

Empowering Professionals

IACA ALUMNUS

the magazine

Issue IX, December 2015

CHALLENGES TO ENGAGE COMPANIES
IN TACKLING CORRUPTION:
PRO-ETHICS BRAZIL

By Renata Figueirido

THE PARADOX OF
COMPLIANCE BECOMING
AN INDUSTRY

By Joel Jelderks

Interview with Leonard McCarthy

A QUESTION OF INTEGRITY

THE WORLD BANK'S FIGHT AGAINST CORRUPTION



Welcome Word

Dear alumni,

Our Alumni community is active and growing as 2015 draws to a close.

Late November saw the successful debut of the IACA Regional Summer Academy - Latin America in Buenos Aires, Argentina. And just last week, several alumni and current students participated in the fourth session of IACA's Assembly of Parties in Vienna.

This issue of IACAlumnus includes an interview with Leonard McCarthy, the Integrity Vice President of the World Bank Group and a lecturer at the IACA Summer Academy 2015, about the Bank's fight against corruption. Maija Burtmanis, a participant at the same programme, shows why we should be paying very close attention to Corporate Integrity Agreements. Renata Figueirido charts the development of the Pro-Ethics company registry in Brazil, while current Master in Anti-Corruption Studies (MACS) student Joel Jelderks asks whether the compliance industry might eventually become too big.

We wish you a happy festive period and every success in 2016. Additionally, we encourage you to write for IACAlumnus, share your progress and achievements with us, and let us know how we can serve you better.

Sincerely,
The Alumni Team

CREDITS

IACAlumnus - the magazine is the alumni magazine of the International Anti-Corruption Academy (IACA), addressing alumni around the world who have participated, or are currently taking part in trainings designed and implemented by IACA.

IACAlumnus - the magazine welcomes contributions by alumni. As a forum to exchange ideas, latest developments, and feature the career paths of our alumni, we seek to provide you with a medium to stay connected. For contributions please contact alumni@iaca.int.

IACA reserves the right to select and edit any contribution to suit the publication. We will not consider contributions that have already been published, in any form, in print or online.

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CONTENTS

DECEMBER 2015

MAPS P4

IACA ALUMNI
Mapping by Country

INTERVIEW P6

THE WORLD BANK'S FIGHT AGAINST CORRUPTION

Interview with Leonard McCarthy



BRAZIL P10



CHALLENGES TO ENGAGE COMPANIES IN TACKLING CORRUPTION: PRO-ETHICS BRAZIL

By Renata Figueirido

CORPORATE INTEGRITY P14

CORPORATE INTEGRITY REQUIREMENTS FOR LIFE SCIENCE COMPANIES

By Maija Burtmanis



COMPLIANCE P18



THE PARADOX OF COMPLIANCE BECOMING AN INDUSTRY

By Joel Jelderks

RESEARCH P22



HOW TO RESEARCH CORRUPTION

UPCOMING P23

WHAT'S NEW AT IACA ?

