

## Development of new technologies in oncology: do the advantages justify the cost?

A perspective from within the industry Pierre Dodion, Executive Director, Pfizer Inc., New York, USA  
 Pierre. F. Dodion@pfizer.com

Pharmaceutical companies, whether publicly traded or privately owned, have the objective, like in any business segment, to be profitable. But pharmaceutical companies fully measure the very particular nature of their business, i.e. the improvement of human health and the quality of patients quality of life which may of course translate in several aspects such as alleviating symptoms, prolonging life, curing or preventing a disease,... In reality the two objectives (profit and patients welfare) go intimately together. It is unlikely that a pharmaceutical company that would market medicines of limited interest for the patients would stay successful in the long run. Conversely and in particular in oncology, the most successful companies from the economical perspective are those that have been able to develop and commercialize true advances for the patients. Beyond these general considerations, we have then to decide what a significant interest or advance is and what will be the price the society is willing to pay to stimulate innovation and to allow the company to sustain financial stability. — There is no simple way to define what a significant advance in oncology is. A 25-30% relative improvement in survival or progression-free survival versus the standard of care is commonly accepted for regulatory approval (Johnson). However, while this may correspond to an improvement of survival by several months in the adjuvant setting, it may also represent, for refractory cancers, a minimal survival advantage of a few weeks with some toxicity — which may not constitute a big advance; however, the same survival advantage with limited or no toxicity may represent such a significant advance. Finally, for some patients, even a short survival advantage with toxicity may be important. In the US, for example, advocates have asked that patients with certain diseases could continue receiving drugs of unproven benefit (Okie). In reality, the various stakeholders — regulators, oncologists, patients, payers and others — have different views about what represents a significant advance. That decision is currently pretty much in the hands of regulators, clinical investigators and the pharmaceutical industry. The commonly accepted advance in survival or progression-free survival could require adjustments in a broader discussion involving all stakeholders on a more regular basis.

The other side of the equation is price. The price of new medications is often perceived as excessive. There are however certain economical facts that cannot be ignored (Scherer). The development cost of a new drug is currently around 1 Billion dollars and there is no indication that regulatory and clinical requirements will decrease in the future; on the contrary, many recommend additional studies in particular in the domain of safety (Psaty). Furthermore, a development program is by no means successful in all cases; the failure rate remains around 50% en at the stage of phase III clinical trials. Failure rates are of course much higher at earlier stages of development. Revenues from successful drugs have of course to be used to support these unsuccessful developments. The average net cost of a drug development (encompassing the successful and unsuccessful developments) is in fact much higher than 1 Billion dollars. How can one conclude on these considerations? It all comes down to the concept of value: considering its cost, does a given medication bring added value to the patient and to society (Cutler)? The value concept encompasses benefits, safety considerations, price and other considerations (including subjective ones). Customers are actually reasoning in terms of value in many acts of every day life; as an example, some customers prefer to buy a standard car, others prefer to buy a more luxury and costly car, because despite its higher price, it represents value for the buyer. In the domain of health care, the interaction is more complex than the standard one between a buyer and a seller. In particular, the patient does not choose to be sick; in addition, he is rarely aware of the true price of a medication; on the other side, payers and providers may not have a full understanding of the benefit of a medication, as they are not exposed themselves to the disease. In other words, no single partner is in a position to truly assess the value of a medication, It can be anticipated that the debate around cost of new medications will continue and may even increase in the future, especially at light of finite resources. Progress in this challenging domain could be achieved by bringing more often all stakeholders to the table of the discussion — not just the pharma industry and payers and by shifting the discussion from price to value.

*Reprinted with permission from the journal du Réseau du cancer de l'Université Libre de Bruxelles.*

**References**

1. Cutler OM, Roset AB, Van S. *The value of medical spending in the United States, 1960-2000.* *N Engl J Med* 2006; 355:920-927.
2. Johnson JR, Williams G, and Pazdur R. *Endpoints and United States Food and Drug Administration approval of oncology drugs.* *J Clin Oncol* 2003; 21:1404-11.
3. Olde S. *Access before approval-a right to take experimental drugs?* *N. Engl J Med* 2006; 355:437-40.
4. Psaty BM and Burke SR *Protecting the health of the Public - Institute of medicine recommendations on drug safety.* *N. Engl J Med* 2006; 355:1753-55.
5. Scherer FM. *The Pharmaceutical industry - prices and progress.* *N. Engl J Med* 2004; 351:927-32.

**Editor Disclaimer**

Health Economics and cost effectiveness studies have been incorporated in the treatment algorithm

decisions in the developed countries and in some developing countries where medical services were mainly supported by governmental bodies. Point of views from private and governmental institutions, patients, industries and third party payers are developed. We would like to share with our readers and different stakeholders of the medical community their opinions.

Perspectives from the regulatory bodies, patients, institutions and industry are welcomed and will be published in upcoming numbers of the PAJO. This article is a first comment that we republish today because it serves the discussion which is actually going on especially with the development of new expensive treatments. As usual the opinions expressed are solely those of the author.