Mini Summit 20: Agg Spend 2.0: The Next Generation of Agg Spend Solutions, including Data Collection and Adjudication Challenges, Integration with Compliance Controls and Monitoring and Global Challenges

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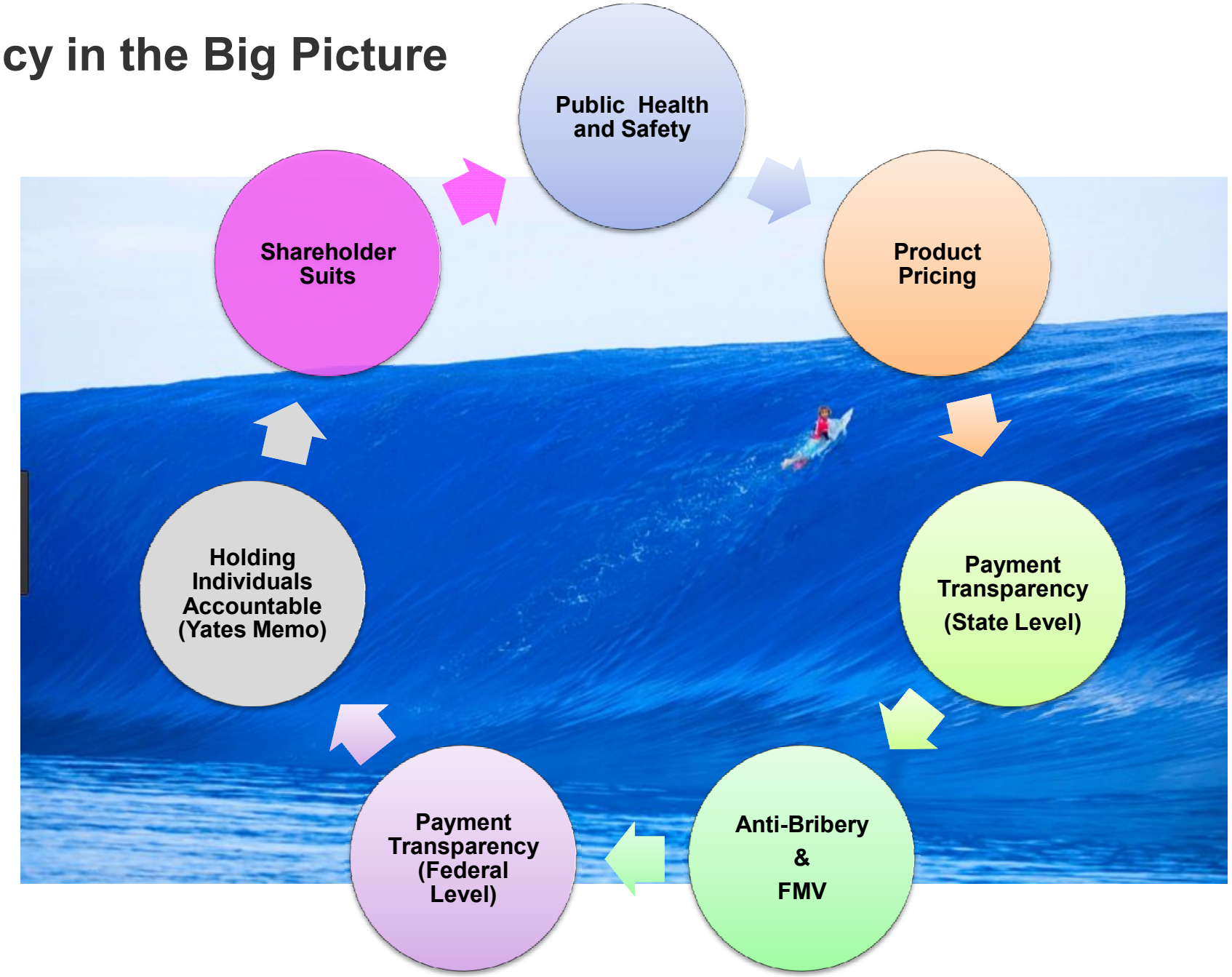
Transparency in the Big Picture



