

Blowing the Whistle on cGMPs: the Next Big Challenge for Compliance

Global Compliance **Luis Moreno Ocampo**



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GETNICK & GETNICK LLP

**620 FIFTH AVENUE
ROCKEFELLER CENTER
NEW YORK, NY 10020
WWW.GETNICKLAW.COM**

Dodd-Frank



- Any securities law violation (including FCPA) by a company listed on a US exchange or with substantial US contacts can be the subject of an SEC whistleblower action

FCPA recent healthcare cases focus on bribing abroad to win business, what would be next?



- Koninklijke Philips Electronics (Apr. 2013): Poland
- Eli Lilly and Company (Dec. 2012): Russia, Brazil, China, and Poland
- Pfizer and Wyeth (Aug. 2012): Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia
- Orthofix International (July 2012): Mexico
- Biomet (Mar. 2012): Argentina, Brazil, and China
- Smith & Nephew (Feb. 2012): Greece
- Johnson & Johnson (Apr. 2011): Europe and Iraq

Outsourcing production to agents in foreign countries will not eliminate responsibility



- FCPA prohibits officer, director, employee or *agent* of the issuer from offering anything of value to:
 - ...(3) any person, while knowing that all or a portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any foreign official, to any foreign political party or official thereof, or to any candidate for foreign political office...
- Includes corrupt payments made through third parties or intermediaries (DOJ and SEC FCPA Resource Guide)
- “Agents can include third party agents, consultants, distributors, joint-venture partners, and others” (SEC Spotlight on FCPA)

Healthcare companies also risk enforcement actions by non US authorities



- GlaxoSmithKline (July 2013): China's Ministry of Public Security announced investigation of GSK for bribing doctors and public officials to increase its sales
- Allegations brought to light by whistleblowers
- Over \$450 million allegedly funneled through travel agencies
- 18 GSK managers, including UK and USA nationals were jailed
- Other pharma companies now under investigation, including Eli Lilly, Sanofi and Novartis

