A Perfect Storm for Innovation

RN Williams

To the Editor: The March issue produced two outstanding articles that should make us all sit up and seriously contemplate the future of clinical pharmacology and the biopharmaceutical industry in general. The Editorial by Honig and Lalonde described the financial pressures facing drug development, and Kaitin’s Development article discussed the failing business model and potential innovative solutions. Both articles reflect the sea changes taking place in the biopharmaceutical industry as well as the absolute necessity to create innovative approaches to the development process.

Over many years, we have clearly seen the decline of the biopharmaceutical industry. However, Kaitin’s analysis showing that a handful of top-tier pharmaceutical companies have lost >$650 billion in market capitalization in the past 8–9 years is alarming. This development is particularly poignant because, during this same time frame, companies have “merged,” “reengineered,” “reinvented,” and “redesigned” their operations in an attempt to improve productivity. It would appear that, although such approaches are important for achieving short-term efficiencies, they do not address the issue of innovation. Operational excellence is not strategy. This is not to say there have not been innovations in the development paradigm over the years. As described by Kaitin, the Lilly/Chorus model and the relationships between functional service providers and contract research organizations are probably helpful strategies for cost containment. In fact, Chorus has reported that it can take a molecule through to proof of concept for $5 million, whereas traditional development pathways would require $30 million and 12 months longer. Such an approach would therefore add up to about $300 million less for the overall cost of development. This number provides, in part, an astounding example of the time value of money as discussed by Honig and Lalonde.

So why are we so hesitant to experiment with new development processes and business models? Are we really so enamored of empirical business models that are unsustainable and failing? There will never be a better time to explore innovative ways of redesigning the development process. Financial pressures, soaring health-care costs, globalization, and the explosive growth of basic science have coalesced to create the perfect storm to drive change. Innovative business and development models will certainly be welcomed by all stakeholders, but especially by patients in need of new lifesaving therapies. The Editorial by Honig and Lalonde, as well as the article by Kaitin, acknowledges a rather grim situation. Surely such clear evidence of functional distress must force us to seek contemporary business models/development paradigms to reverse the downward trajectory of an essential health-care industry.

CONFIDENTIALITY
The author declared no conflict of interest.

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Response to “A Perfect Storm for Innovation”

KI Kaitin

To the Editor: The global biopharmaceutical industry is at an inflection point. Increasing product-development timelines, high candidate attrition rates, and rapidly escalating development costs are, as depicted by Williams in his letter, one front in a perfect storm that is driving change in the research-based industry. As I have described previously, the other fronts are represented by expirations of patents for many high-revenue-generating products, growing regulatory demands, reimbursement pressures, declining shareholder values, and decline in public support. Given this dire situation for drug developers, it is reasonable for Williams to ask, “So why are we so hesitant to experiment with new development processes and business models?” My answer is, as the old expression goes, it takes a long time to turn the Queen Mary around.

The current drug development paradigm was established during a period of rapid growth for the pharmaceutical sector. Profits were high, debt was low, and enough cash was available to continually pour money into a drug development process that was inefficient and often wasteful. In the past, “taking more shots on goal,” i.e., pushing more compounds into clinical development to address productivity concerns, and throwing more money into late-stage candidates that were showing poor...
study results, were common industry practices. The result was that few companies designed or implemented rigorous mechanisms for determining which drug candidates were likely to succeed and should therefore be given more resources and moved through the clinical development pipeline, and which were destined to fail and should be terminated early. In today’s environment, however, these old approaches are no longer an option.

Change is coming to the pharmaceutical industry. But change will not come without a major overhaul of the structure of the sector. The key to success will be the ability of companies to manage the enormous risk of developing and marketing their products. Risk-sharing arrangements will become de rigueur. In the new model of biopharmaceutical innovation that I have proposed, all major stakeholders—large pharma, small/mid-tier pharma and biotech, academia, contract service providers, patient groups, and public–private partnerships—will play a crucial role in the development of new products. Only by leveraging the core strengths of each component will we see an improvement in the efficiency and productivity of biopharmaceutical innovation.

CONFLICT OF INTEREST
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