Enforcement Overview and Trends

2016 Highlights

- DOJ Enforcement against drug/device: $1.4B to gov't
  - *$2.5B for all healthcare*
- $4.7B total in civil settlements and judgments
  - *3rd highest annual recovery*
  - *Largest recoveries came from drug/device*
- 800+ new FCA cases filed
  - *2nd highest number of cases in any year*

2017 Mid-Year Highlights

- DOJ: We remain "fervently committed" to enforcement in drug/device industry
  - Will *vigorously pursue fraud*
- **$984M in FCA settlements with 11 companies**
- *Shire*: $350M AKS settlement
- *Mylan*: $465M for rebates
- REMS violations
  - *Aegerion*: $35M
  - *Novo Nordisk*: $58M
- *Mallinckrodt*: $35M suspicious order monitoring (DEA CSA)

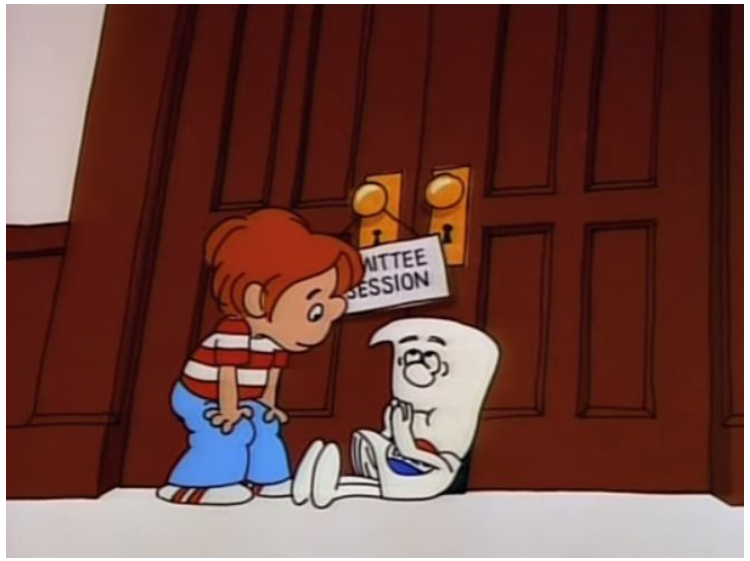
Evolving Scrutiny

- **Increased Scrutiny:**
  - Risk Evaluation and Mitigation Strategy ("REMS")
  - Suspicious Order Monitoring
  - Donations to Patient Assistance Programs ("PAPs")
  - Speaker payments vs. Medicare Script data
- **Decreased Scrutiny:**
  - Off-label Promotion of Drug/Devices

Congress “Inaction”

Affordable Care Act (“Obamacare”) Repeal Efforts

- 2010 enactment through EOY 2012: 33 partial or whole repeal attempts
- 2013 – March 2014 - 54 partial or whole repeal attempts
- 115th Congress (2017-2018)
  - January 2017: Senate vote included budget resolution to repeal ACA
  - March 6, 2017: House announces ACA replacement
    - March 24, 2017: House withdraws; not enough votes to pass
  - **May 4, 2017 – House passes partial repeal of ACA**
    - June 22, 2017 – Senate unveils its own version of partial repeal
  - July 27, 2017 – ‘Skinny repeal’ defeated in Senate
  - September 13, 2017 – Graham-Cassidy amendment to May 4/June 22 version of bill submitted
  - September 26, 2017 – Senate announced it will not vote on amendment



2017 HHS OIG Work Plan

Open Payments in the Crosshairs

NEW: **Data Brief on Financial Interests Reported Under the Open Payments Program**

The Physician Payments Sunshine Act (from the ACA § 6002) requires that manufacturers disclose to CMS payments made to physicians and teaching hospitals. Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians. We will analyze 2015 data extracted from the Open Payments website to determine the number and nature of financial interests. We will also determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations. We will determine the volume and total dollar amount associated with drugs and DMEPOS ordered by these physicians in Medicare Parts B and D for 2015.

OEI: 03-16-00420 Expected issue date: FY 2017

- "We will analyze 2015 data... to determine the number and nature of financial interests."
- "We will determine ***how much Medicare paid for drugs***… ordered by physicians who had financial relationships…."

