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#### Cost of Doing Business?

#### Drug Company Settlements 2006-2015

Company*	Total Penalties S	lumber of ettlements 006-2015**		
GlaxoSmithKline	\$7.628 billion	26		
Pfizer	\$3.458 billion	28		
Johnson & Johnson	\$2.822 billion	18		
Merck	\$1.890 billion	26		
Abbott	\$1.822 billion	15		
Eli Lilly	\$1.706 billion	14		
Teva	\$1.471 billion	13		
Novartis	\$1.230 billion	18		
Amgen	\$901 million	12		
AstraZeneca	\$669 million	10		
Purdue	\$646 million	5		
Allergan	\$601 million	2		
Daiichi Sankyo	\$586 million	6		
Bristol-Myers Squibb	\$583 million	10		
Mylan	\$566 million	20		
Others	\$3.812 billion	151		
Total	\$30.391 billio	n 374		

Source: Public Citizen

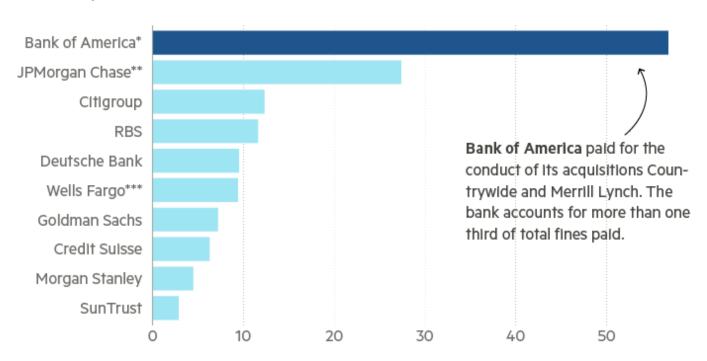
Parent company at time of settlement.

<sup>\*\*</sup> Includes civil settlements and criminal penalties paid to federal and state agencies.
Calvin Alagot/FairWarning



#### The sins of others

Total fines paid (\$bn), 2008-2017

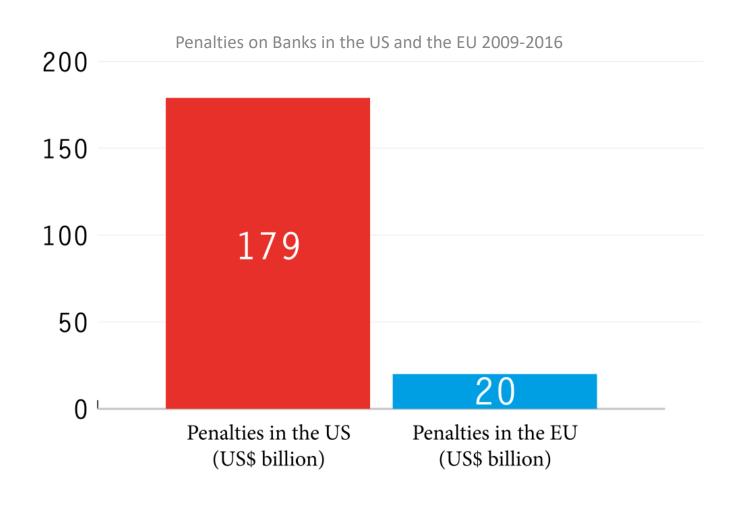


<sup>\*</sup> Fines include conduct related to Bank of America, Countrywide and Merrill Lynch

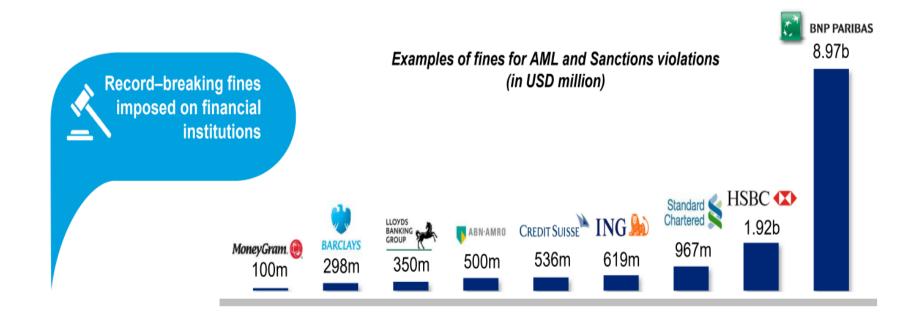
<sup>\*\*</sup> Fines include conduct related to JPMorgan, Bear Stearns and Washington Mutual

