

Best Practices for Calculating Profit Disgorgement

November 7, 2019

Agenda

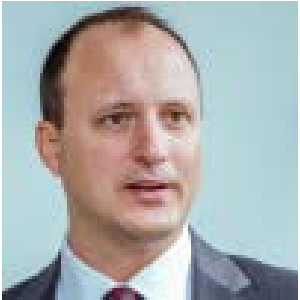
- **Introduction**
- Evaluating Allegations and Initial Discussion with the SEC
- Best Practice of Disgorgement Analysis and Financial Modeling
- Sample Analyses
- Questions and Comments

Introduction



Speaker: **Patrick Phelan**, JD
Partner, Covington & Burling LLP, Washington DC

Patrick is a litigator who has extensive experience representing major companies in civil and criminal investigations by the Department of Justice, the Securities and Exchange Commission, and other federal agencies concerning alleged violations of the False Claims Act, Anti-Kickback Statute, and Foreign Corrupt Practices Act. His experience includes frequently working with accountants and other experts on potential exposure and disgorgement analyses.



Speaker: **Brad Mroski**, CPA, CFE
Managing Director, AlixPartners, Former Assistant Chief Accountant, Division of Enforcement, U.S. Securities & Exchange

Brad is a forensic accountant who specializes in accounting, reporting and corruption related investigations. He has performed complex profits disgorgement analyses on numerous occasions for multi-national companies and while at the SEC. He is frequently called upon to provide expert advice and testimony related to accounting, auditing and financial matters in litigations and regulatory proceedings.



Moderator: **Yogesh Bahl**, CPA, MBA
Managing Director, AlixPartners

Yogesh works at the nexus of legal, compliance, and the business to execute high profile compliance initiatives, qui tam investigations, and corporate transactions. He has more than 20 years of experience in the life sciences and healthcare industry. Yogesh has been helping private equity firms evaluate companies for acquisition and has a deep knowledge of clinical trial operations and execution. He has also served as an expert in litigation involving commercially reasonable efforts, post-close transaction disputes, and breach of contract actions.

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Evaluating Allegations and Initial Discussion with the SEC

- Evaluating allegations
 - Investigate alleged conduct and identify potential revenue impact scenarios
 - Identify fact patterns for disgorgement analyses
 - Statute of limitations considerations
 - Engage expert
 - Start early
- Initial discussion with the SEC
 - Proactive vs. Reactive
 - Scope of discussion

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Based on the investigation, which factors will frame the negotiations and calculation of profits?

- What are the potential time periods that are the subject of disgorgement?
 - Statute of Limitations
 - Date conduct discovered/ceased
 - Period(s) of alleged activity
 - Other timing considerations, scheme theories, etc.
- Which products/NDCs/SKUs/indications are in scope for profitability calculations?
- Which country/region sales have the fact patterns of the most concern to the regulators?
- What financial data is needed vs available? Which systems in which countries?
- Which costs are attributable to the revenues at issue?
- What are the legal entities involved and are they all the same?

Translating the findings from the investigation into an assessment of profitability and potential disgorgement requires appropriate framing at the very beginning

Is the business model and fact pattern the same among countries and the regions within each country?

Areas to Consider

- Country's regulatory landscape
- Product launch strategy and budget
- Company's supply chain, associated processes, and data
- KOLs, consultants, other industry experts involved in the process
- Grants, research agreements, consulting agreements, etc.

Steps to Take

- Interview personnel in relevant government affairs, medical science, and marketing
- Review communication with government entities, market filings and approvals, etc. for relevant dates
- Review compiled communications between companies and KOLs, consultants and other industry experts involved in the process
- Evaluate the impact of relationships between KOLs, consultants and others with associated government entities.

Questions to Ask

- How /where were the products manufactured, sold/promoted?
- How and when was market authorization obtained?
- What was the product approval process?
- Which government entities were involved?
- What formal and informal (advisory) roles and positions did the KOL/consultants hold in government entities?
- Which research agreements, consulting agreements, etc. were approved when? Which KOLs/Consultants were involved?

Understanding the areas to consider, the steps to take, and the questions to ask at the beginning is key to avoiding work delays and budget overruns

Is the data needed for the disgorgement analysis available?

