Attorney General has authority to investigate and obtain remedies
- Attorney General may obtain separate relief for each violation

# Maine's Prescriber Data Law

ME. REV. STAT. tit. 22, § 1711-E (2007)

Allows physicians to opt-out of drugmaker access to their data

Prohibits the use of prescriber data "for any marketing purpose"

Imposes an annual fee on manufacturers of prescription drugs whose drugs are dispensed to members of the MaineCare program

## Enforcement

- A violation constitutes a violation of Maine Unfair Trade Practices Act (Attorney General may pursue injunctions and civil penalties)

# Massachusetts Code Of Conduct

105 MASS. CODE REGS. 970.005(2) (2009)

Final regulations became effective on July 1, 2009

Manufacturer must offer prescribers the opportunity to opt-out before utilizing their data for marketing purposes.

Pharmaceutical companies using non-patient identified prescriber data must respect the confidentiality of data, develop and train employees on data policies, identify disciplinary actions for data misuse and

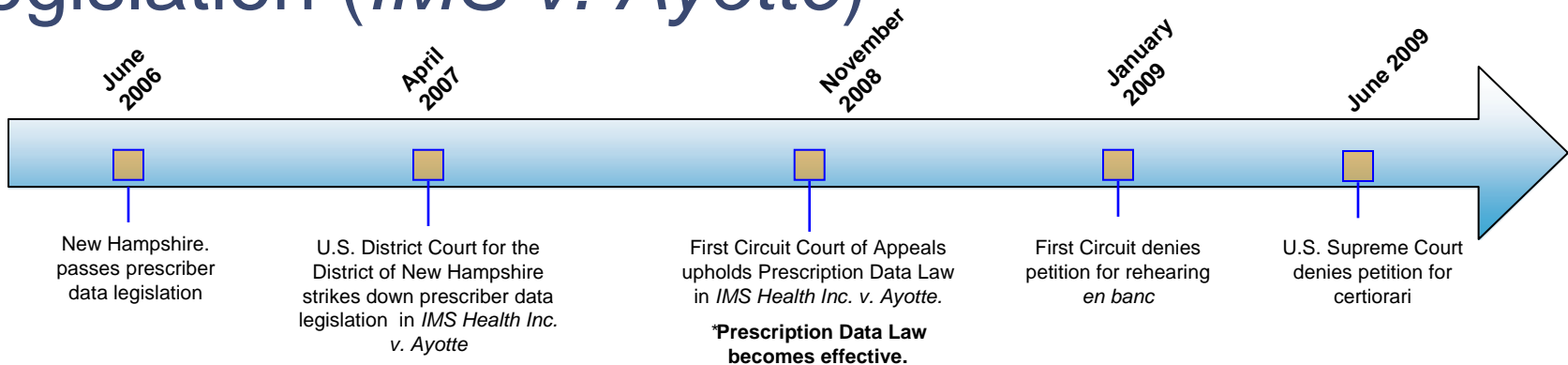
- Designate an internal person to handle inquiries about data use
- Comply with health care providers' requests not to make their data available to sales representatives

## Enforcement

- An authorized entity may impose fines and file a civil complaint upon a failure to pay a fine