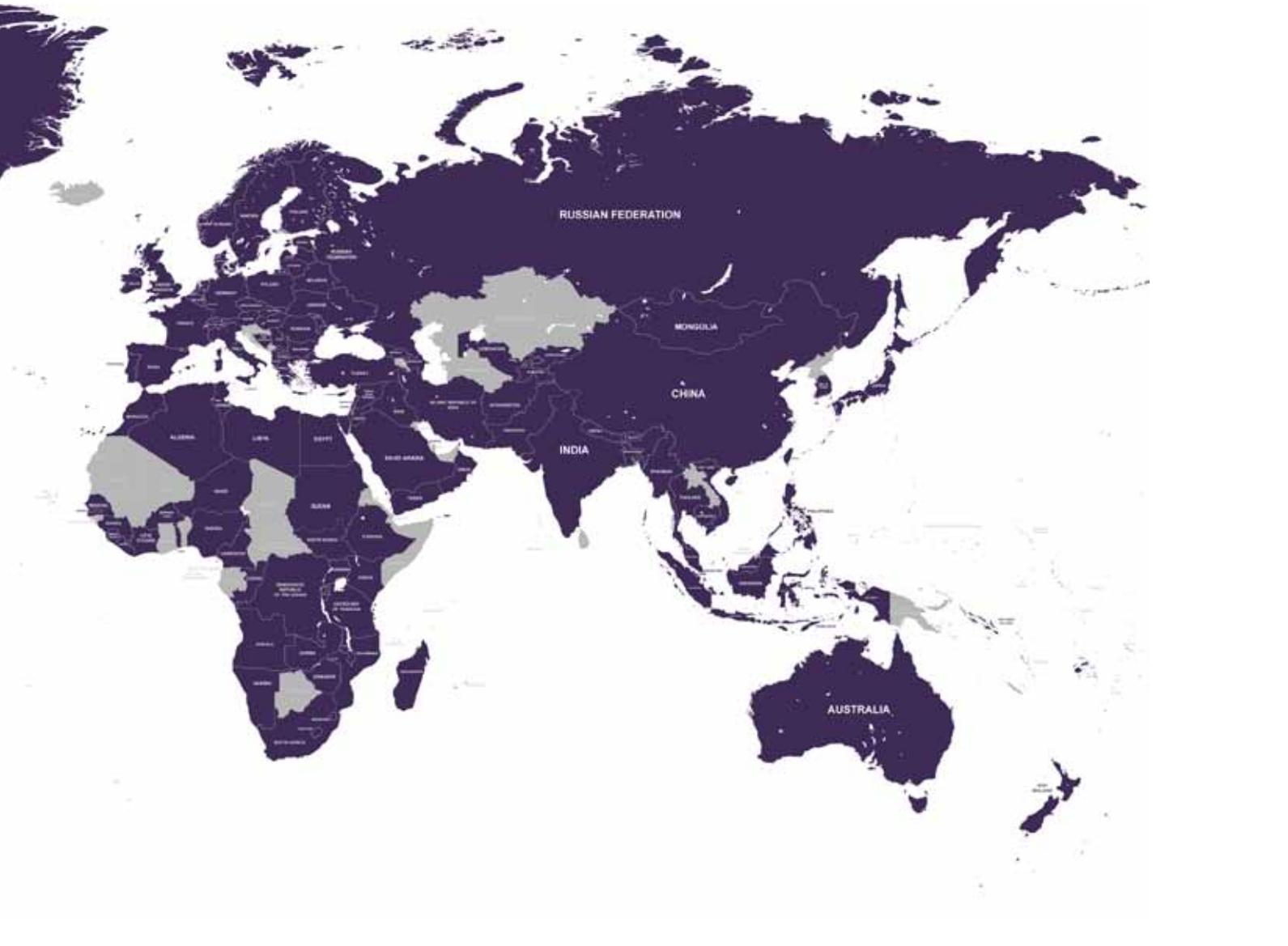
IACA ALUMNI MAPPING BY COUNTRY



STATUS AS OF 27 NOVEMBER 2015

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|----------------------------|--------------------------------------|------------------------------|----------------|
| 01. Afghanistan | 21. Cambodia | 41. Finland | 61. Kyrgyzstan |
| 02. Albania | 22. Cameroon | 42. France | 62. Latvia |
| 03. Algeria | 23. Canada | 43. Gambia | 63. Lebanon |
| 04. Angola | 24. Cayman Islands | 44. Georgia | 64. Lesotho |
| 05. Argentina | 25. Chile | 45. Germany | 65. Liberia |
| 06. Australia | 26. China | 46. Greece | 66. Libya |
| 07. Austria | 27. Colombia | 47. Grenada | 67. Lithuania |
| 08. Azerbaijan | 28. Congo | 48. Guinea | 68. Luxembourg |
| 09. Bahrain | 29. Côte d'Ivoire | 49. Haiti | 69. Madagascar |
| 10. Bangladesh | 30. Curaçao | 50. Hungary | 70. Malawi |
| 11. Belarus | 31. Cyprus | 51. India | 71. Malaysia |
| 12. Belgium | 32. Czech Republic | 52. Indonesia | 72. Malta |
| 13. Bermuda | 33. Democratic Republic of the Congo | 53. Iraq | 73. Mexico |
| 14. Bhutan | 34. Denmark | 54. Ireland | 74. Mongolia |
| 15. Bosnia and Herzegovina | 35. Dominican Republic | 55. Islamic Republic of Iran | 75. Montserrat |
| 16. Brazil | 36. El Salvador | 56. Israel | 76. Morocco |
| 17. British Virgin Islands | 37. Egypt | 57. Italy | 77. Mozambique |
| 18. Bulgaria | 38. Estonia | 58. Japan | 78. Myanmar |
| 19. Burkina Faso | 39. Ethiopia | 59. Jordan | 79. Namibia |
| 20. Burundi | 40. Fiji | 60. Kenya | 80. Nepal |



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|-------------------------|---|----------------------------------|
| 81. Netherlands | 101. Sierra Leone | 120. Tunisia |
| 82. New Zealand | 102. Singapore | 121. Turkey |
| 83. Niger | 103. Sint Maarten | 122. Turks and Caicos Islands |
| 84. Nigeria | 104. Slovakia | 123. Uganda |
| 85. Norway | 105. Solomon Islands | 124. Ukraine |
| 86. Oman | 106. South Africa | 125. United Kingdom |
| 87. Pakistan | 107. South Sudan | 126. United Republic of Tanzania |
| 88. Peru | 108. Spain | 127. USA |
| 89. Philippines | 109. Sudan | 128. Uzbekistan |
| 90. Poland | 110. Swaziland | 129. Venezuela |
| 91. Portugal | 111. Sweden | 130. Viet Nam |
| 92. Republic of Korea | 112. Switzerland | 131. Yemen |
| 93. Republic of Moldova | 113. Syrian Arab Republic | 132. Zambia |
| 94. Romania | 114. Tajikistan | 133. Zimbabwe |
| 95. Russian Federation | 115. Thailand | |
| 96. Rwanda | 116. The former Yugoslav
Republic of Macedonia | |
| 97. Saint Kitts | 117. Timor-Leste | |
| 98. Saudi Arabia | 118. Togo | |
| 99. Senegal | 119. Trinidad and Tobago | |

Interview
with Leonard McCarthy

A QUESTION OF INTEGRITY

THE WORLD BANK'S FIGHT
AGAINST CORRUPTION

WORLD BANK
HEADQUARTERS
WASHINGTON DC



“You don’t always need a million people to win a war.”

You’ve been the Integrity Vice President of the World Bank Group since June 2008. Looking back at your World Bank career to date, is there anything you would have done differently?

You know, I hope it doesn’t sound arrogant when I say “nothing”. Maybe we’ve just been lucky that we had an excellent script and a good strategy. The environment was conducive for doing the things we wanted to do, accelerating initiatives, putting new things in place, and working with others. And the time was right for the Bank. The appetite was there, the political will was there, and the world was also looking at what we were going to do. So I wouldn’t change anything.

■ **And how does the way forward look?**

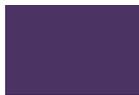
There are two things I think we should do at the Bank as we move forward. The first – and I hear this a lot when I speak to people, including when I was at IACA – is to really develop a greater ground presence and look at whether we are making maximum impact in the way we operate.

Second, I like Einstein’s thinking that intellectuals solve problems and geniuses prevent them. When I look at some of the patterns and schemes we’ve encountered, one often asks “couldn’t we have anticipated this?” so that any top team going forward could write some precautions and checklists into these mega-projects to prevent fraud and corruption.

■ **Has the nature of corruption in development projects changed since 2008? What patterns and trends do you see, and what lessons has the World Bank learned?**

Yes, it has been evolving. Corruption in my view is like an amoeba, an organism that’s capable of changing its shape. What we’ve seen in the last year is that the misconduct we look into is more intercontinental, more multijurisdictional. It’s more cross-functional, both across countries and contracts. The sectors where we’ve opened most cases in the last two to three years are transport, health, agriculture, and water. This says, I think, that a lot of corruption is tied up with infrastructure, and it’s clearly an area that will require additional due diligence.