- Data retention policy and record keeping practices may vary in different countries
- Financial structure may vary depending on go to market strategy and enterprise-wide tax strategy
 - For example, an entity in one country may only be established for patient advocacy and education whereas another country may have complete manufacturing, promotion, and distribution functions.
- A company may not have stand-alone financial statements for specific countries, regions, NDCs, or SKUs at the granularity needed to calculate profits.
- Certain expenses may be tracked only at the enterprise/consolidated level and allocations performed in the ordinary course may not be performed. Examples of such expenses could be:
 - Global marketing expenses
 - Headquarter-specific expenses
 - Master distribution fees
- Countries may not have product cost information outside of transfer pricing established for tax purposes

Assumptions and allocation methodologies need to be discussed at a detailed level with business units, finance, accounting, tax, IT, legal, and country specific teams

A dynamic profit and loss financial model is required to effectively plan for negotiation scenarios

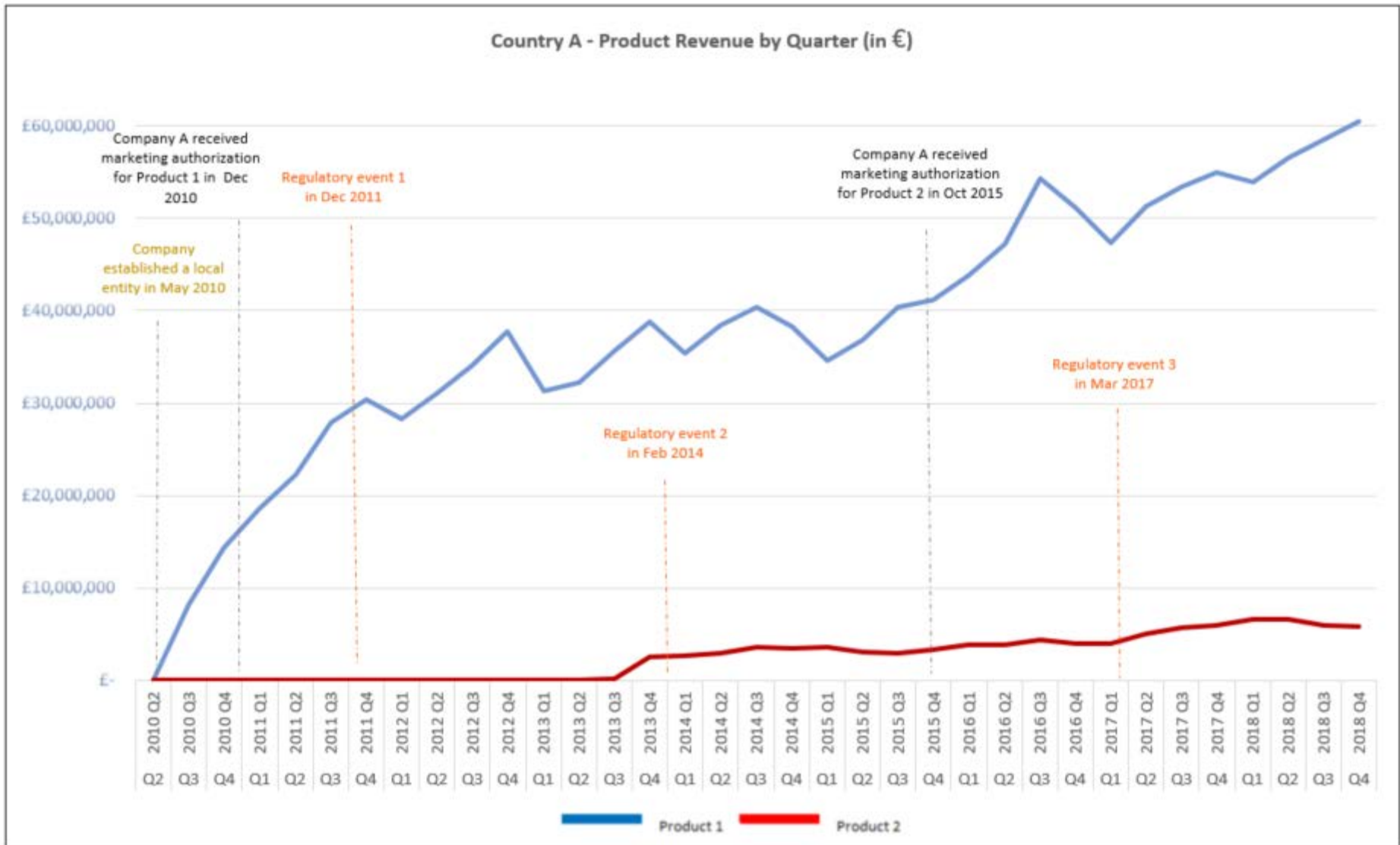
- Each country/region has its unique issues that need to be modeled across various timelines
- In order to be dynamic and effective, the financial model should include the following for each geography at issue:
 - Revenue: units (e.g., bottle/pill/vial) and price (gross and net)
 - Costs: COGS (standard/moving average), SG&A, allocated costs (marketing, distribution fees), and transfer pricing
 - Distribution Margin vs. Net Income
- Other factors to consider:
 - Incorporate timing of approvals, product launch, regulatory changes
 - Evaluate the sales trend against the country events (product registration, market authorization, KOL activities, and financial engagement of KOLs) for various periods
 - Assess correlation vs. causation among events, promotional efforts, sales revenue and patient acquisition
 - Analysis of costs to determine which ones would have been avoided but for the revenues generated

