ETHICS IN ACTION

May 2018

Welcome to the first edition of Ethics In Action, the newsletter of the Ethics Society. Our goal is to bring you news about our members together with interesting and useful information for compliance professionals in the healthcare sector.

REMINDER: The Ethics General Assembly will be held on October 4 and 5, 2018 in Paris. Mark your calendars!

INTERVIEW WITH ROELAND VAN AELST THE NEW PRESIDENT OF ETHICS

Roeland is Vice-President, Healthcare Compliance EMEA & Canada, Johnson & Johnson

Roeland, thank you for agreeing to this interview. Give us a bit of background about your early career. I was trained as a physiotherapist, but only worked three months in that profession before being hired by J&J to join their pharma sales force in Belgium. After spending several years in sales and marketing roles, both national and global, I was named Marketing Director for Belgium.

How did you end up switching to healthcare compliance? A compliance job opening with international responsibilities became available at J&J in 2005. The company was looking for a project leader and not a lawyer. I fit the requirements and was very interested in taking on an international position again. Also, I saw that change was coming to our industry and concluded that it is better to be part of the change rather than standing by and watch it happen. Since I knew the pharma business, I thought I could help in ramping up the new compliance team. My manager told me that I would also have to learn about the devices and consumer businesses, which seemed to me to be an interesting challenge.

The new job must have been very different from what you were doing previously. Yes, but in many respects I found compliance to be more interesting than my previous jobs. It is intellectually challenging and professionally stimulating. Although the rules take a bit of time to learn, the big challenge is to solve practical day-to-day problems, which sometimes can be very difficult, but very rewarding when positive outcomes are achieved.

Do you think compliance people should stay in compliance as a long-term career or should they also cycle in and out of other business teams? Moving from compliance into the business sectors is still unusual, but it does happen and is probably a good thing since it makes for a more rounded business person. The subtleties of compliance are often missed by employees who have not had the opportunity to experience compliance decision-making first hand.

What are the biggest compliance challenges you see facing medtech and pharma compliance officers in the mid-term? The speed of change is greater than it used to be. Business models are evolving rapidly and moving into areas we do not know a lot about, such as Artificial Intelligence. Compliance programs are not currently adapted to follow those changes. For example, how do we handle

situations where AI software is making decisions? What about business partnerships with hospitals or other forms of vertical business integration? In those cases, existing procedures and rules may not be adapted to the new realties that we are facing.

What do you like most about your job? Constant change and the belief that we are making things better.

In February you issued a very clear and comprehensive statement on your goals for the Ethics Society in the near to mid-term future. What are your strategic goals for Ethics in the longer term? Today Ethics is focused on members with international EMEA responsibility generally, but not so much on local countries. In the future we plan to develop local chapters at the country level in different parts of the world. We have started in this direction, but this is a difficult task since it requires a great deal of commitment and work by our members who are already very busy. Also, as a group, we need to be setting standards for healthcare compliance officers and developing competency models. One idea that we have considered is creating a Certificate of Competency. To accomplish this, we need a real curriculum focused on the key elements of the competency model reflecting skills and content. The INSEAD and SciencesPo/Seton Hall training courses are a start and there are other valuable training programs available, but more work needs to be done before we can achieve this objective. Finally, I would like to see Ethics issue whitepapers on key issues, such as code convergence.

MEMBER PROFILE

In each edition of ETHICS IN ACTION we will present a member profile so that you can learn more about your fellow members.

INTERVIEW WITH ROSA MAGISTRI
Head of Legal & Compliance, Europe, SeaGen International GmbH

Education: Universita Cattolica del Sacro Cuore, Law Degree (Qualified as an Attorney at Law -Avvocato – Milan Bar); CIPP/E (Certified Information Privacy Professional/Europe); INSEAD Compliance Implementation Leadership program.

Previous employment: KStudio Associato (KPMG) Law Firm – Associate; Roche Pharma & Diagnostics Milan – Corporate & Compliance Manager; Shire AG Switzerland – Associate Director Compliance; AbbVie – Regional Director OEC Office of Ethics and Compliance.

