PharmaVOICE

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New revenue streams

Generics coming home to roost...

By now, everyone in the pharmaceutical industry realizes that billions and billions of sales of branded products are going away, and the impact of this is going to be huge. According to IMS Health, the 5% to 8% compound annual growth rate during the next five years is going to reflect the impact of leading products losing patent protection in developed markets. Market growth is projected at almost $300 billion over the next five years,which would bring sales to about $1.1 trillion in 2014 — numbers that are staggering, yet still below what may be necessary to continue to drive higher growth in those therapy areas where there is a need for innovative science.

The loss of patent protection for so many blockbusters has many companies re-evaluating their business models and strategies. And as a result, this has many prominent thought leaders also looking to the future.

This year's annual DIA meeting in Washington, D.C., is a great opportunity to learn what industry luminaries have to say about the industry's possibilities in the near and far term. The conference will feature sessions that aim to address what is needed for innovation, as well as health outcomes. A multitrack plenary session will look at the implications on innovation from comparative effectiveness research and the needs of payers. More than 25 special topics are available this year, including sessions devoted to oncology, biosimilars, pediatrics, and social media.

The DIA also will feature John Crowley and the innovative work of Amicus Therapeutics. His amazing story was showcased in the January 2009 issue of PharmaVOICE. PharmaVOICE also conducted a podcast with Mr. Crowley, whose story led to the making of the movie Extraordinary Measures. In our podcast, Mr. Crowley shares his personal journey to find viable treatments for Pompe disease, a neuromuscular condition that affects two of his children.

The perennial challenge of speeding the development process for drugs to reach the market faster remains a main topic at DIA. Patient recruitment, CRO/sponsor relationships, data capture, and regulatory issues are just some of the many issues to be addressed.

In this issue, the Forum takes a look at one idea for speeding development: the use of adaptive trial designs. The flexibility of an adaptive design allows sponsors to make course corrections during a trial based on interim data, but ensuring integrity of the study and controlling against bias are two issues that need to be addressed in up-front planning. The FDA's new draft guidance on the subject should help to provide more clarity.

Our experts also address the use of cloud computing in research, which can provide sponsors with the speed, agility, and deeper analysis of data to improve efficiency. Pharma and biotech companies are just starting to put their toes in the water in this arena, but experts say there will be rapid adoption when the industry realizes the opportunities for R&D.

See you in Washington, D.C. And don't forget to stop by the PharmaVOICE booth — No. 400 — and say hello.