

Title

Towards a sustainable system of drug development

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Abstract

Drug development has become the exclusive activity of large pharmaceutical companies. However, the output of new drugs has been decreasing dramatically for the last decade and the prices of new drugs have risen steadily, leading to access problems for many patients. By analyzing the history of drug development and the pharmaceutical industry, we will identify the main factors causing this system failure. Although many solutions have been suggested to fix the drug development system, we believe that a combination of reforms of the regulatory and patent systems is necessary to make drug development sustainable. These reforms must be combined with a larger, open-access role for public research institutes in the discovery, clinical evaluation, and safety evaluation of new drugs.

Keywords

Sustainable drug development, pharmaceutical innovation system.

Developing new medicines was traditionally a recession-proof activity, trusted to produce double-digit growth figures and continuing innovation that was marketable at high prices. This confidence has been thoroughly shaken during the past decade, as the number of new drugs introduced has reached an all-time low.¹ Even more worrying is the lack of added value over existing treatments for the great majority of these new medicines.² In addition, drug prices are rising at a rate that blocks access to essential drugs in the developing world, as well as in Europe and the United States.³ Increasing costs of development⁴, and medications going off-patent, are eroding the financial position of major companies and their capacity to develop new drugs.⁵ Some major and extensively publicized safety problems with new medicines have led to early market withdrawals of several drugs (i.e. the Baycol (2001) and Vioxx (2005) scandals). As a result, the reputation of the pharmaceutical industry and the public trust in the regulatory system has been seriously damaged.⁶

This previously unheard of accumulation of negative facts is considered by some industry-watchers to herald the demise of the current system of drug development. The question is whether solutions can be found within the existing pharmaceutical system to remedy this matter of great public concern, as the need for effective treatments has in no way diminished.

Accordingly, the research objective of this paper is to analyze the most important impeding factors that have led to this current system failure in drug development. We will analyze the impacts of the solutions offered to repair the pharmaceutical innovation system, and we suggest an alternative model for sustainable drug development that is capable of providing affordable, safe, effective, and innovative medicines, especially for unmet medical needs on a global scale.

In such a sustainable system, we expect that a structural reform would take place; the medical and scientific community in universities and other public research institutions would have a larger responsibility for the discovery, development, and evaluation of the efficacy and safety of new drugs. Scientific research should be funded by public money, and all results should be made publicly available. The biomedical world already has the resources to take on this responsibility, as shown in other areas of medical intervention. Actually, new innovative surgical procedures are developed and tested in patients after the trials have been approved by ethical committees, and their efficacy is published in the scientific literature. Professional bodies make the guidelines in which the best treatments are recommended, without patents being involved in novel surgical procedures. Why should the situation with new drugs be different? More than the pharmaceutical industry, which spends most of its resources developing “me too” drugs, the scientific community will concentrate exclusively on drugs with a potential added value. This reform would also bring medical problems central to the development process, a precondition for the development of affordable personalized medicine, which is the biggest promise of new scientific developments. The market exclusivity offered by patents and data exclusivity is claimed by the pharmaceutical industry to be necessary for companies to recoup their large investments in research and development. In a world without drug patents, the research and development would be performed by public funds and would be accessible to all parties, and these investments by industry would no longer be necessary.

In order to realize a transition to such a sustainable model of drug development, various activities in the current drug development system must be transformed. A sustainable drug innovation system requires novel forms of cooperation within and across the value chain, an open exchange of information, and innovation through various global knowledge networks without any patent restrictions. Drug development and pharmaceutical innovation should then be guided by expectations, research outcomes, and policy targets instead of commercial gains alone.

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