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Rosa, tell us about your current employer, SeaGen. In 2017 I decided to leave big pharma and join SeaGen International in Zug Switzerland, a subsidiary of Seattle Genetics Inc. in the U.S. which is an emerging global multi-product biotechnology company that develops and commercializes innovative targeted therapies for the treatment of cancer. We can say that SeaGen is in a start-up phase in Europe and does not yet have sales or direct customers. At the present time, I am in charge of both legal and compliance. As we ramp-up our operations, I am developing the European compliance program with a focus on compliance procedures and processes applicable to Europe which will be used by our future sales force.

Does working in the research and development field present compliance issues that are different from the classic pharma-medtech industries? Yes. At this stage I am working mostly on "pre-label" compliance topics. Also, since we have products that may be marketed by SeaGen in partnership with other companies, I have to work together with the Compliance Teams of those companies to make sure that we are both satisfied about how activities relating to those drugs are organized and managed.

Some of the companies you have worked for have combined legal and compliance departments and others have separate departments. In your view, what are the pros and cons of each type of arrangement? Both arrangements can work, but if the legal and compliance functions are not combined into a single department there has to be close coordination between the legal and compliance teams. Otherwise, there is a risk that employees may "forum shop" internally. By this I mean they may go to a

lawyer for what is really a compliance matter or to a compliance person for a legal matter in order to get the advice they want to hear. As we all know, just because something is strictly legal does not mean that it is free of compliance risks and a matter that may not raise a compliance issue could be a legal problem.
How will the new General Data Protection Regulation impact your work in compliance – particularly in the areas of research and clinical trials? We are not only collecting clinical trial data, but also biological samples worldwide for our clinical trials. With GDPR going into effect on May 25 of this year, we have been working to ensure that our internal privacy procedures will be compliant by that time. All of our clinical trial activities are now covered by GDPR-compliant internal company processes and transfer agreements as are our third party contracts. This means that we will be able to use in our R&D in the U.S. data generated here in Europe.
What are the major challenges you face in your current job? No matter how big or small a company is, the major challenge is to get the buy-in of all employees at all levels. To do this, it is critical to create a "culture" of compliance. Most employees do not immediately understand the importance of compliance, how it benefits the company or where the risks lie.
What do you like most about your job? The most rewarding aspect of my job is when my non-compliance colleagues tell me that they recognize the added-value that compliance brings to the business. To achieve this, compliance officers need to really understand all aspects of the business, whether it is marketing, distribution, sales, finance, R&D, regulatory or medical. We have to be able to view the company from a 360° perspective.

A TRUE STORY FROM THE FRONT LINES

HOW SAYING "NO" CAN SOMETIMES MAKE YOU A HERO (Anonymous)

Quite a few years ago, I was contacted by the general counsel a U.S. medtech company which was a client of the law firm where I worked. The call related to a training event that the general manager of the French subsidiary was organizing on an exotic island for a large group of physicians and their spouses and partners. At that time, the company did not have a compliance officer or a formal compliance program so the general counsel asked me to look into the matter.

After lengthy discussions with the French general manager, it became quite clear that this so-called "training event" was, in fact, a five day party with no real training, lots of cocktail outings and fancy dinners, plus golf, sailing and other forms of entertainment. To make matters worse, the physicians in question were purchasing decision makers in the hospitals where they worked, including for products made by my client.

I got back to the general counsel and advised him not to authorize the event. As could be expected, the French general manager went ballistic. Not only would he have to "un-invite" the physicians (his best customers), but the company had purchased non-refundable first class airline tickets and had made a significant down payment to the hotel resort which could not be recovered. Despite my explanations, the general manager could not understand where I was coming from, particularly since his competitors had recently organized similar events. Nevertheless, the general counsel maintained his decision and the event was cancelled. The general manager then told me he would never work with my firm again and would tell other medtech companies in France about how incompetent I was.

A few weeks later, the French economic police (DGCCRF) raided a number of French medtech companies which were competitors of my client. From there, the story took a very unexpected turn.

