Interview: Andrew von Eschenbach – FDA Commissioner (2006 to 2009)

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Speaking exclusively to PharmaBoardroom at the 2017 BIO Convention in San Diego, former FDA Commissioner Andrew von Eschenbach lifts the lid on the 'FDA Beyond Our Borders' project that he initiated.

Dr. von Eschenbach, you were the FDA Commissioner for three years, from 2006 to 2009. What do you see as your greatest achievement during this period?

'FDA Beyond Our Borders' is something that I remember with a great deal of pride and satisfaction, primarily because it was a major transformation for the agency to have a presence in other parts of the world. It required a tremendous amount of diplomacy in order to be welcomed in most places and not be seen as an imposition.

This is one of my deepest memories, but of course there are many – the Viva White Oak Project** in Maryland is obviously another great example.

** *Viva White Oak is being developed as a public-private partnership between Global LifeSci Development Corporation (an affiliate of Percontee, Inc.) and Montgomery County, Maryland. Located just steps away from the campus of the FDA (the gateway to the US health market) and squarely in the middle of the thriving Washington-Baltimore corridor, Viva White Oak is ideally positioned to become one of the world's next great hubs for research and discovery, and a great place to reside or do business in a walkable, mixed-use, 21st century community.*

How did ‘FDA Beyond Our Borders’ actually start and why was it important to you?

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If FDA just sat in Maryland or Washington DC, we would be missing the opportunity to engage in global dynamics. This is how we started this project and opened offices in Europe, Central & South America, China and the Middle East. Healthcare is a global matter, drug approvals are global matters, so the FDA had to be global too

The idea emanated from the fact that each year, the USA imports a tremendous amount of products – including food, animal feed, human and veterinary drugs, vaccines and other biologic products, cosmetics, and medical devices – that enter the United States, coming from more than 150 countries and territories around the world. The FDA regulates a large number of these products and is responsible for ensuring that they meet US standards for safety and quality and do not jeopardize public health or national security. But, since the volume of imports regulated by FDA has increased by 35 percent in the past five years and it continues to multiply, this increasingly global economy presented new challenges and growing international work for the agency. Hence why we launched the initiative.

The idea was the following. We wanted to better address international challenges to public health and national security by increasing collaboration with our foreign counterparts, learn more about foreign exporters and their products, provide technical assistance to foreign regulators and industries, and finally, establish overseas offices within some foreign countries as I just mentioned.

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As a result, beginning in 2008, FDA established foreign offices in China, Europe, India and Latin America. In the past five years, the number of FDA agreements with its regulatory counterparts throughout the world more than doubled and it continues to grow. FDA today boasts 120 international agreements with about 30 countries and multilateral partners. Relationships with the FDA therefore now have multiple layers, and there is never going to be one global regulatory agency.

That being said, FDA approvals are what counts today for pharmaceutical companies in all countries. Would you not say that despite the presence of very efficient regulatory bodies in other parts of the world such as the European Medicines Agency (EMA) to name just one, the FDA still has a dominating role?

It does not dominate, if anything it leads – there is a difference. The FDA is more than 100 years old and greatly benefits from this thorough experience. So, it should lead but not dominate. What I hope it will do is forced cooperation among regulatory agencies where, firstly, every individual body makes individual decisions and then agrees to common policies by sharing data. There are a lot of examples of where this is being done already. We can share the workload so that agencies do not waste their resources. One specific example is the inspection of facilities; we should agree that there are common standards that we want to assess in an inspection.

What do you think is going to happen to the EMA, currently headquartered in London, UK after the Brexit?

I don’t know for certain but one possibility is it will move to another EU member state, and the UK will set up its own agency.

What has been occupying your time since you left the FDA in 2009?

I am still very active in the field of healthcare at the Milken Institute which looks at healthcare policy from an economic perspective. It deals with issues such as the economic advantages of making significant advances in eliminating suffering and death from cancer . I am also active at the Bipartisan Policy Centre in Washington DC where I focus much more on discovery and development, looking at the kinds of policies we need to foster innovation that will ultimately nurture our ability to continue to find solutions to fight cancer and Alzheimer’s. And there are of course also tax policies, investment policies and so on.

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