Consistent coordination among the company, external counsel, in-house counsel, and the forensic accountants are critical; weekly checkpoints are required at a minimum

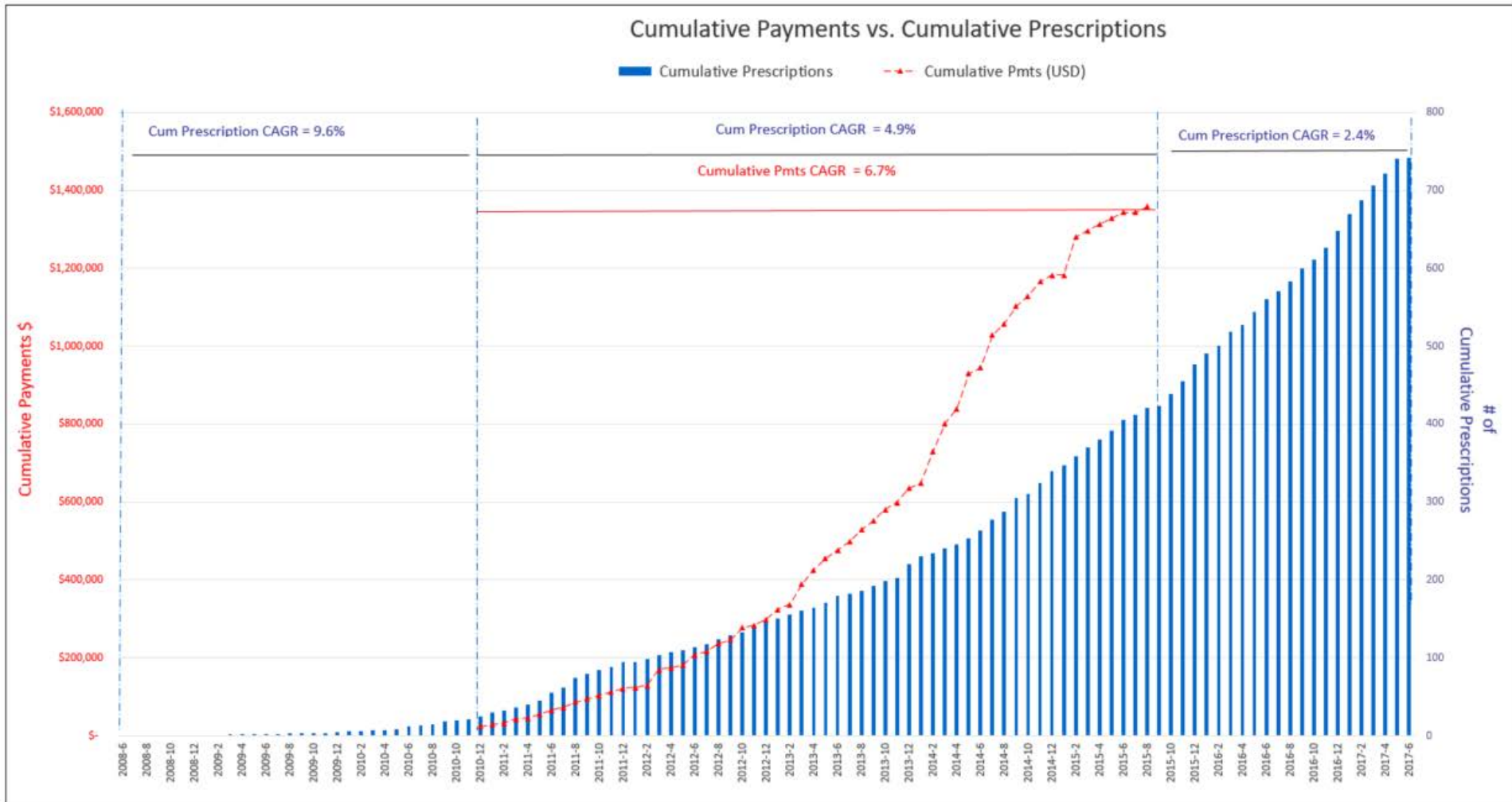
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Sample analysis 1: Quarterly Sales by Country