# New Hampshire - Litigation of Prescriber Data Legislation (*IMS v. Ayotte*)



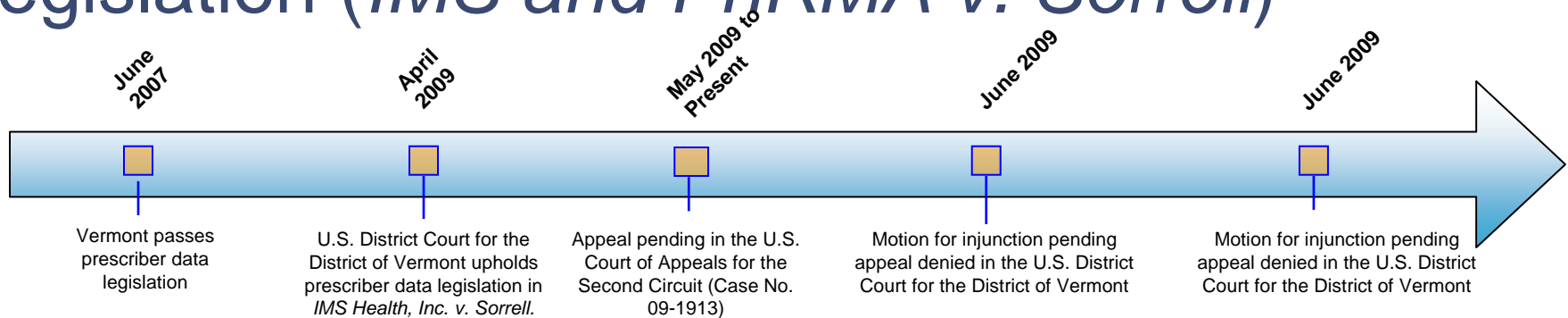
June 2006: Prescriber data legislation passed, lawsuit filed  
July 2006

April 2007: New Hampshire District Court holds that law violates the 1<sup>st</sup> Amendment

November 2008: 1<sup>st</sup> Circuit upholds the law in *IMS Health Inc. v. Ayotte*. **New Hampshire's prescriber data law becomes effective.**

June 29, 2009: Supreme Court denies certiorari

# Vermont - Litigation of Prescriber Data Legislation (*IMS and PhRMA v. Sorrell*)



June 2007: Prescription data legislation passed

July/August 2008: Trial held, adverse decision by Judge Murtha

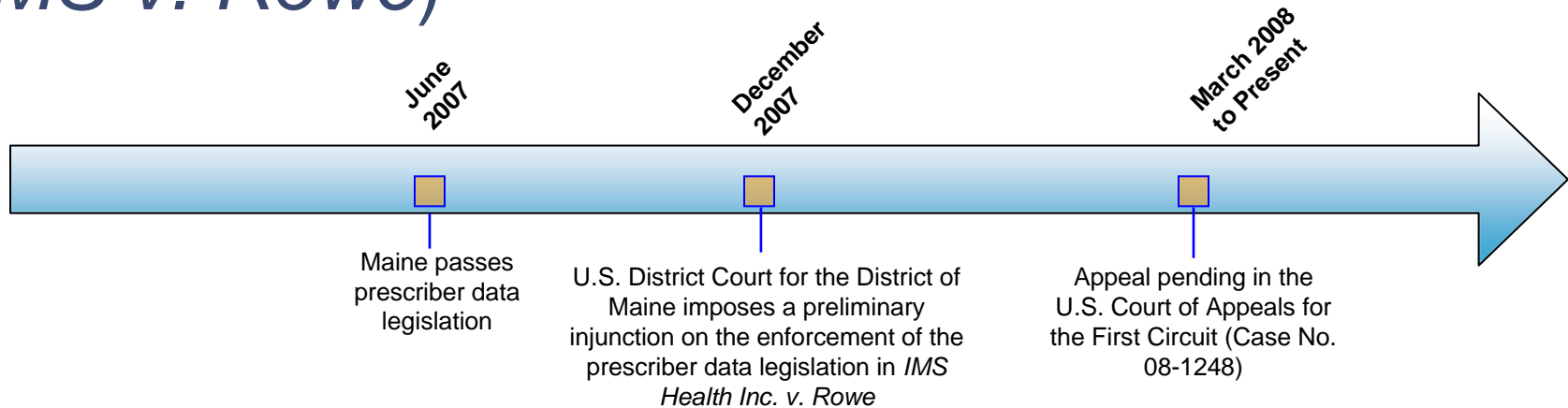
April 2009: Vermont District Court upholds the law in *IMS Health, Inc. v. Sorrell*.  
**Vermont's prescriber data law becomes effective.**

May 2009 to Present: Appeal pending in the 2<sup>nd</sup> Circuit Court of Appeals