2017 HHS OIG Work Plan

Open Payments in the Crosshairs (continued)

Review of Financial Interests Reported Under the Open Payments Program

Manufacturers are required to disclose to CMS payments made to physicians and teaching hospitals (ACA § 6002). Manufacturers and group purchasing organizations must also report ownership and investment interests held by physicians. The Open Payments Program provides public transparency about provider-industry relationships. We will determine the extent to which data in the open payments system is missing or inaccurate, the extent to which CMS oversees manufacturers' and group purchasing organizations' compliance with data reporting requirements, and whether the required data for physician and teaching hospital payments are valid.

OEI: 03-15-00220 Expected issue date: FY 2017

- "We will determine the extent to which data… is ***missing or inaccurate***…."
- "We will determine… ***the extent to which CMS oversees manufacturers'***… compliance with data reporting requirements…."

US Transparency Update

Connecticut

- First report was due 7/1/17 (for CY 2016 transactions)
- New APRN covered recipient list expected November 2017

Federal (CMS Open Payments)

- 2018 Hospital List and Thresholds published (for March 2019 report)
- Updated functionality provided to public Open Payments site (for additional analytic capabilities)
- 1st *official* warning letter sent out to manufacturer (other late filing letters sent)

Vermont

- Enforcement appears to have lessened
- VT no longer requires an email notification of mergers/acquisitions, or accepts a delay in reporting due to any such merger/acquisition.
- Each co which was in existence or newly formed during a reporting period will be responsible for filing disclosures
- New guidance on name of reporting company (and no consolidation with other corporate entities)
- Confirmation that Federal Sampling report does not preempt VT report

US Transparency Update: *New Jersey*

Jersey Rules -- Proposed Regulations to Limit Prescribers' Acceptance of Items of Value and Compensation from Pharmaceutical Manufacturers and Related Disclosure Obligations

- The proposal would prohibit New Jersey prescribers from accepting certain items of value or compensation of certain amounts from pharmaceutical manufacturers and their agents, e.g., items that do not advance disease or treatment education (pens, notepads, mugs, items with company logo, gift certificates)
- The regulations would **not** impose prohibitions on manufacturers themselves (a distinction from many other laws that regulate industry-HCP interactions)
- In promotional contexts, meals would be limited to four times per year per prescriber and no more than $15 per prescriber
- As a general matter, aggregate compensation that a prescriber could receive across **all manufacturers** would be capped at $10,000 per year for promotional speaker programs, advisory boards, and consulting activity (not a cap per manufacturer)
- Written agreements for services would be required to contain very detailed information that most companies currently do not include in their consulting agreements, e.g.: manner by which the prescriber will maintain records concerning the arrangement and the services provided by the prescriber; the venue and circumstances of any meeting in which the prescriber participates, if applicable, addressing how it is conducive to the services provided and advances the primary focus of the meeting; an attestation that the prescriber's decision to render the services is not unduly influenced by a pharmaceutical manufacturer's agent
- Prescribers speaking at a continuing education event or at a promotional activity would be required to directly disclose to attendees, either orally or in writing, at the beginning of the presentation that they have accepted payment for bona fide services from the sponsoring pharmaceutical manufacturer within the preceding five years. Prescribers employed by a pharmaceutical manufacturer and who also provide patient care are required to disclose to a patient either orally or in writing his/her employment by the pharmaceutical manufacturer

US Transparency Update: *Chicago*

Chicago Bull

- Beginning **July 1, 2017**, drug reps who market or promote pharmaceuticals within the City of Chicago for more than 15 days per year are required to obtain a license
  - When requested by the Chicago Department of Public Health, ***drug reps also must disclose information*** related to the marketing or promotion of the products
  - Tracking started **October 15, 2017**
  - Report requests will not be made until January 1, 2018 (at the earliest)
- Disclosure only applies to interactions related to “any Schedule II medications, as defined by the Title 21 United States Code Controlled Substance Act”
- Report (“Disclosure Log”) includes 63 columns of data, including:
  - Location of Interaction (venue)
  - Duration of interaction
  - Sampling info
  - Drug-related materials (e.g., brochures or demo models)
- Preemption? Possibly not

