

Editor-in-Chief's Commentary: The Changing Landscape of Drug Companies

Therapeutic Innovation
& Regulatory Science
2014, Vol. 48(4) 412
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DOI: 10.1177/2168479014538415
tirs.sagepub.com

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This is an interesting time in the history and evolution of companies involved in the discovery, development, marketing, and distribution of therapeutic interventions. In the brief time I was on vacation in April, there were several mergers and attempted takeovers, swapping of over-the-counter portfolios, and divestments and purchases of research therapeutic areas. Most of the discussion in the media around these events focused on potential economic outcomes. Certainly, impact on employment, tax implications, and stocks and investments all are important. There has been relatively little discussion, however, about the impact of such activities on the development and subsequent availability of important new therapeutic advances. This is a time of renewed creativity in the discovery and development of new medicines, particularly targeted therapeutics, often with linked biomarkers and diagnostics, helping get the right medicine at the right dose to the right patient. Paradigms are shifting, regulatory responses based on advancing science are changing, and the hope for real advances is increasingly based on ever-better science.

Thus, the article published in this issue of *TIRS* by DiMasi, Kim, and Getz¹ is particularly timely. They examine a large number of drug development programs from 2000–2011, about half of which were underway during corporate shifts, with in-licensing being the most common of these activities. Programs affected by such “collaborative and shared innovation” activities experienced a 20% longer development time, a median increase of 14.8 months. Regulatory approval time was not statistically significantly affected. The authors comment that their study provides initial benchmarks and insights that hopefully can be used to make a positive impact on portfolio planning and drug development in an ever-changing environment.

Studies such as this are important for several reasons. There are few data available to help us understand the consequences

of business decisions on the development of new medical products. While many decisions may be driven by financial considerations, it is important to consider the effects of the ultimate availability of potentially important therapeutic products for patients in need. Any data we have about what really happens as companies merge and products are shifted from one sponsor to another will help us prevent unnecessary delays. As well, ongoing data will help inform companies about the impact and wisdom of mergers and other approaches to theoretically modifying risk in the difficult processes of drug discovery, development, and marketing. From the perspective of medical practitioners and their patients, who hope that advancing science will bring new products to market in a timely, efficient manner, having several sponsors pursuing similar products and therapeutic targets has some real advantages. This is not merely “me too” research. If some products are delayed due to other aspects of corporate decision making, we trust that other similar products will move forward more expeditiously. Just as we hope that biologic science will advance our ability to help our patients, so too we hope that increased understanding of the processes enhancing and impeding the availability of new advances will lead to wiser, more efficient, and profitable processes for converting biology into therapy.

—Stephen P. Spielberg, MD, PhD
Publications Editor-in-Chief, DIA

Reference

1. DiMasi JA, Kim J, Getz KA. The impact of collaborative and risk-sharing innovation approaches on clinical and regulatory cycle times. *Therapeutic Innovation & Regulatory Science*. 2014;48(3): 482–487.