

February 2020

A MESSAGE FROM THE PRESIDENT OF ETHICS

Dear ETHICS members – As we start the New Year we are pleased to present you with the February edition of our newsletter. It includes a review of the General Assembly which took place in Paris at the end of November, a report on our new Professional Competency Framework Position Paper, an interview with Anthony McQuillan and an editorial by John McLoughlin on the rumors from Washington about the future of the Foreign Corrupt Practices Act. Enjoy the reading.



Roeland Van Aelst

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REMEMBER TO REGISTER for the International Pharmaceutical and Medical Devices Congress which will be held in Munich on April 20-22, 2020. Click here for more details: <https://www.internationalpharmacongress.com/>

RUMORS FROM WASHINGTON

By John McLoughlin – Editor of Ethics in Action



On January 17th Larry Kudlow, President Trump’s chief economic advisor and Director of the National Economic Council, told reporters that the Trump administration is looking at “making changes” to the Foreign Corrupt Practices Act. It is no secret that President Trump does not particularly like the FCPA. Over the years he has criticized the legislation for impeding the ability of U.S. companies to do business overseas. According to Kudlow the U.S. administration is working on a package of reforms. He said “Let me wait until we get a better package” before giving details.

There is clearly a paradox here. Since 1977 when the FCPA became law in the United States many countries have enacted anti-corruption legislation under pressure from the U.S. government and international organizations such as the World Bank and the International Monetary Fund. At the same time, the United States courts have extended the extra-territorial scope of the FCPA which has resulted in huge fines being assessed not just on American companies but on many foreign businesses, including for violations which occurred outside of the United States. If the United States government gives up its role as a leader in the world-wide anti-corruption drive, one wonders whether the progress made over the past two decades will falter or even evaporate. It also raises a question about the future of corporate compliance programs. We will all be watching closely as this story develops.

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ETHICS General Assembly - November 20 and 21, 2019, Paris

By Anne-Sophie Bricca



The 2019 ETHICS General Assembly was clearly a great success. Once again, it took place in the beautiful offices of Clifford Chance in Paris. We had the best turnout ever with over 70 members attending and the participation of a number of guests as well as more than twenty speakers, panelists and moderators. The agenda centered around the themes of putting Ethics first in company culture, the role of the Ethics and Compliance Officer and new business models.

Day One

The first day opened with a morning session for members only which was dedicated to the activity report of the association. Arthur Muratyan, the Secretary General of ETHICS, asked members to approve several resolutions - all of which were adopted unanimously. He was followed by Thomas Hauser, the ETHICS Treasurer, who reviewed the organization’s finances and pointed out that the financial situation of ETHICS is positive and continues to improve as the membership increases. Also, the great majority of members are paying their dues on time. During 2019, 31 new members joined ETHICS, which brings the total membership to 122.

Stephen Nguyen, the co-chair of the ETHICS Strategic Committee, gave an update on the activities of the Committee and its six workstreams (Members Development & Education,

Compliance Officer Training, International Development, Governance & General Assembly, Innovation & New Technology, and Communications). After Stephen, Dominique Laymand, ETHICS' honorary President, reviewed the ETHICS Education Programs and described the partnerships that have been established with universities and business schools as well as the support given to compliance officers in certain countries. She also highlighted some of the webinars and breakfast roundtables that have been organized during the past year.

The afternoon program was opened by ETHICS' President, Roeland Van Aelst, who welcomed both ETHICS members and guests and thanked the organizers for putting together an excellent agenda. He also reminded everyone to use the breaks and free time to network.

