

INSIGHT

THE VALUE OF DRUG REPOSITIONING IN THE CURRENT PHARMACEUTICAL MARKET

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Drug repositioning is the process of developing new indications for existing drugs or biologics; it is also called repurposing, redirecting or reprofiling.¹⁻⁴ Increasing interest in drug repositioning has occurred due to sustained high failure rates and costs involved in attempts to bring new drugs to market.^{1,5,6} It has been estimated that it may cost more than USD 800 million to develop a new drug de novo and USD 1.2 billion to develop a new biologic.⁶⁻⁸ In addition, due to regulatory requirements regarding safety, efficacy and quality, with extensive requirements for testing in animal models and in multiple, phased, human clinical trials, the time required to develop a new drug de novo has been estimated to be 10 to 17 years.^{1,9,10} The percentage of de novo candidates reaching approved status once human testing begins may be as low as only 10%.⁵ De novo drug discovery and new, once highly touted drug discovery technologies (structure-based drug design, combinatorial chemistry, high-throughput screening) have failed to efficiently address many unmet medical needs and supply pharmaceutical company pipelines.^{1,6,8} R&D productivity is insufficient to meet the requirements of pharmaceutical companies, with the FDA approving 18 to 20 new drugs per year despite current pharmaceutical industry research outlays of USD 60 billion per year.^{6,11} In this era of increasing competition, decreasing profits, pharmaceutical company downsizing, and increasing patent expirations, the necessity of improving drug dis-

covery efforts efficiently has become of primary importance (Table I).^{6,8}

Drug repositioning has the potential to provide solutions that both patients and pharmaceutical companies require. Patients and physicians need new drugs or biologics that address unmet medical needs, or which provide better solutions to medical needs which are only partially addressed by existing agents. Repurposed drugs or biologics have the advantage of decreased development costs and decreased time to launch due to previously collected pharmacokinetic, toxicology and safety data. Expensive and time-consuming phase IV studies, examining the safety of existing products in the postmarketing environment, provide expansive data that characterize the safety profiles of existing agents, before their launch into repositioned indications. This pre-existing safety data provides a cogent argument that repurposing should be a primary strategy for both pharmaceutical companies and the FDA to reach the goal of more quickly and efficiently addressing medical needs that have continued to be unmet despite extensive de novo drug discovery efforts.^{1,3,4,6}

The value of drug repositioning to patients and physicians in addressing unmet medical needs may include the following (Tables II and III):

IMPROVED EFFICACY COMPARED WITH EXISTING DRUGS

Repositioned drugs may also address medical diseases or conditions for which there exists effective treatment, but for which

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SUMMARY

Drug repositioning is the process of developing new indications for existing drugs or biologics. Increasing interest in drug repositioning has occurred due to sustained high failure rates and costs involved in attempts to bring new drugs to market. It has been estimated that it may cost more than USD 800 million to develop a new drug de novo. In addition, due to regulatory requirements regarding safety, efficacy and quality, the time required to develop a new drug de novo has been estimated to be 10 to 17 years. De novo drug discovery has failed to efficiently supply pharmaceutical company pipelines. A rational approach to drug repositioning may include a cross-disciplinary focus on the elucidation of the mechanisms of disease, allowing matching of disease pathways with appropriately targeted therapeutic agents. Repurposed drugs or biologics have the advantage of decreased development costs and decreased time to launch due to previously collected pharmacokinetic, toxicology and safety data. For these reasons, repurposing should be a primary strategy in drug discovery for every broadly focused, research-based pharmaceutical company.

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