Speeding new medicines to patients

The author explains why 'speed' has become a watchword in the pharmaceutical industry

In 1989, *Fortune Magazine* published an article on the importance of speed in conducting a business[1]. The article made the case that in order to beat the competition, a business should simply become faster than its rivals. Technology, especially communications technology, is driving the opportunity to be faster in virtually every aspect of business, especially in product development, customer service, manufacturing and cycle times.

In the 1980s, R&D executives became very concerned about the high cost of drug discovery and development, but speeding up the process was not necessarily the main concern. That now has changed. The industry is re-examining its discovery and development goals, processes and budgets, in an attempt to speed the entire process of getting innovative drugs to patients.

Why has speed now become so important to the pharmaceutical industry? Studies from the Tufts University Center for Drug Development show that the time from first synthesis of a new drug to receipt of marketing approval has increased from about 8 years in the 1960s to more than 14 years in the 1990s[2]. In addition, drug development costs have spiralled from about US$54 million in 1976 (Ref. 3) to US$359 million in 1992 (Ref. 4). A careful analysis of the R&D productivity crisis by Dr Jurgen Drews, President of International R&D at Hoffman LaRoche, shows that the present rate of productivity of only 13 new compounds introduced to the market per year by the top 50 pharmaceutical companies must dramatically increase in order to sustain present levels of R&D spending[5].

The changing healthcare business environment is also having profound effects on the industry. Most notable is the change in customer from the physician and patient to the managed-care professional, who is demanding demonstrably improved patient and cost outcomes from new medicines. In this managed-care marketplace, it is no longer viable for a new medicine to demand a high price on the basis of a new or novel mechanism alone. Such pressures all occur in the face of numerous unmet medical needs and at a time of great discovery in molecular biology, combinatorial chemistry and genomics. The industry remains the dominant provider of life-saving and important new medicine – 95 of the top 100 selling medicines in the US were patented and developed by the private pharmaceutical industry. This industry truly has been the 'the goose that has laid the golden eggs' of new medicine.

All of these pressures point to one thing about the future for the industry – we cannot continue with the present cost structure and traditional processes and approaches to R&D. Today, every aspect of drug discovery, development and regulatory approval is under intense scrutiny in order to reduce the time and costs so that we don't kill the 'goose'.

The Prescription Drug User Fee Act gave the FDA the authority to charge user fees to hire additional staff for the review of NDAs in return for faster reviews and approvals. This has had a positive impact in reduced overall NDA review times, especially for NDAs for new chemical entities. FDA reform aimed at further speeding drug approvals and reducing unnecessary regulations and requirements is on the agenda in the US Congress, with new legislation likely in 1996. The industry is also undergoing reform. Nearly every major pharmaceutical company has re-engineered its drug development processes in order to reduce the time from IND to NDA as well as reducing costs.

In drug discovery, substantial improvements are needed. The work from Tufts University showed that the time from first synthesis of a new molecular entity to an IND has nearly doubled in the past 30 years, from an average of 3.2 years in the 1960s to 6.1 years in the 1990s. Drug discovery is still the only unregulated portion of the entire new drug development process. It begs the question as to why it is taking longer, especially given the technological advances and discoveries in biology and chemistry that should be shortening the process.

The time from target selection to selection of the lead must be reduced. Biotechnology and molecular biology were the driving forces behind new products and techniques for discovery of new products in the 1970s and 80s, and no doubt combinatorial chemistry and genetics will fulfil this role in the 1990s. The challenge for the drug discovery scientist is to translate these innovations rapidly into new drugs which can be taken from the laboratory to the patient faster than before.

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