The first afternoon session was entitled "Elevating Company Culture" and was moderated by Piergiorgio Pepe of Quantum Ethics. He was joined by Beatrice Bauer of the SDA Bocconi School of Management and Nadège Rochel, a member of ETHICS and Global Compliance Manager at Hollister. The focus of the session was on the Fresenius Medical Care case. Fresenius is a Germany-based dialysis clinic operator. It paid \$231 million to the U.S. government in 2019 to resolve criminal and civil charges involving bribery in multiple countries including Saudi Arabia, Morocco, Angola, Spain and Mexico. The U.S. Securities and Exchange Commission and the U.S. Justice Department found that senior management was complicit in these bribery schemes and prioritized profits over compliance. The company had a compliance team as well as compliance policies and procedures in place, but both were ignored. Furthermore, the compliance department was given insufficient resources and the results of compliance audits were not acted upon. After a detailed review of the case, Mr. Pepe opened a discussion with the audience. The topics addressed were: What should compliance officers do in situations such as this? Resign? Go directly to the authorities? And what is their accountability if they fail to detect or report violations?

Beatrice Bauer followed-up by addressing "how to manage your boss" as well as techniques to implement cultural change in an organization. Nadège Rochel concluded the session by giving examples of how to motivate employees to buy into compliance through training tools, films and games. She also recommended that compliance officers adopt an "open door" policy in order to be available when employees have issues.

The last session of Day One was "Elevating Our Impact as Ethics & Compliance Officers". The moderator was Roxana Family of the University of Cergy-Pontoise. This session was split into two parts: The first addressed the accountability of CEOs under French law. It was presented by Charles-Henri Boeringer and Alice Dunoyer de Segonzac of Clifford Chance, Paris. The second part was hosted by Stephen Nguyen and Piergiorgio Pepe. They spoke about the new code of conduct for compliance officers which is currently being drafted by an ETHICS working group which they are leading. Stephen explained that although compliance officers are not regulated by law in the same manner as lawyers or accountants, they nevertheless act in the public interest. Having a code of conduct could contribute to securing the trust of public authorities. Stephen said that the first draft of a code will be presented to the ETHICS Bureau in March 2020. There will then be a members consultation in April and May followed by a final submission to the Bureau at the end of June. The idea is to have a document ready for approval by the ETHICS General Assembly in November 2020. A discussion then followed during which the audience was divided into groups to consider various questions raised by such a code. Each group leader made a presentation to the entire audience regarding their group's views on what should and should not go into the text of the code.

Day Two

The second day began with a presentation by Guido Palazzo, who is a professor of business ethics at Lausanne University. He described how the environment of an organization can breed corruption through such things as a climate of fear, undue psychological pressure to meet objectives, violent language by superiors, managers who do not listen to their employees and retaliation against employees who speak up when they identify problems in the organization. In professor Palazzo's view, organizations must have zero tolerance for any forms of retaliation. He went on to say that employees who draw the attention of management to issues relating to compliance and possible corruption should be rewarded.

The second session on Day Two was split into two parts which were both focused on How Ethics fits to New Business Models.

The first part of this session was a panel discussion on Value Based Healthcare. It was moderated by Diva Duong, Head of Compliance Solutions at IQVIA. The speaker was Claude Le Pen of the University of Paris-Dauphine. He presented several charts showing how value-based pricing and reimbursement work in the French healthcare system. This was followed by a panel discussion with four panelists: professor Le Pen, ETHICS member Anthony McQuillan of Medtronic and Claudia Vaz, who is a global value based consultant at Roche. The discussion centered around new business models for providing healthcare to patients including companies partnering with government healthcare facilities or actually operating healthcare laboratories, clinics and hospitals as a government contractor. It was recognized that these new types of arrangements present numerous legal and ethical issues that still need to be resolved.

The second part of the session addressed Digital Health. Participating speakers were Ceri Thompson, Deputy head of EU's DG CNECT unit, Anaïs Rességuier, of Trilateral Research and Iordanis Kerenidis, Research Director of Quantum Computing and Algorithms at the French National Research Institute (CNRS). Ms. Thompson and Ms. Rességuier explained what the European Union is doing to facilitate and expand digital healthcare through EU-wide initiatives which will favor the secure transmission of patient data for both patient treatment and medical research. Mr. Kerenidis gave a fascinating and very clear presentation on how artificial intelligence is assisting medical practitioners in the diagnosis and treatment of diseases. He also explained the principles of artificial intelligence self-learning - a key tool in improving patient diagnoses. These new developments raise important patient privacy and confidentiality issues and there is a major concern that the technology is moving faster than the regulations can keep up.