June 2009: Motions for injunction pending appeal denied in both the Vermont District Court and the 2<sup>nd</sup> Circuit Court of Appeals

2010: Decision expected

# Maine - Litigation of Prescriber Data Legislation (*IMS v. Rowe*)



June 2007: Prescriber data legislation passed

December 2007: Maine District Court imposes a preliminary injunction on legislation's enforcement

March 2008 to Present: Appeal pending in the 1<sup>st</sup> Circuit Court of Appeals

**Maine's prescriber data is not yet effective**

Once decision entered, to continue at district court

# Recent Litigation of Prescriber Data Laws

## Arguments Against Prescriber Data Laws

In *IMS Health, Inc. v. Ayotte* and *IMS Health, Inc. v. Sorrell*, the plaintiffs argued that prescriber data laws:

- Violate the First Amendment by regulating Constitutionally protected commercial speech
- Are not supported by empirical evidence that they would control costs or improve public health
- Frustrate the benefits to patients and physicians that result from manufacturers using prescriber data to target their marketing initiatives

# Recent Litigation of Prescriber Data Laws

## Courts' Reasoning Upholding Prescriber Data Laws

In *IMS Health, Inc. v. Ayotte* and *IMS Health, Inc. v. Sorrell*, the First and Second Circuits held that the New Hampshire and Vermont prescriber data laws:

- Survive the “intermediate scrutiny test” and justifiably restrict commercial speech because these laws:
  - Further substantial state interests in cost containment and public health promotion
  - Directly advance those interests
  - Are narrowly tailored to serve those interests

# Recent Litigation of Prescriber Data Laws

## Courts' Reasoning Upholding Prescriber Data Laws (Cont.)

The First and Second Circuit held differently on whether prescriber data laws regulate conduct or speech

- In *Ayotte*, the First Circuit held that New Hampshire's prescriber data law regulates conduct not speech (the First Circuit added that the law would still be Constitutional if it were understood to regulate speech)
- In *Sorrell*, the Vermont District Court held that the Vermont prescriber data law regulates speech (but that this regulation was Constitutional)

# **INTEGRATED BUSINESS PROCESSES AND COMPLIANCE OPERATIONS**

Dave Wysocky

Director, Pharmaceutical and Life Sciences Advisory Services

PricewaterhouseCoopers

# Aggregate Spend Reporting – Current Landscape

How Do You Connect These Pieces Together?

Sales	Marketing	Finance	Medical Affairs	R&D	Compliance and Ethics	IS
			Engagement of HCP			
			Speaker Programs/Consulting Agreements			
			Grants and Contributions			
			Meals and Educational Items			
			Other ....			