In the weeks that followed, the press reported that criminal charges were being brought against certain medtech companies and their management for bribery (but not my client). Also, a group of travel agents were being investigated for being involved in what appeared to be a kick-back scheme involving physicians. Finally, a number of physicians faced disciplinary action by their local medical boards.

Some months later, I received a visit from my client's general manager who wanted to apologize for getting angry at me. He told me that he had received numerous calls and emails from the physicians whom he had "un-invited" thanking him for cancelling the event. He was also receiving new orders from hospitals that had never worked with his company, several of which told him that they did not want to purchase products from the companies that were under investigation. Thanks to me, he said, business had never been better and the company's reputation among hospital physicians and staff was among the best in the industry. He concluded by letting me know that he had directed his staff to only use our law firm for all of the company's French legal work.

Sometimes tough compliance decisions have happy endings for all concerned.

RECENT CONFERENCES

March 8 - E&Y Breakfast Meeting – Paris, by Arthur Muratyan

On March 8, the Ethics Society and Ernst & Young jointly organized a breakfast meeting on the topic "Anti-Corruption: How to manage relations with third party business partners?". This was the second joint meeting involving our association and E&Y. The previous session was entitled "How to conduct investigations". After an introductory slide presentation by Anne-Sophie Bricca, the participants were asked to review practical case studies corresponding to complex hypothetical situations that compliance officers could face in their day-to-day work. Participants were then asked to comment, identify risks, and propose practical solutions and share know-how based on their personal experiences. The most remarkable aspect of the meeting is that it was conducted via live weblink on 5 sites in parallel: Paris, Brussels, Madrid, Zürich and Frankfurt with participants at each site, including Ethics Members, E&Y staff and guests. The meeting was perfectly managed and a success from all points of view. Many thanks to the E&Y teams (most particularly to Laura Pessanha and George Fife) and to the Ethics organizers (particularly Anne-Sophie Bricca and Sue Egan) who were instrumental in the preparation and implementation of this great event. No doubt Ethics will soon renew its cooperation with E&Y to organize new events in the future.

March 20 – 21 IPCAA Conference – Berlin, by Sue Egan

IPCAA (International Pharmaceutical Congress Advisory Association) held its annual compliance seminar in Berlin this year with a special emphasis on the practicalities of applying the Codes, laws and ethical practices. The IPCAA seminar is unique because its membership includes industry members (pharmaceuticals and medical devices), conference organisers (and other third parties) and HCP associations, and because the organisation focusses on congresses

and conferences. This unique combination means that a good dialogue usually takes place among all the key stakeholders involved in congresses for HCPs.

The annual compliance seminar usually begins with a pre-conference session for those who are new to healthcare compliance so that they can "get up to speed" before the main seminar sessions begin. This year, the organising team decided to hold an interactive workshop instead where participants were seated at tables and all discussed a case within the table before being brought back together to discuss the case across the room. Several cases were discussed during the morning. The feedback was so good that ETHICS will adopt this approach for our pre-conference session at the forthcoming International Pharmaceutical and Medical Device Compliance Congress in Vienna in mid-May.

Other sessions during the seminar included the almost obligatory Codes Panel, a discussion on "How to Ensure High Quality Exchange in this Regulatory World", and a "Codes in Action" panel before moving on to "Patient Centricity and Code Complexity".

Throughout many of the discussions I was struck by the large chasm that still exists in understanding between the various groups. In recent years, Compliance Professional (and others) in Life Science companies have spent much effort to help our third party event management partners to understand the Codes, the reasons for the Codes, and what we can and cannot do under the Codes. It was obvious that most people in the room from these organizations had a good understanding of these points. However, we still have much work to do with HCP Associations to help them understand the Codes, and perhaps they would say that they still have much work to do to wean us off our Codes.

Steve Sealy from European Respiratory Society posed an interesting question: "Do the Codes help us to collaborate for patient care?" His response was "possibly not". This got me thinking about why the Codes exist and whether they focus on the right things. Perhaps we have become too focused on the tiny details and forget to regularly stand back to look at the big picture? Should we perhaps look again at the Codes and think about what we can remove so that we can focus on what really matters? Or maybe the Codes are not detailed enough, and we need to add more details so that there can be no room for interpretation? Whatever your point of view, this debate is not going away and may be the next key topic for us to tackle to gain (or regain) credibility with HCPs and HCP Associations.