In conclusion, the feedback from participants at this year's General Assembly was extremely positive. The sessions were interesting and members were able to reconnect with each other and meet new colleagues who have recently joined ETHICS. We are all looking forward to the next General Assembly in November 2020.

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INTERVIEW WITH ANTHONY McQUILLAN



Vice President Legal & Compliance EMEA Medtronic
Email: anthony.mcquillan@medtronic.com

Education:

Guilford College of Law – Solicitors Final Examination (1989-1990)
University of Cambridge – Bachelor of Laws (BA) (1986-1989)

Employment:

Medtronic International (2002 - to date)
Hewlett Packard - Senior Attorney (2000-2002)
Elf Trading - Legal Counsel (1996-2000)
Herbert Smith - Solicitor (1991-1996)

You joined Medtronic in 2002. Today you are Vice President, Legal & Compliance EMEA. One of your first jobs at Medtronic was as Legal Director for Emerging Markets with both legal and compliance responsibilities. Compliance was pretty much in its infancy at that time. Tell us about your early experiences.

Historically, compliance and legal have been closely aligned at Medtronic in the international space. My job starting in 2004 was, among other things, to strengthen the compliance program for our subsidiaries in emerging markets of India, LatAm, CEE, MEA and Russia. At the time, compliance had more limited resources. We were growing rapidly in those markets which meant that our work was very challenging. In 2007, following a self-disclosure made by J&J involving illicit payments in Greece, the U.S. authorities launched an FCPA investigation of several medtech companies specifically targeting operations in many emerging markets. Medtronic was one of those companies. Ironically, the day we received the first of two letters officially advising us that we were under investigation, I was making a presentation rolling out our just updated distributor compliance program. The investigation lasted six years, on and off, and, at times, was very intense. The good news is that in June 2013, the SEC and the DOJ both sent letters to Medtronic advising that they were closing their investigations without pursuing any enforcement action or charges against the company. The company has nevertheless taken upon itself to continue taking strong internal measures to prevent compliance problems in the future, both in terms of strong programmatic investments, and thorough reviews and mitigation of any potential issues that might arise.

What lessons were learned from that experience?

We realized that our compliance teams on the ground in emerging markets needed to be expanded. Although the U.S. authorities had not sought any enforcement action, we concluded that we would need more manpower in rapidly expanding high-risk markets to regularly follow-up with the employees of those units to make sure that they correctly understood those programs and procedures and were properly implementing them, both in form and in substance. As a result, we significantly increased the size of our local legal and compliance teams and made major investments in various compliance programs, particularly in respect of how we manage our many distributor partners around the world. In addition, we conducted an extensive in-person training program for all our managers in the region, focusing on practical case studies, creating an ethical culture in the company and the importance of doing the right in the first place.

What would you say is the most difficult skill for a compliance officer to acquire?

I think that there are two critical skills that a compliance officer must develop over time: First, to have “x-ray vision” and spot red flags even when everything seems to be in order and all the boxes have been checked. Second, to have the courage to act on those red flags when you do not necessarily have hard evidence that something is wrong. An example is a situation where the audit of a distributor turns up no proof of bribes being paid, but where some money flows do not make business sense. Rather than just assume everything seems compliant on the surface and move on from there, it is important to go one step further to try to determine what is really happening. Going beyond normal due diligence sometimes turns up potentially significant problems. However, despite our best efforts, we cannot always get to the bottom of things and definitively prove that something is wrong. In such cases, an experienced compliance officer has to have credibility with management and be able to rely on their judgement and instinct and say “no” if she or he is convinced that a business partner presents a potential compliance danger. Surprisingly, those types of instinctive decisions often turn out, over time, to be the right ones. However, they require tact and patience to communicate, and careful planning to execute, since blocking a contract or terminating a relationship with a local partner may unnecessarily disrupt the operations of a business unit, particularly if the local partner holds inventories, owns product registrations and has the customer relationships.