<sup>\*\*\*</sup> Fines include conduct related to Wells Fargo and Wachovia





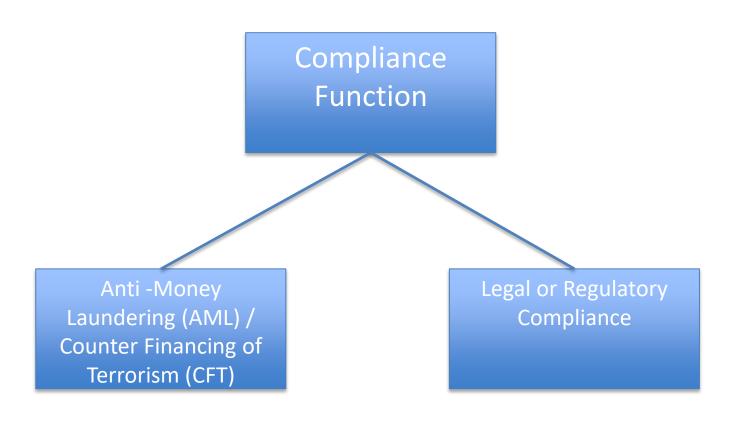






- Compliance refers to conformity with both external and internal laws and regulations.
- The compliance function should have a preventive, advisory and supervisory role.







There are several common archetypes for compliance organizations.



Organization chart





#### Ever feel like this?





OWI	VENS	
BOARD/AUDI	T COMMITTEE	
AGEMENT		
2 <sup>ST</sup> LINE OF DEFENCE	3 <sup>ST</sup> LINE OF DEFENCE	
Risk Management Compliance	Internal Audit	

UMMEDS

**SENIOR MANAGEMENT** 

Operational controls performed by line management.

**1ST LINE OF DEFENCE** 

**Operational Management** 

Internal

**Controls** 

Various forms of ongoing risk management monitoring and control activities which are performed by administrative and control functions.

**Others** 

The internal audit function will provide objective assurance on the effectiveness of the processes for governance, risk management and control, including the manner in which the first and second lines of defence operate.

External accounting control providing an independent opinion of financial reporting.

**External** 

**Audit** 



#### **Compliance Officer and Internal Auditor Responsibilities**

#### **Main Similarities:**

- Perform risk assessment procedures to evaluate the effectiveness and efficiency of operations.
- Communicate findings and provide recommendations to management / board to guarantee the compliance with the internal controls, policies, applicable laws and regulations.
- Perform on-going monitoring and follow-up to ensure remedial actions have been taken.
- Access to entire organization



## Compliance Officer and Internal Auditor Responsibilities Main Differences:

Compliance Officer	Internal Auditor
Focused on Compliance with Laws and regulations	Reviews the reliability and integrity of financial reporting and internal controls
Obtains and or establishes policies and procedures	Ensures the safeguarding of assets
May reports directly to management	Reports directly with the Audit committee or Board
Limited independence	Must be independent from the operation
Liaison with external regulators	Audit the compliance program





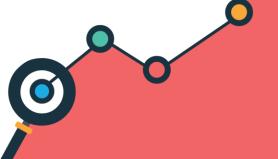
 How Audit Committees are looking for auditing compliance function?

 How the CAE should approach the Audit Committee request?





# Auditing Legal Compliance Framework



Baseline Control	Maturity Level of Internal Audit Function								
IA Maturity	Foundation	Positioning for Success	Mature Practice						
<b>→</b>	Poter	ntial Internal Audit Act	ivities						
Auditing your entity's compliance framework	- Compliance activities (micro-level 'bits and pieces')	- Compliance committee meetings - Compliance governance	- Compliance frame-work (overall) - Central regulatory coordination						



Features	Key Elements of Corporation	Related Internal Audit Activities							
Maturity Level - Foundation									
Compliance Activities	A high-level policy and procedures register (aligned where necessary to the compliance register) listed all of the corporation's significant policies and procedures, approval dates, related legislation/regulations, accountabilities, and review dates	Individual audits in the approved internal audit plan considered whether established controls over compliance risks were operating in practice in line with established policies and procedures							



Features	Key Elements of Corporation	Related Internal Audit Activities							
Maturity Level – Positioning for Success									
Internal audit capability	CAE developed a Strategic Competency Plan (using the IPPF Practice Guide)	Internal audit staff were suitably trained and developed to fulfil the full ambit of their responsibilities under their charter and in the risk-based internal audit plan							
Governance	Board or executive committees that covered different elements of compliance.	Facilitate the CAE or a senior delegate to periodically attend key board or executive compliance committee meetings as an observer, and report on signifcant insights to the audit committee. (Each of the compliance committee charters should contain suitable wording to preserve audit independence)							