The preventive services unit here at the World Bank analyzed about 300 investigations and 3,600 complaints about corruption between 2009 and 2014. We learned three things in particular. First, the corruption equation is two sides of the same coin, with equal roles for the demand and supply side. This is something that the public and the private sectors need to look at. Second, we found that 63% of the 3,600 complaints highlighted the critical role of government officials. Third, we found that fraud during the project implementation phase can often fund corruption.



LEONARD MCCARTHY

The World Bank has reached several settlements in which companies admit wrongdoing in return for shorter debarment periods. Is the Bank's current debarment practice enough of a deterrent to companies out there?

We've entered into 53 settlements over the past seven years. And we've had debarments coming out of settlements in cases like Siemens, Alstom, Oxford University Press, and SNC Lavalin. This demonstrates the Bank's ability to get to the bottom of things, and hold its own in dealing with complex issues.

In my view, settlement achieves two objectives. First, it serves as a deterrent. When I speak to people in the private sector, one of the things they ask the most is "what is the risk of a debarment?" I still maintain that this is one of the best antidotes to corruption. Second, companies start adjusting the way they contract, anticipate risk, and take precautions in a way that things actually get better.

When I came here, some of these cases were languishing in the system and the world was waiting to move forward. I think settlement is a pragmatic way of solving something that's beneficial to both sides and we can still all go home and sleep at night. And there are cases where the settlement was as equitable and imposing and effective as the outcome of litigation. So I have no reservations about it. I think it's one of the best things we could have done.

You have often said that the private sector could be a huge force for good in the fight against corruption. What should be the top priority for corporate CEOs here? Is self-reporting the key to success?

It's about more than just self-reporting, compliance, monitoring, due diligence, and the like. Many companies that we've investigated had the best ethics and compliance charts on the wall, but then we got to a can of worms and said "what happened here?"

I think we need to see more activist CEOs. These are captains of industry bringing about transformational change in the fight against corruption by making a philosophical argument to capture the minds of the business community. It involves conveying to intelligent people that clean business makes both economic and financial sense. I think if you look at the things happening in the private sector in the last five years in the aftermath of the financial crisis, it's clearly something that they need to address head on. And we're working with them on many fronts and are obviously happy to assist, cajole, and convene as much as we can.

The World Bank's investigations often involve tracing flows of money across borders. What are the biggest challenges when dealing with multinational investigations? How can your office help to make mutual legal assistance (MLA) more efficient?

It's an interesting question. In 2009, we created the International Corruption Hunters Alliance, which brings together about 380 senior officials from regulatory authorities in 130 countries. We advocate new ways of thinking as we target corrupt entities, and we do a lot to develop cutting-edge investigative solutions.

But when it comes to transnational, multinational crime, the architecture of financial flows, and illegal traffic, I think we need another script to get ahead of the game. Criminal organizations



Leonard McCarthy (South Africa) is the Integrity Vice President of the World Bank Group, a position he has held since June 2008. He also has a leadership role in the World Bank's Stolen Asset Recovery (StAR) Initiative and the implementation of the Bank's Governance and Anti-corruption (GAC) Agenda.

Prior to joining the World Bank Group, Leonard was Head of South Africa's Directorate of Special Operations (DSO), overseeing crime analysis, investigation, prosecution, asset forfeiture, and civil litigation.

He also serves as the Chair of the World Economic Forum's Global Agenda Council on Anti-corruption & Transparency and is an ex-officio member of its Partnering against Corruption Initiative (PACI). Leonard was a lecturer at the IACA Summer Academy 2015.

can move money at the push of a button from here to Hong Kong to the Cayman Islands to Nigeria and vice versa. And we're still locked in an MLA system that was designed between 1960 and 2003.

There have been advances by the US authorities, the UN, and the OECD. That's great, but I think it's time we start defining something new and find a new energy.

Given the large size of the World Bank's loan portfolio, and the potential corruption risks to which this is exposed, how can the Integrity Vice Presidency (INT) deploy its relatively limited resources most effectively?

It's always a balancing act. The results we have had at the Bank in the last seven years are largely because the people I work with here at INT have really been punching above their weight. And I have every reason to believe they'll continue to do so.

I think it helped that we created seven divisions. One does analysis, a second one does large investigations, and a third deals with all legal issues, like a litigation unit. We also have our own version of internal affairs, about ten people who investigate serious fraud and corruption involving Bank staff, because we have 15,000 people and we have to keep our house clean.

Fifth, we have the preventive services unit, a group of very smart systems thinkers that works with the operational arm of the Bank to try and safeguard our projects. We also have a forensic services unit to help deal with investigations that are rich in transactions and paper. Finally, the compliance office also falls within INT.

So with a bit of design and a bit of fortitude we have several disciplines fairly well synchronized and led by people who are effective in what they do. I subscribe to the view that you don't always need a million people to win a war. Everyone has to economize and live within their means these days. I think in that environment we're doing quite well.

During your most recent visit to IACA in July 2015, you met the participants from our fifth annual Summer Academy. What did you learn from your session with them?

The fact that you have that programme and were able to convene such a large group of people from around the world was impressive, and I found it quite exhilarating. I found the engagement and the intellectual traffic in the room quite thought-provoking. That hour and a half there, as exciting as it was, tired me out. It made me intellectually and emotionally drained.

What struck me clearly was a generational shift. I thought that there was much greater awareness among the group than when I was at a similar stage of development. The nice thing is that I left the session with hope for the future. If we could take that group and replicate similar-minded people around the world, we can make this world a better place. I think the Academy's doing excellent work, and I wish you well.



Challenges to Engage Companies in Tackling Corruption: Pro-Ethics Brazil

1) GENERAL CONTEXT

BRASILIA,
BRAZIL

by Renata Figueirido

GENERAL CONTEXT

Tackling corruption is a challenging and ongoing process that demands careful study, experience, and long-lasting efforts to achieve real results. Regardless of a country's maturity in this process, most would agree that one approach is not enough to be effective. Different actions must be implemented if a country really wants to engage government, civil society, and companies in the fight against corruption.

In Brazil, the enactment of the Clean Company Act – CCA (Law 12,846/2013) has triggered numerous discussions about fostering integrity in the private sector. The CCA provides for strict civil and administrative liability for legal entities that carry out wrongful acts against national or foreign public administration agencies, and prescribes severe sanctions for violations, such as fines of up to 20% of company revenues.