Do you find it hard to maintain a standard company compliance system or are you having to tailor compliance programs to individual countries?

We have a global compliance policy and standard common denominators throughout our compliance units with base-line strategies worldwide. However, there are local adaptations to take into account such things as GDPR and other local rules and regulations. At the end of the day, however, doing the right thing is a judgement call and this can and should cut across all boundaries. This really should not be so difficult.

What is the right profile for a compliance officer?

To be effective, compliance teams need to include a mixed bag of people, not just lawyers but individuals who have various skill sets such as finance, audit, IT and sales. Sometimes people get bogged down in details relating to their own background and simply miss the big picture. Having a well-rounded, multi-skilled team tends to produce the best results.

What do you see as the major challenges facing compliance officers in the healthcare sector in the next five years?

We need to shift our focus to new challenges. In the past, compliance officers were worried about such things as generating compliance procedures or sponsoring doctors to go conferences. Those days are largely over, and businesses are moving away from this traditional model. We need to move quickly into better governance in the new world of artificial intelligence, robotics, integrated business models and data protection. For example, at Medtronic we have operations which provide a wide range of hospital solutions, ranging from running cath. labs to operating diabetes clinics in which physicians are essentially company employees. In those cases, we may supply both capital equipment and medical devices, and we need to ensure appropriate governance for these operations to ensure clinical independence and, where needed, Chinese walls separating these operations from the rest of Medtronic’s mainstream business. These new models require new types of contracts and new ways of thinking about compliance. To my mind, it is vital to think holistically about the many closely connected legal and compliance issues relating to public tenders, data protection, competition law, ethical interactions with healthcare professionals that arise with these new models. Compliance teams need to understand and set standards and metrics for these new models, and an ongoing close

collaboration with Legal is essential to achieve this. To be successful, Legal and Compliance cannot operate in silos.

When I joined Medtronic nearly 18 years ago, every seven seconds a patient was treated with a Medtronic device. Now it is every two seconds-around 80 million patients a year. This makes it even more important that in this fast changing world we do the right thing, both technically and ethically, in order to maintain the trust of the patients we serve. This is what makes my job so challenging and worthwhile.

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ETHICS Competency Framework Position Paper

By Tamara Tubin, Katalin Pungor, Vincent Nys, Andy Gascard and Sue Egan



Tamara Tubin



Katalin Pungor



Vincent Nys



Andy Gascard



Sue Egan

We are proud to introduce the new Competency Framework Position Paper that we wrote for our members and our internal and external stakeholders.

The Position Paper serves as a tool to further raise awareness for our Healthcare Ethics and Compliance Profession and sets out what it takes to be successful in our profession as part of the highly regulated Life Sciences environment. It further explains the vision we have for the value we bring to our organizations, our stakeholders and ultimately to the patients.

Let's also not forget that because of fast changing business models we also need to anticipate future trends such as the use of Artificial Intelligence in healthcare.

Our focus in the Position Paper is on the skill sets and responsibilities we need in order to be able to make the right judgments and to promote ongoing business accountability of ethical business decision-making. As you are aware, diversity of skill sets and experience are necessary to successfully navigate the highly regulated and complex environment of Life Sciences businesses.

All of this is in the context of how to strategically best position ourselves as a Healthcare Ethics and Compliance function for promoting an ethical culture within the organization and how to best preserve our independence by having sufficient autonomy, resources and organizational seniority.

We hope you enjoy reading the Position Paper and are looking forward to your feedback.

FOR THE FULL TEXT OF THE COMPETENCY FRAMEWORK POSITION PAPER [CLICK HERE](#)
(please login to the ETHICS website when prompted).