Features	Key Elements of Corporation	Related Internal Audit Activities
Maturity Leve		
Compliance Framework	The Entity has a compliance framework consistent with international standards and internal policies and procedures	Conduct a periodic high-level internal audit to assess the compliance framework at a macro level, including:  a. benchmarking against the international or local compliance standards  b. assessing the soundness of compliance policy and its alignment to the entity's strategies and business/ statutory objectives,  c. determining how well the core elements are embedded into business processes and operating in practice,  d. evaluating the availability of appropriate resources to develop, maintain and improve the compliance program,  e. assessing the effectiveness of compliance reporting to the board, audit committee and senior management, and  f. forming an opinion on the overall culture of compliance



Features	Key Elements of Corporation	Related Internal Audit Activities
Maturity Leve	el – Mature	
Regulatory Reviews	Regulators have the right to independently assure themselves that the entity is compliant with legislation and egulations related to their jurisdiction. They have the right to periodically conduct documentary and/or onsite reviews of the corporation's policies, procedures, operations, activities, systems, premises and related information. In some situations, the outcomes of the regulatory review might be reported to the parliament and/or the public.	Provide a central regulatory coordination point for the regulator's review team for any high risk or high profile regulatory reviews. Then monitor the implementation of signifcant regulatory recommendations in the internal audit activity's process for monitoring and reporting on the implementation of recommendations.

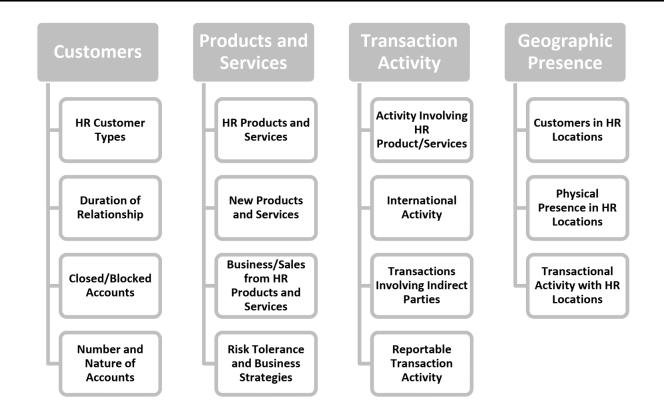


Auditing
AML/CFT
Function



How to build your Audit Risk Assessment tool to Combat Money Laundering and Terrorist Financing

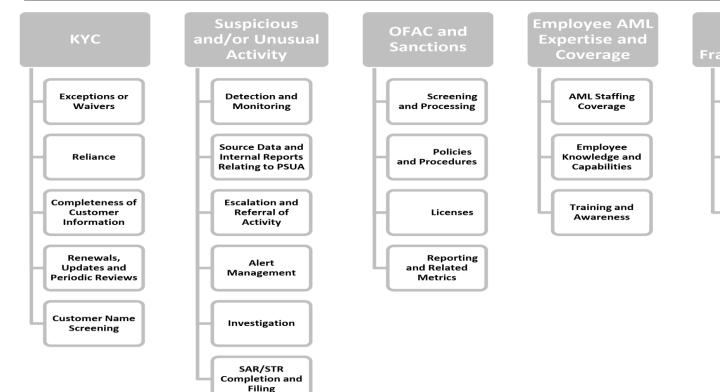
#### INHERENT RISK CONSIDERATIONS

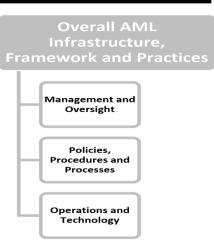




How to build your Audit Risk Assessment tool to Combat Money Laundering and Terrorist Financing

#### **CONTROL ENVIRONMENT CONSIDERATIONS**







#### Interpretating and Using the Results

Example - for	illustrat	tion purp	ooses on	ly	INHERENT RISKS			CONTROL ENVIRONMENT								
	Line of Business	Country	AML Risk Trend	Prior Coverage	Customers	Products and Services	Transaction Activity	Geographic Presence	Know Your Customer	Suspicious and/or Unusual Activity	OFAC and Sanctions	Staffing and Training	Oversight and Governance		Procedures,	AML SCORE
Business Unit A	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"
Business Unit B	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"
Business Unit C	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"
Business Unit D	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"	"_"





Q & A