US Transparency Update: *Nevada*

What happens in Vegas… gets posted publicly on a government website

- By **Oct 1**, (or w/in 30 days of hire), drug manufacturers must provide list of Nevada sales reps to DHHS
  - Only includes reps who physically operate* in Nevada for 5 or more days annually AND perform covered activities
    - Guidance includes MSLs. Scoping issue?
  - Reps not on the list cannot market drugs to any Nevada-licensed HCP/HCO or Nevada resident

- By March 1, each covered sales rep* must report to the DHHS:
  - A list of HCPs/HCOs/staff that the rep provided "compensation" exceeding $10, or $100 in aggregate
  - Name of the Drug, manufacturer, and recipient for all free samples

- Aggregate report posted to the internet by June 1 each year
- **Penalties**: $5k/day for manufacturers; $500/day for sales reps

- Law also requires reporting by nonprofit organizations

Global Transparency Reporting Numbers… and counting…

Global Reporting Every Month!

Canada (Ontario)

Proposed Bill

- Introduced September 27, 2017
- Applies to drug, device and generics
- Covers HCPs and HCOs
- Includes FFS, meals, travel/lodging
- Reported to a central database
- Tracking would begin in 2019

Industry Codes

EFPIA Disclosure Code

Medicines for Europe *Code of Conduct*

- **Applies to European Generics Medicine** Companies

- Covers Transfers of Values to HCPs and Patient Organizations
  - Includes fees for services and consultancy

Data collection started ***January 1, 2017***

Data Reported by ***June 30, 2018***

Industry Codes

MedTech Europe *Code of Ethical Business Practice*

- Association represents the medical technology industry.

- 2 members:
  - **EDMA**, the European Diagnostic Manufacturers' Association, representing the European in vitro diagnostic industry;
  - **Eucomed**, representing the European medical devices technology industry associations.

- Covers educational grants to HCOs

*Data collection started **January 1, 2017***

*Data Reported by **June 30, 2018***

*Data will be published by **August 31, 2018***

Identifying Future Trends

Blurred Lines: Drug Transparency and Payment Transparency

- Drastic increases in drug prices (e.g., Turing, Valeant, Mylan) causes spike in drug pricing legislation
- By the end of Q1 2017, Congress and 30+ US states proposed drug pricing legislation, including laws that would:
  - (1) limit drug prices or (2) impose new pricing transparency requirements on manufacturers
- Spend transparency inevitably linked to increased spending by government programs

Global Data Protection Regulation (GDPR) – a single privacy law for the EU

- Takes effect May 25, 2018

- Extra-territorial reach and expansive scope:
  - Applies to any organization, *regardless of it's geographic location, that handles personal data of EU citizens*

- The GDPR replaces the Data Protection Directive 95/46/EC, with the aim to:
  - Harmonize data privacy laws across the EU
  - Enhance the protection of EU citizen's data privacy
  - Reshape the way organizations approach data privacy.

- In summary, GDPR introduces the following changes
  - ✓ **Increased territorial scope**
  - ✓ **Stringent penalties** for non-compliance/violations
  - ✓ Additional conditions for **consent**
  - ✓ **"Privacy by Design"**
  - ✓ Increased **data subjects' rights**

GDPR & Transparency – what you need to know

Consent and Data Subject's Rights

Consent

- Affirmative
- Informed and unconditional
- Specific
- Right to withdraw

Access

- Why
- What
- Who
- When

Breach

- Identification and impact
- Right to notification under some circumstances

Erasure

- "Right to be forgotten"
- Systems and procedures

Correction

- Right to rectify

Data Portability

- Transfer
- Commonly-used format

GDPR readiness tips

GDPR Compliance Roadmap

Build Team	Assess Exposures & Risks	Design & Implement Operational Controls	Create Awareness	Demonstrate Ongoing Compliance
• Identify stakeholders • Allocate resources • Define program mission and objectives	• Conduct data inventory & data flow analysis • Conduct current state analysis • Conduct gap analysis	• Develop & Implement Compliance roadmap • Remediate & Implement Solutions • Obtain & Manage consent	• Identify functions implicated • Develop & Implement training program • Develop communication for data subjects	• Develop & Implement auditing / monitoring plans • Define internal / external reporting • Evaluate compliance program & controls effectiveness

Discussion & Questions

Questions?

Comments?

Best practices to share?