Review of the 13th Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Washington DC, USA, 5th – 7th November 2012

With twelve successful conferences already under their belts, the organisers of this event were challenged to live up to the high standards already set within this forum. Having attended four of the twelve forerunners, I can safely say that this conference did not disappoint.

There were many well-known presenters from the various US government departments on the agenda for day one, which focused on updates from the US lawmakers and prosecutors. Among the interesting nuggets for all companies within this part of the conference was a statement from a member of the US attorneys panel that those small and mid-size companies that think they are successfully flying under the radar of the US prosecutors are delusional! I took that as a clear message that the larger companies have probably yielded all the low-hanging fruit that is available and the net will now be spread more widely. Indeed, in late December 2012, Victory Pharma agreed to pay $11.4m to resolve kickback allegations[1].

Day two began by looking at *qui tam* cases and state enforcement before moving on to an interesting panel discussing best practices in negotiating and implementing Corporate Integrity Agreements (CIAs). There has been much debate regarding which elements of CIAs really make a difference in changing the behaviour and attitudes of company employees, and which merely serve to impose an effective financial sanction on companies for no benefit to patients, or healthcare in general. One such example is the requirement to send letters to physicians, which can cost around $3-4m for 850,000 letters. These letters often elicit fewer than 10 responses, which are often anti-government in nature rather than anti-company. If return receipts are required, this can add another $1m to the costs. In addition to the costs incurred to send the letters, companies often have large teams of people involved in implementing CIAs, with 400 people involved in 32 work streams pre-implementation and over 1,000 people involved in post-implementation activities quoted by one company. This adds up to a huge burden on companies, which begs the question why companies do not put more effort into preventative measures so that they do not incur these costs as the result of entering into a CIA. Perhaps that is the real aim of the enforcers.

The panel discussing state disclosure laws also posed some interesting questions, such as if one or two states have very different requirements to the other states does it make sense for companies to alter their processes and IT systems to suit these "worst case scenario" states, to implement manual procedures in those states, or to simply stop some activities in those states? I suspect that companies will look at each requirement separately to determine the most sensible approach. Again, perhaps the real aim of those bringing in these state laws is to discourage companies from engaging in particular activities within those states; it might even work!

The three sets of concurrent mini summit discussions on the afternoon of day two covered a wide range of topics, both domestic and global. These included global transparency requirements, compliance issues in global research and development and medical affairs, compliance issues specific to devices companies, fair market value update, global pharmaceutical and devices issues, and enforcement threats against individuals. Two sessions that caught my attention were those on

[1] See the statement from the FBI at http://www.fbi.gov/sandiego/press-releases/2012/victory-pharma-inc.-of-san-diego-pays-11.4-million-to-resolve-kickback-allegations-in-connection-with-promotion-of-its-drugs

particular issues faced by smaller companies and "compliance program innovation". The first of these sessions provided practical advice to those responsible for compliance within smaller companies, where they are often a "team of one" or they may have a single team member to assist them. The challenges facing these companies are usually around prioritisation and resource utilisation to ensure the biggest impact from the smallest resources. The panel also gave good advice regarding the timeline of what to focus on when a compliance officer first comes into the role. As each company will be different, the panel suggested that the key risks should be highlighted by carrying out a compliance effectiveness audit. Other good suggestions included using those staff members who will already have a "regulatory mind-set", such as those working in Quality Assurance, Regulatory, and related roles. The session on "compliance program innovation" looked at using existing metrics within companies in innovative ways to predict and prevent problems. For example, if financial data show that a business unit missed its target in one quarter, what might it do in the next quarter to make up the shortfall, and could this constitute a compliance risk for the company? Staff surveys could elicit behavioural indicators from questions on speaking out and how staff members view their own managers and management generally. The panel also suggested that companies should look at the reasons for tenure and turnover of key staff, since these may point to underlying problems or specific strengths.

Day three began with a much larger audience than I had expected given that it followed election night. That was probably due to the great speaker line-up, with Susan Dentzer delivering the first keynote address of the day. The interesting comments by Susan included a quote that the Institute of Medicine has stated that "half of all medical care delivered has no evidential basis", which led her to conclude that if all the "junk that doesn't work" was removed, America could afford to give much better healthcare overall and could also invest more in health Research and Development. This session was definitely worth getting out of bed for on the morning after election night!

Throughout the agenda of this conference were sprinkled ample opportunities to network with people in various compliance roles across the whole industry, including those working in pharmaceutical, biotechnology and devices companies, as well as consultants and lawyers. I had many interesting coffee break discussions, indicating that another strength of these conferences is the audience that they attract.

To find out more about the Pharmaceutical Compliance Forum (PCF), their website is www.pharmacomplianceforum.org. To find out more about the Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum congress, including how to get copies of the congress presentations, the congress website is www.pharmacongress.com.

Sue Egan MBA, Director, Sue Egan Associates Limited, Editor@SueEgan.co.uk

Sue has been a Compliance Officer at all levels from single marketing company and European Compliance Officer for GlaxoSmithKline (GSK) to international VP for AstraZeneca (AZ). At GSK, Sue established the Risk Management and Compliance Board for the UK marketing company under the leadership of the UK Finance Director. As GSK's European Compliance Officer, she gained a reputation for a pragmatic approach by providing practical help and guidance to Marketing Company Presidents who were keen to manage their compliance risks effectively. As VP Compliance for AZ's International Sales and Marketing Organisation, Sue was responsible for ensuring compliance in every country in which AZ had commercial operations except the USA and Canada.

In January 2010, Sue established the management consultancy, Sue Egan Associates Limited, specialising in Corporate Governance, Compliance, Risk Management and Change Management. Sue works with clients in various sectors (life sciences companies, charities, a government agency, and other industries) to help them find innovative ways to conduct business ethically and sustainably.