The CCA has caused the business sector to be much more aware of the importance of consistently investing in anti-corruption programmes to avoid being held liable under the law. But although the Act is extremely relevant in Brazil's current context, this article will show that Pro-Ethics, an initiative launched in 2010 to compile a national registry of companies committed to ethics and integrity, is a result of concerns about corruption that existed before the CCA came into force. How Pro-Ethics started, its main experiences, and the new perspectives it gained are the focus of this paper.

PRO-ETHICS 1.0: FEATURES, RESULTS, AND LESSONS LEARNED

In 2010, the Brazilian Office of the Comptroller General (CGU) and the Ethos Institute of Business and Social Responsibility (Ethos) joined forces to launch a new initiative to prevent

corruption: the National Registry of Companies Committed to Ethics and Integrity, commonly known as the Pro-Ethics Company Registry. Important institutions joined the Steering Committee, most of them representing the private sector in the following areas¹: trade and investment, the stock market, national industries, financial institutions, internal control, and small companies, as well as the Ministry of Development, Industry, and Foreign Trade.

The main objective of the registry was to recognize companies that voluntarily adopted policies intended to foster ethical behaviour and integrity and actively worked to prevent and fight corruption. The underlying idea was to motivate businesses by publishing their positive efforts in these areas and stimulate public approval of their good conduct, which would in turn serve as an incentive for other companies to adopt similar practices.

The main features of Pro-Ethics when it was launched in 2010 were:

- Questionnaire: to apply for Pro-Ethics, companies filled out an online questionnaire containing over 50 questions intended to assess their anti-corruption measures in six areas: ethics and conduct, internal controls, relationship with the public sector, training, transparency, and collective actions. The questionnaire was then submitted to CGU for evaluation through the online system.
- Assessment methodology: companies had to answer 'yes' to 100% of the mandatory questions on the questionnaire, and to at least 50% of the optional ones.
- Instances of evaluation: the first round of analyses was carried out by the CGU team, and the final decision as to whether or not a company was approved for the Pro-Ethics registry was made by the Steering Committee.

Renata Figueirido (Brazil) has been a federal public servant in Brazil since 1995. Over the last four years, she has been working at the Secretariat of Transparency and Corruption Prevention of the Brazilian Office of the Comptroller General (CGU) and currently co-leads the internal and technical administration of Integrity Coordination at CGU. This Coordination is responsible for fostering integrity measures in the public and business sectors, implementing conflict of interest policies in the executive branch, assessing compliance and ethics programmes in Brazilian companies, and coordinating efforts to engage and assist small companies in adopting compliance measures. Renata Figueirido was a participant at IACA's Legal Incentives for Corporate Integrity Training in 2014.



- Publishing: after each application period – usually two or three per year – approved companies were added to the registry and published on the CGU and Ethos websites.
- Reassessment: after two years companies were reassessed, following basically the same procedure as for the first application.

Between 2011 and 2014 seven rounds of evaluations were conducted and only 17 companies qualified for the registry. However, this low number does not represent the significant advances that were made as a result of the initiative. To begin with, in 2010 Pro-Ethics was a completely innovative initiative aiming to bring government and companies together to discuss ideas on how to tackle corruption in the business sector. Having several important public and private institutions working together on the Steering Committee was a clear example of mutual interests converging on the same idea.

Second, the new experience gained in assessing anti-corruption measures, combined with the low number of companies qualifying for the registry, served as a warning that bold action had to be taken to attract more firms to the initiative. Ongoing training about corporate compliance enabled the CGU team to pinpoint specific problems in Pro-Ethics 1.0, as specified below:

- A company's profile had not been considered when assessing its anti-corruption measures, and the final score was based on yes/no answers to the questionnaire. One of the basic principles of compliance, that one size does not fit all, had been ignored.
- The questionnaire had not covered other essential elements for evaluation such as third-party due diligence, risk assessment, and monitoring.
- The questionnaire had been created based on best practices implemented by large companies, making it virtually impossible for small and medium-sized businesses to meet the requirements for the registry.
- Publicity for companies that made it onto the registry had been

carried out on a small number of websites and was extremely timid.

It is important to mention that the implementation of the CCA was extremely relevant to the process of reviewing and adjusting Pro-Ethics. The new Act made preventing and punishing fraud and corruption the new hot topic amongst companies doing business in Brazil, creating a more favourable scenario for implementing changes in Pro-Ethics that aligned with the CCA.

Here it is necessary to explain briefly what Brazil calls the Integrity Programme, and its connection to both the CCA and Pro-Ethics. The Act establishes that sanctions applied to legal entities should take into consideration their internal integrity and audit mechanisms and procedures, incentives for whistleblowers, and the application of corporate codes of ethics and conduct. Recently, the Decree that regulates the CCA (Decree 8,420/2015) defined these conditions as a corporate Integrity Programme, which is intended to detect and remedy embezzlement, fraud, irregularities, and illegal acts against national or foreign public administrations.

Thus, assessments of both legal violations and Pro-Ethics applicants focus on a company's Integrity Programme, specifically verifying its anti-corruption measures rather than its compliance programme as a whole, which necessarily includes several other aspects such as environmental and social responsibility, labour relationships and customer service, and antitrust policies.

PRO-ETHICS 2.0 – WHAT CHANGED

In light of the lessons learned, the CCA provisions, and the knowledge that was acquired about compliance programmes, approximately one year was spent developing and discussing proposals with CGU authorities, the Steering Committee, and companies that had been part of the first version of the registry.

RENATA FIGUEIRDO

On 7 May 2015, Pro-Ethics 2015 was officially launched with totally restructured rules and procedures, as shown below:

- **More comprehensive evaluation process:** One of the main additions is assessing company profiles as the first step in the evaluation procedure. This phase is essential for identifying a company's primary risk of corruption or vulnerabilities in its different interactions with the government – either in public biddings or contracts, or in other forms such as requesting public licences and dealing with public officials or regulatory authorities. A company's profile is the lens through which its anti-corruption measures can be evaluated.

