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THE CHALLENGES OF A NEW CENTURY


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Despite a history of new product launches, strong growth, and increased research spending, it is clear that the pharmaceutical industry is in a period of major transition. The challenge facing the industry is one of creating a sustainable pipeline that can generate the long-term growth needed to fuel the sector. This challenge faces both the established pharmaceutical industry as well as the younger biotechnology sector. In fact, I would go so far as to predict that those companies that successfully focus on addressing the need for a sustainable pipeline and enhanced productivity will define what the winners will look like in the new century —regardless of how they are defined today. These companies, equipped with the knowledge of the genome and of molecular pathways that define disease, will make a major difference in peoples' lives through providing personalized medicines that increase drug efficacy and reduce adverse side effects for patients.

It has been estimated that for the top 10 pharmaceutical companies to maintain an 8% growth rate into the future, they will have to introduce three to four new chemical entities each year. This is a huge challenge to an industry that has seen declining productivity in spite of an increased commitment to research. While some companies have tried to address this challenge through mergers and acquisitions to fill their pipelines in the short term and rationalize overhead costs, the longer-term solution to creating a sustainable pipeline rests squarely on two fundamental building blocks, which are attainable through our understanding of molecular medicine. Companies must increase the number of hits, targets, and leads they can generate at scale, and they must improve the productivity of their discovery and development engines by removing bottlenecks at every stage in the process of bringing a product from gene to patient.

ACHIEVING TARGET NUMBERS

How can the industry achieve these two goals of increasing the number of targets and driving improved productivity? To address this new paradigm, companies need to begin to implement and/or build gene-to-patient research, development, and commercial platforms with the right people, tools, processes, and technology that allows for the high-scale productivity needed to create the new drugs that drive growth.

The challenge of improving productivity remains central to any successful strategy in the new pharmaceutical environment. To achieve a truly sustainable pipeline, the productivity of the entire organization must be continually improved, particularly reducing downstream failures by attacking ADMET and clinical bottlenecks. To achieve this goal, companies need to apply the tools and technology that are in use in discovery today, particularly the growing understanding of molecular pathways. This is a continuous process that begins with the research platform, continues through target validation and clinical trials, and ultimately drives through to manufacturing and the commercial launch of new products.

AN INTEGRATED AND HEURISTIC APPROACH

The traditional linear process of drug discovery and development will be replaced by an integrated and heuristic approach, utilizing a series of feedback loops to capture and integrate molecular, pharmacologic, and clinical data with target discovery and validation in near real-time.

Initiatives, such as personalized medicine, are designed to ensure that the right drug can be delivered to the right patient in the right dose at the right time. Personalized medicine gives the industry a way to increase the efficiency and reduce the risks of the drug development process both in early stages of discovery and in the clinical trials.

In clinical trials, the use of personalized medicine in drug development will allow us to much more carefully select for inclusion in our clinical trials those patients genetically most likely to benefit from the treatment being tested, and those genetically least likely to experience serious adverse reactions. And, again on the discovery side, it will allow us to reduce failures in the clinic by allowing for the identification of better targets in the first place.

Ideally, the use of personalized medicine has the potential to reduce the number of new compounds and number of patients being tested in Phase II and III trials and increase the success rates in Phase III trials. This will create efficiencies in the overall healthcare system where currently we have little ability to determine which drug is best for which patient.

COMMITTING TO PHYSICIANS AND PATIENTS

And this leads me to the final challenge our industry faces. Our challenge is not limited to developing new drugs in an efficient and effective manner. If the pharmaceutical industry is to continue to thrive in this new environment, we must bring that same productivity commitment to physicians and patients. Personalized medicine will provide healthcare professionals with the capability to more effectively manage patients along the entire continuum of care — including diagnosis, prognosis, screening, and treating with better therapies tailored to subsets of patient populations — all based on molecular profiling. And this will help improve the lives of patients and give physicians and other healthcare practitioners the capability of better understanding both disease and its treatment.

As an industry, we are undergoing a revolution. It is a revolution of both process and understanding. It is a revolution of knowledge and technology. But our goal is nothing less than revolutionizing medicine as we know it.

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