Ernst & Young: global trend 1: the rise and rise of emerging markets

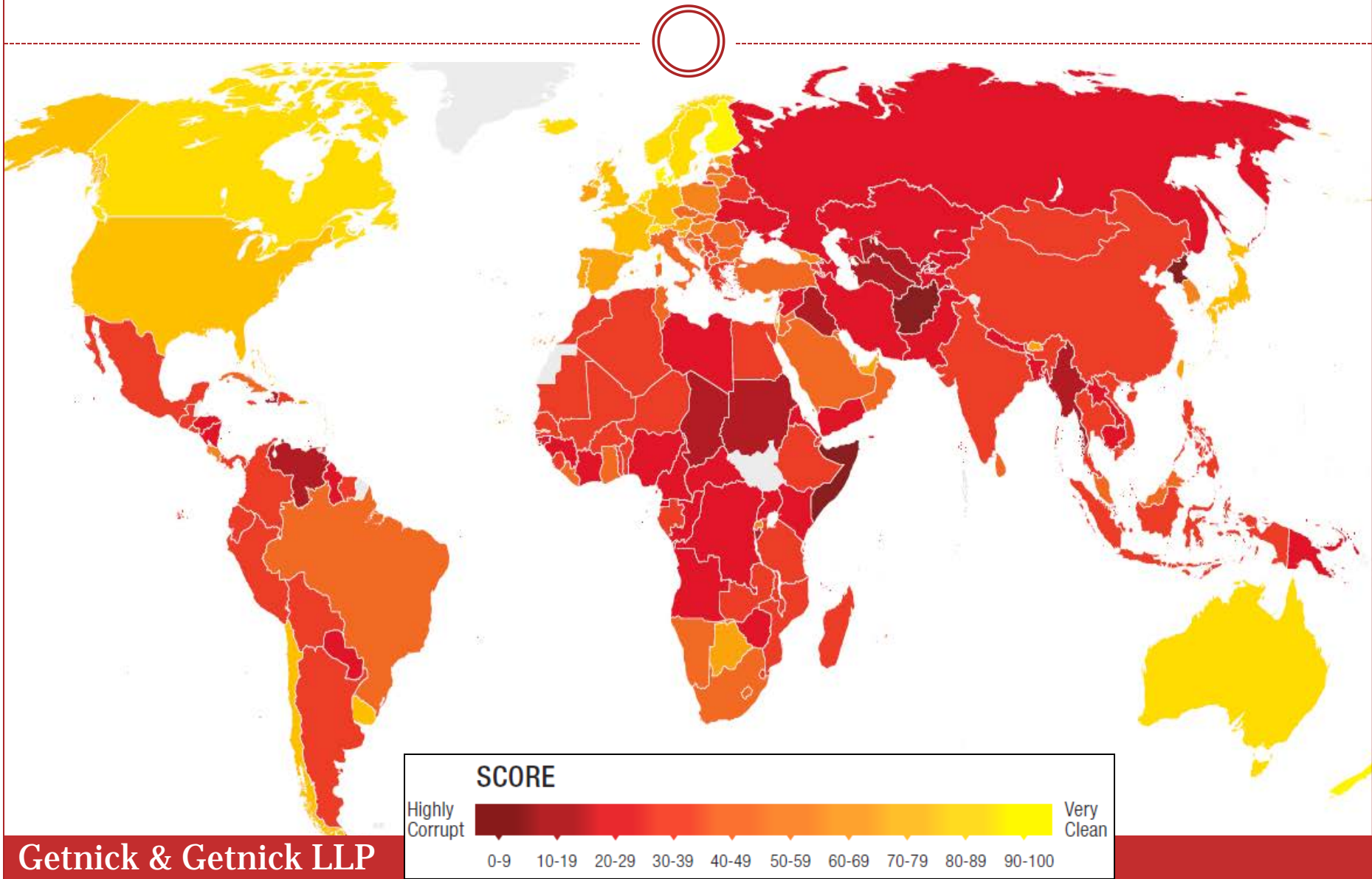


- It would not be an exaggeration to say that the 21st century will be marked by the dominance of emerging markets.
- The list of 6 key questions for global companies to succeed in emerging markets includes:
 - How is your business managing the higher risk associated with some emerging markets?
 - How is your business managing the higher risk associated with operating globally?

<http://www.ey.com/GL/en/Issues/Business-environment/Business-redefined---Global-trend-1--the-rise-and-rise-of-emerging-markets>

Corruption Perception Index 2012. Transparency International

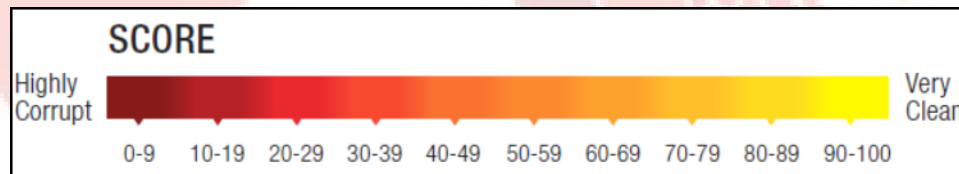
The perception of public sector corruption level in 176 countries



Numbers of FDA-registered manufacturing facilities in high-risk countries



- China: 660 facilities (Score: 39)
- India: 599 facilities (Score: 36)
- South Korea: 184 facilities (Score: 56)
- Mexico: 88 facilities (Score: 34)
- Argentina: 47 facilities (Score: 35)
- Brazil: 18 facilities (Score: 43)



Parallel and compounded enforcement



- **SEC (US)**
 - Whistleblower Program, incl. FCPA
- **DOJ (US)**
 - False Claims Act
 - Securities laws, incl. FCPA
- **IRS (US)**
 - Whistleblower Program
- **New York and other States' AGs**
 - False Claims Acts
- **Non-US national authorities**
 - UK, China, Canada recent legislation criminalizing foreign bribes.

Foreign anti-bribery acts: a growing trend



- **April 2010: UK Bribery Act prohibits bribery of foreign officials; April 2011: issued guidance document for companies to prevent bribery**
- **May 2011: People's Republic of China amended criminal law to prohibit companies from bribing foreign officials.**
- **June 2013: Canada enacted amendments strengthening its Corruption of Foreign Public Officials Act (CFPOA)**

New global risks and opportunities



- **RISKS**

- Company's agents and third parties operating in foreign countries can make the company liable
- Company's managers around the world can denounce company's illegal practices
- Multiple national and international authorities can take action against company
- Foreign companies reporting to SEC could be investigated in the USA

- **OPPORTUNITIES**

- Company's managers around the world can internally report company's illegal practices
- Dodd Frank Act could be applied to improve market's fairness

Advice



- Check reporting lines.
- Focus on manufacturing violations, in particular in factories established in foreign countries.
- Design programs to monitor agents' misbehavior.
- Improve the fairness of your markets. Keep your competitors honest.