ANTI-CORRUPTION UPDATE

Anti-Corruption Publications Highlighted in this Edition of ETHICS in Action

Articles Selected by Sue Egan



Transparency International Corruption Perceptions Index 2019

Transparency International (TI) has been publishing its Corruption Perceptions Index for many years. This “survey of surveys” has become a major source of information regarding how corrupt each nation’s governmental processes are perceived to be by those outside those processes, but who interact with them. The Index is not perfect, but in the absence of a better benchmarking tool it can give us some interesting insights. The scoring goes from 0 to 100 with 100 being perfect. Transparency International defines a score below 50 as indicating a country that has serious corruption problems.

I particularly like to see how countries make progress up or down the scoring and up or down the rankings. The scoring changes show the effectiveness (or otherwise) of the efforts of each country to tackle corruption. The rankings movement shows how well a country is doing relative to other countries. Denmark, New Zealand, Finland and Switzerland have consistently taken the top 3 or 4 spots for the last few years with scores in the high 80s and low 90s since 2012.

The European countries making the most progress over time are Italy, Greece, Latvia, Estonia and Lithuania. Both Italy and Greece have recently introduced anti-corruption agencies and Italy has also adopted a set of new anti-corruption laws.

The Transparency International report highlights USA as having dropped 2 points in the last year and having its lowest score since 2012. However, when the standard errors on the scores are considered, this could represent a level score over time. I would therefore urge caution when drawing conclusions from these numbers alone, despite the TI report stating that “a series of scandals, resignations and allegations of unethical behaviour suggest that the ‘pay-to-play’ culture has only become more entrenched”.

The full report and downloads are available here:

<https://www.transparency.org/cpi2019?/news/feature/cpi-2019>

The FCPA Blog

Ukraine adds awards and protections for whistle blowers

Ukraine has been consistently struggling to effectively deal with corruption for many years as evidenced by its scores between high 20s to low 30s in the TI Corruption Perceptions Index (see above). However, since 2014 it has been strengthening its anti-corruption efforts with the introduction of anti-corruption agencies and an anti-corruption court. It has now introduced measures to encourage whistle blowers to report their concerns. The full story can be read here:

<https://fcpublog.com/2019/12/10/ukraine-adds-whistleblower-awards-and-protections-with-new-amendments/>

Leaked Boeing Emails Show Slippery Slope of a Bad Compliance Culture

Following the grounding of Boeing's 737 max as a result of several serious incidents, this article looks at the culture inside Boeing and compares it with those of VW and Siemens. The article also refers to a 2015 study of corporate culture which should be of interest:

<https://fcpablog.com/2020/01/15/leaked-boeing-emails-show-slippery-slope-of-a-bad-compliance-culture/>



FDA Warning letter regarding misbranding of opioid addiction treatment

There has been a lot of coverage in the media about the opioid addiction crisis in USA (and other countries), which is why this article regarding the FDA's warning letter to Alkermes "for misbranding the drug Vivitrol (naltrexone) because it failed to include information about the opioid addiction treatment's most serious risks in promotional materials" is important. The full article can be found here (note that you may need to subscribe (free) to read the article):

<https://www.firstwordpharma.com/node/1687211?al=5e10f-7ace69fa0112f064484ca03e6ffae30c%5E%7C%5EMTA0ODE0NA%3D%3D%5E%7C%5ENQ%3D%3D&cp1=bmV3c2xldHRlcld9yZWdpb25faWQ9dG9wX25ld3M=>

LEXOLOGY.

Artificial Intelligence and Drug Discovery

Whilst not about corruption, I have included this article as it discusses the future of drug discovery with the help of Artificial Intelligence and is an interesting short read:

https://www.lexology.com/library/detail.aspx?g=e0a478df-0dfb-4454-bb99-eeac20130900&utm_source=lexology+daily+newsfeed&utm_medium=html+email+-+body+-+general+section&utm_campaign=lexology+subscriber+daily+feed&utm_content=lexology+daily+newsfeed+2020-01-28&utm_term=

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