The patents-based pharmaceutical development process: rationale, problems, and potential reforms.

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The Patents-Based Pharmaceutical Development Process

Rationale, Problems, and Potential Reforms

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Abstract

The pharmaceutical industry is facing substantial criticism from many directions, including financial barriers to access to drugs in both developed and developing countries, high profits, spending on advertising and marketing, and other issues. Underlying these criticisms are fundamental questions about the value of the current patent-based drug development system. Six major problems with the patent system are (1) recovery of research costs by patent monopoly reduces access to drugs; (2) market demand rather than health needs determines research priorities; (3) resources between research and marketing are misallocated; (4) the

market for drugs has inherent market failures; (5) overall investment in drug research and development is too low, compared with profits; and (6) the existing system discriminates against US patients. Potential solutions fall into 3 categories: change in drug pricing through either price controls or tiered pricing; change in drug industry structure through a "buy-out" pricing system or with the public sector acting as exclusive research funder; and change in development incentives through a disease burden incentive system, orphan drug approaches, or requiring new drugs to demonstrate improvement over existing products prior to US Food and Drug Administration approval. We recommend 4 complementary reforms: (1) having no requirement to test new drug products against existing products prior to approval but requiring rigorous comparative postapproval testing; (2) international tiered pricing and systematic safeguards to prevent flow-back; (3) increased government-funded research and buy-out for select conditions; and (4) targeted experiments using other approaches for health conditions in which there has been little progress and innovation over the last few decades.

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