NEWS FROM THE COMPETENCY PROFILE TEAM

By Tamara Tubin

Healthcare Compliance Profession Competency Model and the Self-Assessment Tool

The Healthcare Compliance Profession is a profession that we can be proud of. It is an interesting profession that brings diversity and broad insights into the healthcare systems including interaction with stakeholders, governments and the public. As a trusted partner we

bring value to the healthcare sector in the sense that we aim for the right patient - gets the right treatment and the best product - at the right time. We achieve that through our profession with our vision and mission of advancing and promoting a culture of business accountability of ethical decision making with a focus on mitigating risks of non-compliance.

Within our working group, consisting of Andy Gascard, Katalin Pungor, Sue Egan and myself, we have developed for our members a Healthcare Compliance Competency Model and a Self-Assessment Tool that shall help our members with their professional and personal development. We were very passionate about ensuring that we cover the breadth and depth of our profession with those skills and competencies that will make you successful in what you do and what you are trying to achieve.

I am proud to say that not only our working group was very diverse. We also managed to have a lot of fun together and we learned so much from each other at the same time. Having said that - continuous learning and change will follow us throughout our journey as healthcare compliance professionals. We hope that the Competency Model we developed for you and the Self-Assessment Tool will bring you lots of benefits for success in your job and personal life.

Yours Sincerely - and on behalf of an outstanding team,
Tamara Tubin, Katalin Pungor, Andy Gascard, Sue Egan

ANTI-CORRUPTION UPDATE

Anti-Corruption Articles Highlighted in this Edition of Ethics In Action with an introduction by Dominique Laymand

During the past two to three years, combatting corruption has become a top priority in many countries around the world. Anti-corruption legislation has been implemented or enhanced in some jurisdictions. In others, enforcement has been strengthened. This evolution is, in some cases, a reaction to scandals. In others, the goal has been to adopt standards to support sustainable and fair competition. These developments have an impact on how businesses operate both internationally and at the local country level. This also means that all stakeholders, including governments, public officials, businesses and NGOs need to coordinate their efforts in order to address the problem of corruption and the mitigation of corruption risks. We believe that doing so will lead to a better society providing more equal opportunities to all citizens. The members of the Ethics Society are dedicated to supporting this effort by contributing to the education of ethics and compliance professionals in the healthcare sector and providing them with timely and useful information.

For Odebrecht, the Cost of Bribery Is Still Climbing

Thomas Fox of FCPA Blog demonstrates that the costs of a corruption enforcement action can cause extreme financial difficulties for a company and, perhaps, even result in insolvency.
http://www.fcpablog.com/blog/2018/4/26/tom-fox-for-odebrecht-the-cost-of-bribery-is-still-climbing.html

Brazil and China most frequently mentioned in FCPA-related investigations

This article in FCPA Blog shows that companies and enforcement agencies have named Brazil 36 times in disclosures about ongoing FCPA-related investigations. China is named 17 times.
http://www.fcpablog.com/blog/2018/4/26/brazil-china-most-mentioned-in-fcpa-related-investigations.html

France Takes Next Step in Anticorruption Enforcement: First "French DPAs" and What Companies Should Know

JONES DAY | One Firm Worldwide

Three lawyers from the Jones Day law firm explain the new French DPAs under the Sapin II Law in a Lexology article.
https://www.lexology.com/library/detail.aspx?g=ee0614e1-5af5-4177-811b-948cbdea0d21

Mexico's Anticorruption Legislation

SQUIRE PATTON BOGGS

A fascinating series of three articles in Lexology by Jose Martin of the Squire Patton Boggs law firm on the new anti-corruption legislation in Mexico.

https://www.lexology.com/library/detail.aspx?g=8aff2eef-33c9-4ecc-923f-06b6545c93fd
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