Data Integration & BI/Reporting

Compliance Insights

Monitoring

Disclosure

Cost Reduction

Business Decisions

Application Landscape

Master Data Management

Customer Master

Vendor Master

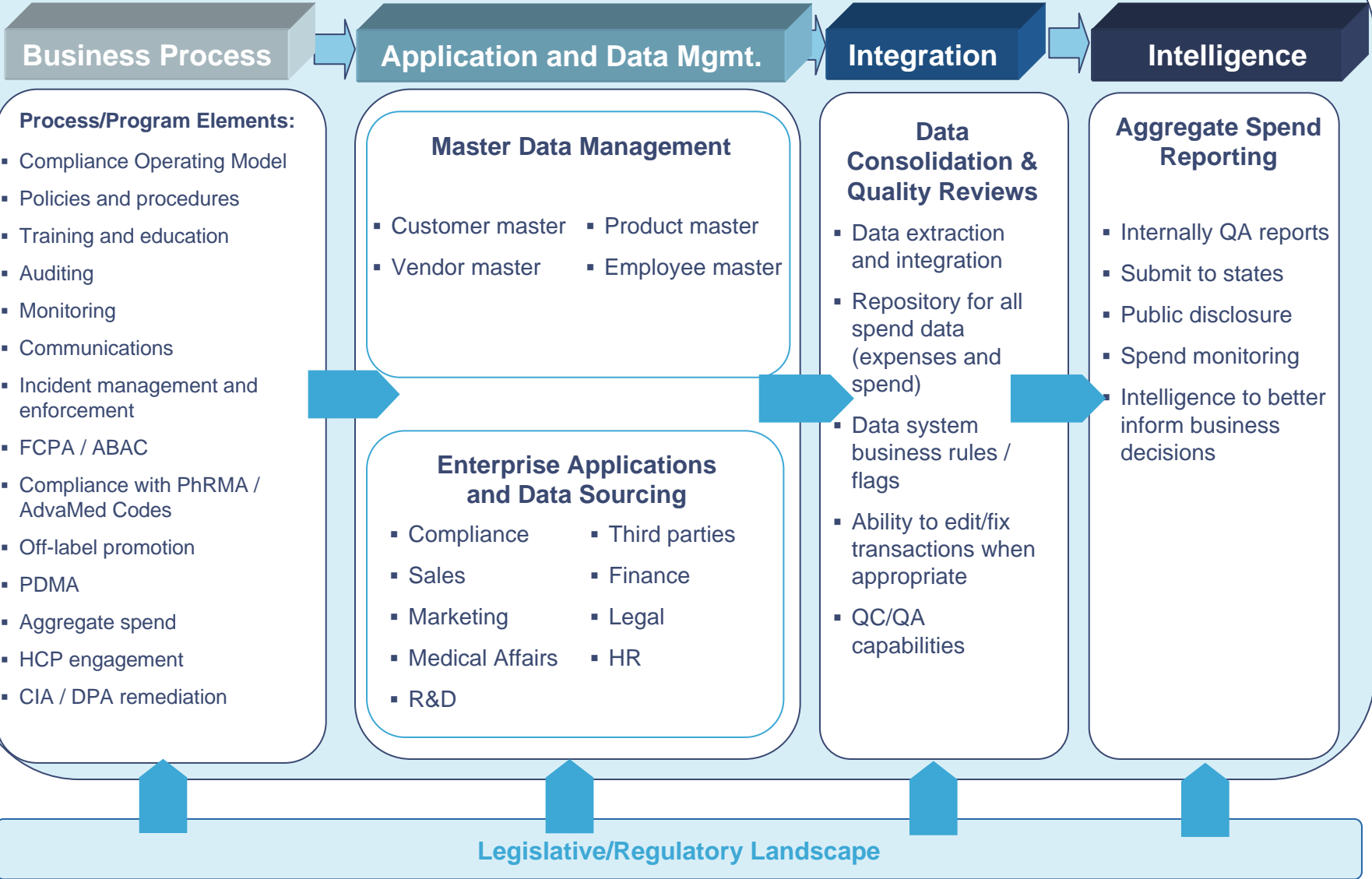
Product Master

Employee Master



# Compliance Operations & Required Building Blocks

**Governance:** Roles/responsibilities and processes to operate and evolve the Aggregate Spend capability



# Changing Landscape

## Challenges

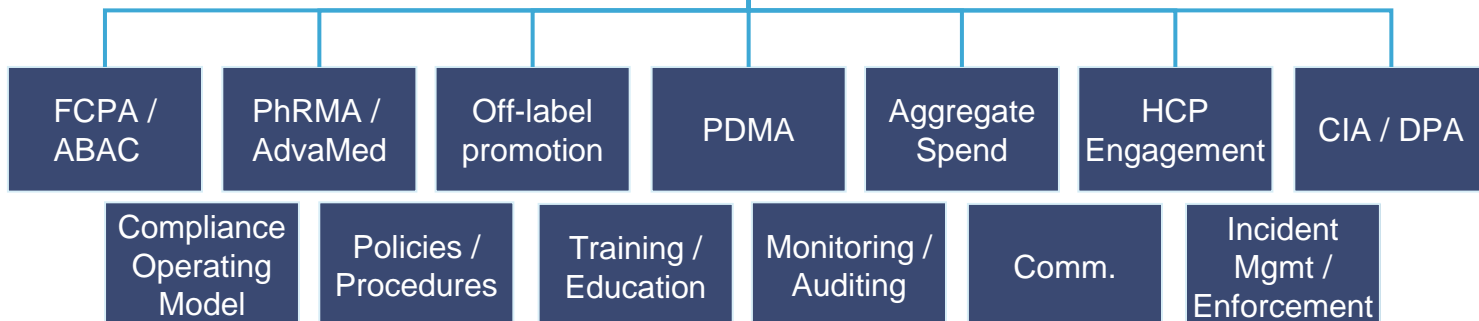
- Growing list of key stakeholders / interested parties
- Large and complex “waves” of data
- Increase in data detail and complexity
- Insufficient level of staff to deal with data volume / complexity
- Difficult to identify emerging trends / issues
- Unclear how prevalent specific issues may be within organization

## Compliance Operations

- **Operations Analysts**
  - Cross-functional skills and approach
  - Data Management focus
  - Monitoring capabilities
  - KPI/Reporting
  - Process focused

## Outcomes

- Shift to intelligence and data driven function
- Increased automation / integration
- Push vs. pull processes
- Increased formalization of cross- functional relationships
- Cross-training across areas / issues, e.g. rotation program
- Cross-disciplinary skills necessary
- Proactive rather than reactive



# Changing Landscape

*Compliance function increasingly data and intelligence driven*

- Too much data to sift through, difficult to identify emerging trends/issues
- Need guidance on where to begin investigating
- More formalized relationships with other functional groups, particularly IT/IS
- Skills needed are rapidly evolving to more cross disciplinary skills that emphasize data mining, performance metrics, reporting

# Disclosure of 3<sup>rd</sup> Party Data Compliance and Beyond

Katie Topolewski  
Senior Counsel, Commercial Business  
Endo Pharmaceuticals Inc.

*The views presented are those of the presenter and do not necessarily reflect those of Endo Pharmaceuticals Inc.*

# Assess Current Practices

What are your current tracking practices?

- Manual, IT solution, or both

Are there anticipated challenges to your current practices?

How can you address those anticipated challenges?

# Challenges to Current Practices

## Further passage of state and federal legislation

- Amount of information required to be disclosed may become unmanageable via your current practices

## Mandated disclosure of payments to U.S.-based physicians in recent Corporate Integrity Agreements

## Company growth

- More employees could mean more payments to report
- Growth via acquisition, merger, co-promote

# Addressing the Challenges

Communication to key stakeholders re: challenges

**Aggregate Spend Evaluation** *(can be conducted internally or by an external consultant)*

- Identify where (and why) the company is making payments, or providing items of value, to HCPs
  - Interviews, surveys, or both with impacted departments