- **New areas of evaluation:** Yes/No questions were replaced by a set of questions that companies answer freely, presenting all the information necessary to understand their anti-corruption measures. These questions cover several areas: tone from the top and commitment to ethics, policies and procedures, communication and training, hotlines and remedial measures, risk analysis and monitoring, transparency, and policies and social contributions.

- **Small and medium-sized companies able to meet requirements:** Because the new questionnaire considers company profiles when assessing their anti-corruption measures, small and medium-sized businesses have real possibilities to demonstrate that they have adopted integrity measures appropriate to their situation. These companies will most likely implement simpler and less formal anti-corruption measures than large firms, but this does not mean that their measures will not be effective.

- **All efforts concentrated in one annual calendar:** Having an annual evaluation gives regularity to the process and allows companies to better plan their participation with enough time to implement any necessary changes for meeting all the requirements to be approved as a Pro-Ethics company. The CGU facilitates this process by providing application documents containing detailed guidelines on how to meet all the conditions. An annual evaluation also optimizes the CGU workforce engaged in the evaluation process.

- **Annual list rather than a registry:** Initially the two might be understood as the same. However, an annual list is not fixed like a registry and requires companies to reapply every year. An approved company has the right to advertise its image as a Pro-Ethics participant by citing the year it made it on the list. This requires companies to demonstrate their efforts in preventing, detecting, and remedying corruption on an ongoing basis.

- **New ways to enhance good publicity for Pro-Ethics companies:** It is not enough to be an ethical company; people must recognize it as such. Thus, the CGU and the entire Steering Committee plan

to hold an annual public event to announce the companies approved for the Pro-Ethics list. Additionally, the best practices of the different companies will be highlighted in an annual publication intended to both recognize their efforts and encourage other firms to implement similar measures. Lastly, the image rights manual was updated in order to define how and when companies can use the Pro-Ethics seal.

CONCLUSION

Since Pro-Ethics was instituted in 2010, its main purpose has always been to incentivize companies to engage in fighting corruption and create a kind of domino effect in which one company can encourage others through examples and concrete initiatives. The restructuring process presented here did not change this ultimate goal but rather reinforced it and added an extra ingredient: high expectations for enhancing a positive chain reaction.

The lessons we learned from Pro-Ethics 1.0 have been extremely important. They allowed us to evaluate what we did right and what needed to be improved in order to attract more companies and earn their confidence as to the seriousness and quality of this initiative. We have had the additional advantage of starting Pro-Ethics 2.0 at a crucial time when Brazil is increasingly engaged in discussions about corporate integrity programmes, especially due to the new provisions of the CCA. The deadline for applying to the Pro-Ethics 2015 was 31 July and at the end of this year we will know which companies will make it onto the list, thus confirming the impact of our concerted efforts to effectively engage companies in the war against corruption in our country.



For more on the CCA and the Decree regulating it, see the article "Brazil Enters a New Era - The Decree of March 2015" by Marcelo Chacón in Issue VII of IACALumnus, May 2015.

ENDNOTES

¹The institutions that make up the Steering Committee are: the Brazilian Office of the Comptroller General (CGU), Ethos (Ethos Institute of Business and Social Responsibility), ApexBrasil (Brazilian Trade and Investment Promotion Agency), BM&F Bovespa, CNI (Brazilian National Confederation of Industry), Febraban (Brazilian Federation of Banks), Ibracon (Brazilian Institute of Independent Auditors), Sebrae (Brazilian Micro and Small Business Support Service), and the Ministry of Development, Industry, and Foreign Trade. In 2014 the ETCO Institute joined the committee.

by Maija Burtmanis

CORPORATE INTEGRITY REQUIREMENTS FOR LIFE SCIENCE COMPANIES

If you haven't ever heard about, been "primed on", or seen a Corporate Integrity Agreement (CIA)-tailored compliance programme for a multinational corporation, you must be working for a very new, obscure, or exceptional company. CIAs are the norm these days and most companies tailor their compliance, ethics, and integrity programmes around them. Many lessons can be learnt by astute legal, risk, and compliance folks - who wish to fine-tune their own in-house programmes - by keeping abreast of the evolution in CIA requirements targeting operational areas of "key concern" (or topical industry interest).

Should a corporation be subject to an investigation for fraud, abuse, or misconduct under a variety of US federal healthcare legislation, then the Office of Inspector General (OIG, attached to the Department of Health & Human Services) will typically negotiate a CIA as part of the settlement of alleged civil false claims.

Given the sheer volume of oversight legislation, the complexity of life science operations on a global stage, the number of "vested financial interests" in the private and public sector, and the imperfections in most companies and organizations which

MAIJA BURTMANIS

Maija Burtmanis (Australia) holds the position of Healthcare Compliance Officer, Asia Pacific Medical Sciences, with Janssen Research & Development (a Division of Johnson & Johnson) and is based in Singapore. In this role, she supports the Asia Pacific Medical Sciences organization with a focus on global Research & Development processes and practices.

Previously, Maija served as a senior compliance professional and lawyer for companies such as Pfizer, Novartis, and AbbVie and has been responsible for legal and compliance programmes in Japan, China, India, the rest of Asia Pacific, as well as Russia. Maija earned her LLB/BSc from the Australian National University and her LLM from the University of Sydney in Australia. She participated at the IACA Summer Academy 2015.



deal across jurisdictions, there is a robust library of CIAs to reflect upon. Indeed, not many “notable” brand-conscious companies are immune or absent from the “CIA Follow-up” list.

Whilst there may be some irony in keeping “good company” with many Fortune 500 companies in the CIA hit list (no pun intended), there is nothing worse than finding oneself in “breach” of a legal undertaking to the US government or even in flagrant ignorance about existing CIA requirements amongst personnel within a leading organization. Importantly, a corporation may be subject to exclusion from US federal healthcare programmes for a material breach of an existing CIA and also subject to monetary penalties for less significant breaches.

The bottom line is that there are so many extant CIAs - highlighting “targeted” activities in which many companies routinely engage – to which smart legal, risk, and compliance professionals should be paying very close attention, in both the short and long term.

Such an investment of time would bring untold benefits to the organization in (i) focusing keen attention on high-value

preventative activities, (ii) educating the workforce, (iii) bridging “compliance gaps”, and (iv) protecting the assets and reputation of the company.

What is the legal framework which sits behind a CIA?