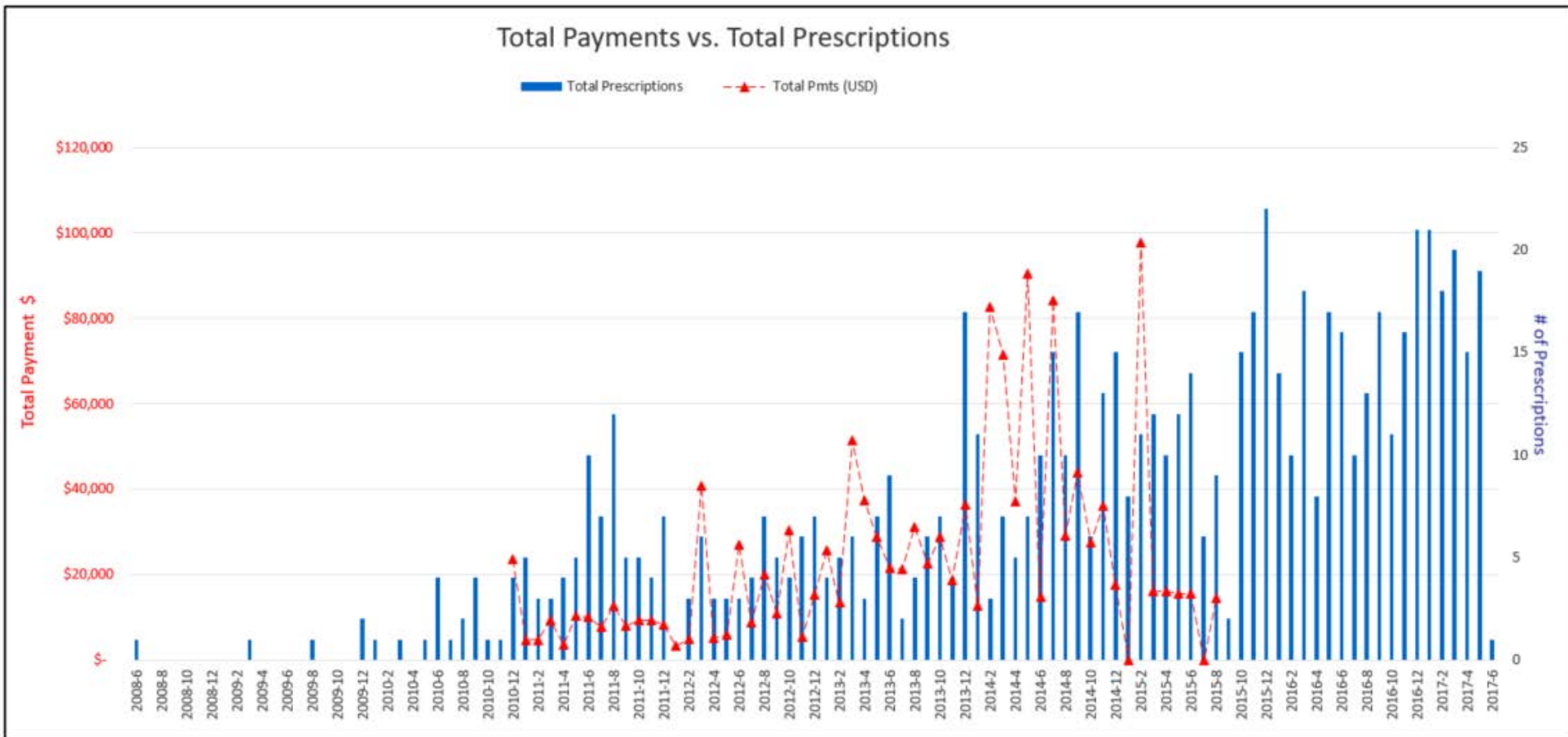


Sample analysis 2: Cumulative Payments vs. Cumulative Prescriptions



Note: The visual is only for the demonstration purpose.

Sample analysis 3: Total Payments vs. Total Prescriptions

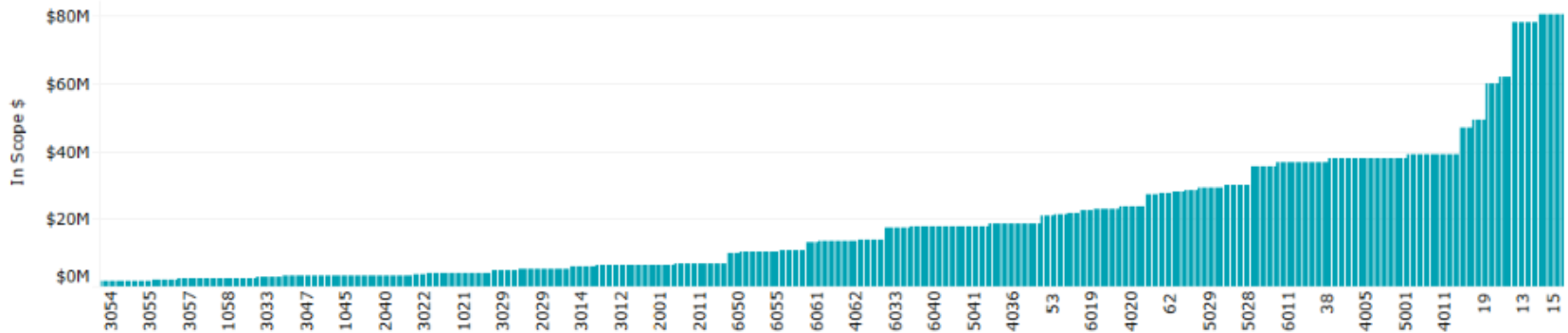


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Sample analysis 4: Financial Model for Profit Disgorgement

Accounting Year: 2015 | Measure: Profit

In Scope Profit by Scenario ID



Profit for Scenario 35 by Categories and Buckets

				In Scope	Out of Scope	N/A	Other
CAT 1	Online	North Region	Type I Indication	\$0M	\$0M	\$59M	\$0M
			Type II Indication	\$0M	\$0M	\$38M	\$0M
			Type III Indication	\$0M	\$0M	\$2M	\$0M
	West Region	Type I Indication	\$0M	\$0M	\$2M	\$0M	
		Type II Indication	\$0M	\$0M	\$1M	\$0M	
		Type III Indication	\$0M	\$0M	\$0M	\$0M	
		Other Revenues	\$0M	\$0M	(\$56M)	\$0M	
	Offline	North Region	Type I Indication	\$0M	\$0M	\$0M	\$0M
			Type II Indication	\$0M	\$0M	\$0M	\$0M
			Type III Indication	\$0M	\$0M	\$0M	\$0M
West Region		Type I Indication	\$0M	\$0M	\$0M	\$0M	
		Type II Indication	\$0M	\$0M	\$0M	\$0M	
		Type III Indication	\$0M	\$0M	\$0M	\$0M	
CAT 2	Online	North Region	Type I Indication	\$19M	\$0M	\$0M	\$0M
			Type II Indication	\$0M	\$12M	\$0M	\$0M
			Type III Indication	\$1M	\$0M	\$0M	\$0M
Total Sales				\$80M	\$54M	\$108M	\$0M
Other Revenues and Costs				(\$42M)	(\$28M)	(\$57M)	(\$45M)
Total Profit				\$38M	\$25M	\$51M	(\$45M)

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Questions and Comments ?

COVINGTON

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WHEN IT REALLY MATTERS.