Impact of 21st Century Cures Act

Congress recently passed the 21st Century Cures Act with $4.8 billion dollars in funding and a purpose of speeding the development and approval of new medicines and medical devices the act has generated significant excitement and discussion. Some of the key components of the legislation include:

1. $4.8 billion dollars additional research funding to NIH over the next 10 years
2. Allowing FDA more discretion regarding the types of studies and endpoints used to evaluate new medicines and medical devices
3. Additional funding for research and treatment of opioid abuse and mental health issues
4. Improving patient input into the drug development and approval process

There is no doubt that the bill will have beneficial effects on health care and the pharmaceutical industry, but will it have a significant impact on the challenges that have been dogging the pharmaceutical industry for the last several years? Specifically, reduced R&D productivity, increasing costs, longer cycle times, increasing regulatory complexity and dealing with an evolving customer landscape.

The bill's focus on funding research in key areas such as regenerative medicine and stem cell therapy may do little to reduce today's log-jam in the therapeutic development pipeline. There is no shortage of innovative therapeutic candidates in development by a multitude of start-up biotech companies. However, these companies face significant financial and regulatory when their candidate drugs and devices move into clinical development. While some may feel the bill does not go far enough, there is hope that its passage may help reduce the development bottle neck.

Portions of the bill will certainly aid pharmaceutical companies as they develop new products. The bill allows FDA to rely more on shorter, more focused, and ultimately more simple clinical trials when reviewing drugs for approval. In addition, the bill may allow the FDA to rely more heavily on the use of surrogate endpoints such as biomarkers in the blood or changes in tumor size, versus harder outcomes data such as reduced death rates. In the medical device sector, the FDA could use smaller studies and real world evidence from company registries and other sources as opposed to the cold standard of a controlled clinical trial. This sector would also benefit from a measure requiring the FDA to provide approval more quickly by using priority review breakthrough products that offer significant improvements over existing devices.

While the 21st Century Cures Act will no doubt lead to moderate improvements in speeding new products to market and in reducing regulatory complexity, it remains to be seen if the bill will truly, and significantly impact the challenges facing the life sciences industry today. There are issues that still need to be addressed, including decreasing R&D productivity, increasing development costs, and the evolving customer landscape as it relates to pricing, reimbursement and patient engagement. Both pharmaceutical and medical device companies must continue the current trend of transforming their businesses to meet these challenges looking for ways to reduce costs, improve efficiency and address the evolving customer needs. Though encouraging, it is too early to breath a sign of relief with passage of the bill.

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