It is an understatement to observe that the legal framework regulating innovative industries in the US is both expansive and expensive.

The starting point is to appreciate the legal landscape in which the corporation operates, both in its resident jurisdiction but also in all international markets in which it has a presence. The US federal healthcare laws and regulatory requirements form the legal basis of CIAs and comprise the following:

- Federal Food, Drug & Cosmetic Act
- US False Claims Act
- Federal Anti-kickback Act
- Foreign Corrupt Practices Act
- Medicaid Rebate Program Act



- Federal Civil Money Penalty Act
- Federal Exclusion Statute
- Sarbanes Oxley

Other US laws and regulations address issues such as privacy, off-label drug promotion, medical education, fraud & abuse safe harbours, as well as the OIG Compliance Guidance for the pharmaceutical industry.

All of these statutes deal with specific areas of business and regulatory operation, and are fundamentally designed to “protect patients and the public purse” against fraud and abuse.

Elements of a CIA

A comprehensive CIA typically lasts five years and includes the following key requirements which a subject corporation should address:

- Hire a compliance officer/appoint a compliance committee
- Develop written standards and policies
- Implement a comprehensive employee training programme
- Retain an independent review organization to conduct annual reviews
- Establish a confidential disclosure programme
- Restrict the employment of ineligible persons
- Report overpayments, reportable events, and ongoing

investigations/legal proceedings

- Provide an implementation report and annual reports to OIG on the status of the organization’s compliance activities

What is “caught” in a CIA?

CIAs exhibit common elements, with each addressing the specific facts at hand whilst also endeavouring to make concessions to accommodate elements of a pre-existing voluntary compliance programme.

An individual CIA will require a corporation to agree to certain “undertakings and commitments” over a period of time in order to redress some alleged corporate misbehaviour. Essentially, these “undertakings and commitments” translate into the corporation promising to take concrete actions to prevent repeat offences and/or to demonstrate that any gaps with internal controls and compliance are being filled or tightened.

Some common “observations” or call-out actions within life sciences CIAs will initially focus on high-level corporate legal requirements and then delve into many specific (regulated) activities, which revolve around the proper legal and ethical management of “promotional” and “non-promotional” practices. Some common CIA observations include the following:

MORAL

COMPANY

PHILOSOPHY

PROFESSIONAL

NESS

DUTY

CRITERIA

ETHICS

VALUES

High Level:

- Accuracy and integrity of books, records, and accounts
- Embedding of company standards, policies, and procedures
- Avoiding conflicts of interest
- Protection of confidential information
- Appropriate meals, gifts, and entertainment

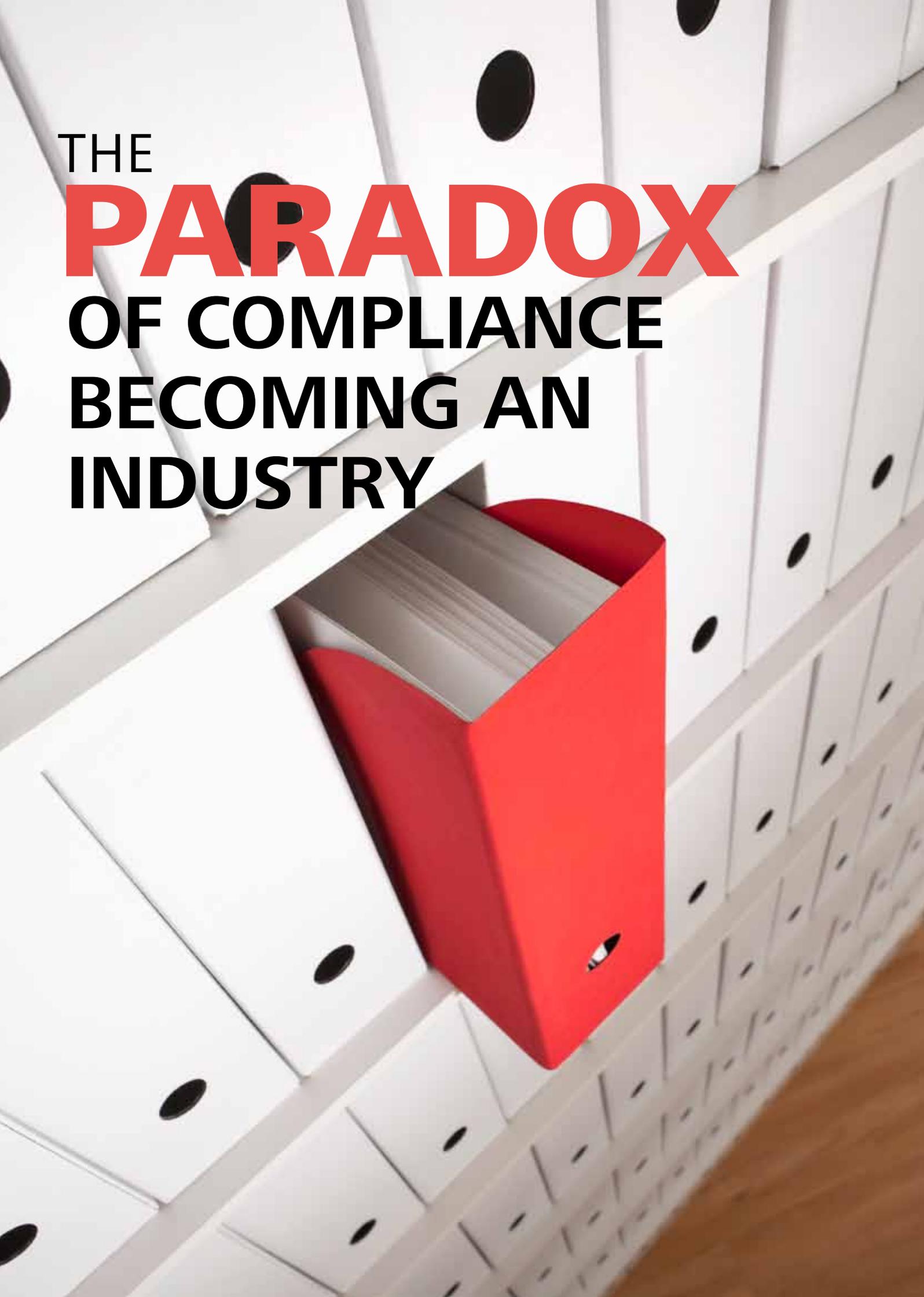
Targeted Activities/Engagements:

- Appropriate promotion of drug/medical device products - including the creation, review, and approval of both promo and non-promo material
- Legitimate use of drug samples
- Evaluation and/or demonstration of medical device products
- Responding to unsolicited requests
- Advisory boards and speaker programmes
- Appropriate corporate representation at certain events (commercial, medical, regulatory, corporate affairs, legal, or finance)
- Sponsorship for "professional services" – purpose, need, legitimacy
- Appropriate use and classification of "grants" and "donations"
- Investigator-initiated trials
- Post-marketing studies and trials
- Scientific publications
- Appropriate distribution of educational items

Today, there is clearly an expectation that all of the above practices - which are frequently engaged in by leading companies - should be dealt with in a satisfactory manner internally. This means investing in a good (visible) CIA internal training programme; having sufficient and appropriately skilled resources in place to review and approve "high value" activities; ensuring that policies and procedures are clear, concise, and "executable"; and being in a solid position to advise senior management about the real risks or gaps in a compliance programme which may be absent with regard to some of the expected key controls.

Having said that, a "bulletproof" compliance programme is definitely a work in progress and is best achieved through an organization's steady and consistent investment and interest in, and reward for, its dedicated personnel. The ultimate aim is to inculcate a natural attitude of "compliant" and ethical decision-making within all quarters of the company, which has a positive impact on the organization's business practices, sales performance, and corporate reputation. A "win-win" situation, all around!



A white metal filing cabinet with a red folder pulled out, containing a stack of papers. The cabinet has multiple drawers, and the red folder is the only one open. The background is a wooden floor.

THE

PARADOX

OF COMPLIANCE
BECOMING AN
INDUSTRY

By Joel Jelderks

Supporters of the fight against corruption are applauding the current crackdown on non-compliant behaviour. But could the rapid growth in compliance-related activity create headaches further down the road? At what point might the compliance industry become too big?

The compliance boom is largely a reaction to increased enforcement, regulations, and risk of non-compliance. This partly reflects aggressive Foreign Corrupt Practices Act (FCPA) enforcement efforts by the United States Department of Justice (DOJ) and Securities and Exchange Commission, and the potential enforcement actions of the United Kingdom's Ministry of Justice under the Bribery Act of 2010. In addition, other US and UK laws related to financial regulation, such as the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank) and the Financial Services Act of 2012, have further bolstered the need for additional compliance measures by financial institutions.

As regulatory demands and risks of non-compliance increase for the private and public sectors, so do their investments in personnel and compliance-related costs. In

the United States the number of compliance officer positions increased by 67% between 2003 and 2014, from 150,000 to 250,000.¹ In 2014, Deutsche Bank invested 1.4 billion EUR in compliance measures, of which 400 million EUR was for personnel.² HSBC now has over 24,000 people working in its compliance and risk departments, representing 10% of the bank's entire workforce, and its compliance costs exceed 800 million USD a year. This is largely the result of a series of law violations that resulted in HSBC reaching a deferred prosecution agreement with the US DOJ in 2012.³ The private sector is not alone; the US government has seen a 19% increase in federal regulatory staff since the Dodd-Frank bill was enacted.⁴

The question is not whether extra compliance costs are worth it because they save money or create value for society as a whole by reducing corrupt, high-risk, or illegal acts. The issue is whether the fast-growing compliance industry will become self-perpetuating, constantly needing to be fed by creating more and more regulation, and managed by more and more people, even after non-compliant acts are reduced.

JOEL JELDERKS

Joel Jelderks (United States of America) is a second year student in IACA's 2014 - 2016 Master in Anti-Corruption Studies (MACS) programme. Originally from the United States, he now resides in Austria with his wife and four children. He currently manages and oversees several small family-owned businesses in the real estate, construction, and coffee sectors operating in Panama and Austria. As a small business owner in sectors at high risk of corruption, he is a proponent of the private sector getting more engaged in the fight against corruption. He also supports government reform to reduce corruption and "smart" enforcement that considers the challenges small businesses face every day operating in such environments.



The theory of industries self-perpetuating is not a new one. This idea has surfaced, for example, in the weight-loss business, which can only exist as long as people have unhealthy eating and exercise habits. Or take the accounting and tax software industries, which lobby against a simpler tax code in the United States because this might reduce the need for their services. Another good example is the military-industrial complex, which only exists if the threat of armed conflict continues around the globe.

The ultimate goal of the anti-corruption movement, realistically, is to reduce rather than eliminate all forms of corruption. This entails developing and agreeing upon standardized measuring mechanisms from multiple sources and perspectives in order to set qualitative and quantitative targets to measure levels of corruption from year to year. This is the only way that government authorities can determine when the amount of regulation and enforcement is achieving its goal of reducing corruption to an acceptable level. At this point, a series of triggers can be developed and activated to automatically reduce regulatory bureaucracy and enforcement.

Companies already have a natural mechanism in place to monitor the growth of compliance requirements. If firms reach a point where the costs and inefficiency of running effective compliance programmes can no longer be

counterbalanced by an increase in prices, then either they need to examine the risk factors of their entire business models, or the enforcement and regulatory bureaucracy has exceeded some natural balance that a society needs to maintain a healthy free enterprise system.

A similar mechanism, based upon pre-agreed measures by the public and private sectors, should be used by governments' regulatory and enforcement bodies as well, otherwise the compliance industry could become an issue in itself.