Analysis of the data and discuss next steps

# DISCLOSURE OF 3<sup>RD</sup> PARTY DATA COMPLIANCE AND BEYOND

Tony Brennan

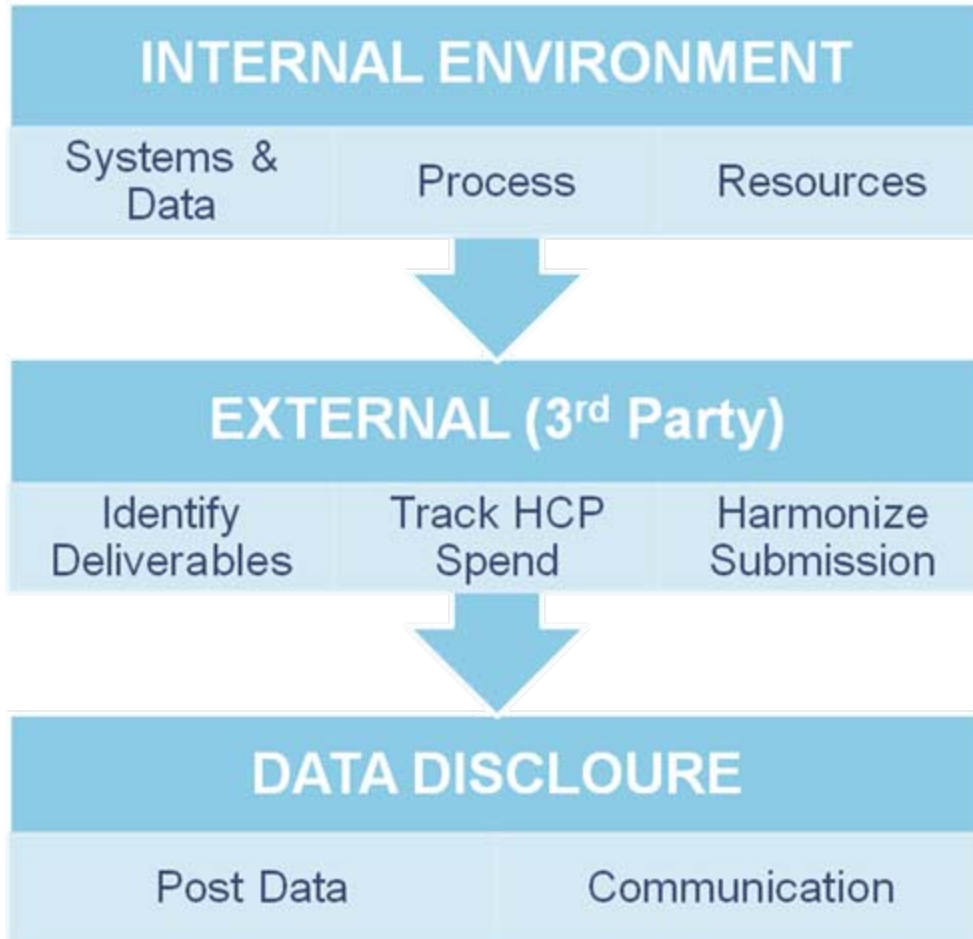
Director, Global Reporting & Monitoring

Johnson & Johnson Pharmaceuticals Groups

*The views presented are those of the presenter and do not necessarily reflect those of Johnson & Johnson Pharmaceuticals Groups.*



# Disclosure 3<sup>rd</sup> Party Data: Compliance & Beyond



- ❖ Develop process and procedures to ensure accurate and timely data disclosure
- ❖ Training & Awareness on data transparency
- ❖ Ensure accuracy of data : testing & validation
- ❖ Post data in a clear, accurate, timely and consistent manner
- ❖ On-going governance to enhance the process
- ❖ Improve management's understanding of HCP data and it's impact to business results.

# INTERNAL

## Data Standards

Identify Direct :  
Indirect Spending  
Conduct a  
Supplier Inventory

Establish unique  
HCP ID#s  
Define HCP data  
Scope

## Standard Process

Sustainable &  
repeatable  
Central System of  
Record

Consolidation  
Process  
(Aggregate spend)  
Frequency  
(Monthly,  
Quarterly)

## Internal Resources

Dedicated  
Clear Roles &  
Responsibilities  
Review &  
Approval

Data Validation  
Ability to Respond  
to requests

# EXTERNAL (3<sup>rd</sup> Parties)

## Deliverables

Data  
Completeness

Data Accuracy

Clear deliverables

In-scope and  
timing

## Capability

Diverse Systems

Supplier  
capability  
Assessment

Sub-contractor  
usage

Data Validation

## Submission

- What to Report

- How to Report

- When to Report

- Correction  
Process

- Resubmission

# DISCLOSURE

## Post the Data

Single vs. multiple sites

Timing of disclosure

Format of data (searchable, flat file, other)

Glossary, FAQs

## Communication

Communication Plan

Internal Communication  
External Communication

Requests for additional information

- HCPs
- Media Requests