ENDNOTES

¹ Compliance Officers. at <<http://www.bls.gov/oes/current/oes131041.htm>>

² Truth, V. of et al. Banks face pushback over surging compliance and regulatory costs - FT.com. Financial Times at <<http://www.ft.com/cms/s/0/e1323e18-0478-11e5-95ad-00144feabdc0.html>>

³ iTrade. HSBC wrestles with soaring costs of compliance - FT.com. Financial Times at <<http://www.ft.com/cms/s/0/0e3f0760-1bef-11e4-9666-00144feabdc0.html>>

⁴ Hall, P. The Cost of Dodd-Frank: \$24 Billion in Compliance. National Mortgage Professional Magazine (2015). at <<http://nationalmortgageprofessional.com/news/54936/cost-dodd-frank-24-billion-compliance>>

COMPLIANCE

CONTROL

LAWS

RULES

RISK

STRATEGY

REGULATION

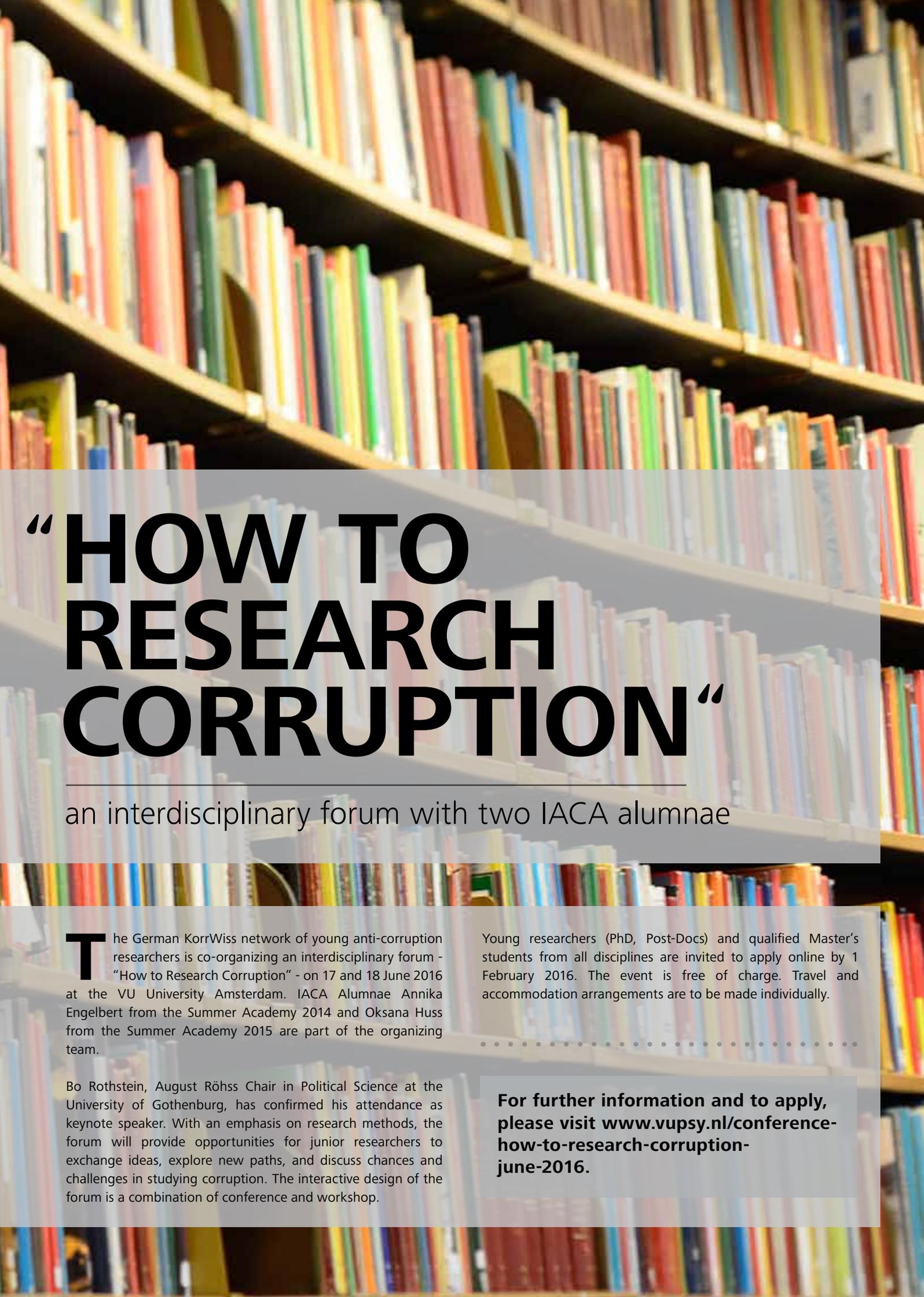
STANDARDS

PRACTICES

GOVERNANCE

POLICY

SECURITY



“HOW TO RESEARCH CORRUPTION”

an interdisciplinary forum with two IACA alumnae

The German KorWiss network of young anti-corruption researchers is co-organizing an interdisciplinary forum - “How to Research Corruption” - on 17 and 18 June 2016 at the VU University Amsterdam. IACA Alumnae Annika Engelbert from the Summer Academy 2014 and Oksana Huss from the Summer Academy 2015 are part of the organizing team.

Bo Rothstein, August Röhss Chair in Political Science at the University of Gothenburg, has confirmed his attendance as keynote speaker. With an emphasis on research methods, the forum will provide opportunities for junior researchers to exchange ideas, explore new paths, and discuss chances and challenges in studying corruption. The interactive design of the forum is a combination of conference and workshop.

Young researchers (PhD, Post-Docs) and qualified Master's students from all disciplines are invited to apply online by 1 February 2016. The event is free of charge. Travel and accommodation arrangements are to be made individually.

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For further information and to apply, please visit www.vupsy.nl/conference-how-to-research-corruption-june-2016.

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JANUARY

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11 - 22 January 2016

JANUARY

IACA Summer Academy,
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applications
open from
15 January 2016

FEBRUARY

Master in
Anti-Corruption Studies
(2016 – 2018 class),
starting autumn 2016,
applications
open from **early
February**

FEBRUARY

Master in
Anti-Corruption Studies
(2015 – 2017 class),
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8 – 19 February 2016

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World Economic Forum
Annual Meeting,
20 - 23 January 2016
(Davos-Klosters,
Switzerland)

FEBRUARY

Interdisciplinary forum
"How to Research
Corruption",
17 - 18 June 2016
(Amsterdam, Netherlands)

apply online by
1 February 2016

MARCH

International Wildlife
Crime Conference,
1 - 3 March 2016
(The Hague, Netherlands)

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