

For Drug Companies, Time is of the Essence



By Josh Bloom — July 15, 2016



Dr. Robert Popovian recently published an opinion piece on the Morning

Consult [website](#) ^[1] in which he discusses an issue that few of us realize: for drug companies, time is the enemy.

Time is a critical factor in every aspect of drug discovery and development. The clock never stops ticking, and every tick means that more money will be spent, and less recouped.

The most obvious time sink is the clinical trial process. This is especially true when phase II trials—where efficacy is determined—usually depend on a defined outcome as the end point. This is the gold standard of clinical pharmacology, but strictly adhering to this model also has its downside.

For example, a 2102 study estimated that the cholesterol-fighting statin drugs have had an "aggregate social value" of more than \$1.2 trillion since their inception in 1987. Yet, during the 25 years that it took for this to become evident, virtually all statins had lost patent protection and are now sold as the generic versions.

The clock ticks most loudly when it comes to patent protection. Patents for novel drugs provide 20 years of exclusivity for the company that made the discovery from the time at which the patent is filed. During this time, predevelopment and clinical evaluations are being made at a frenzied pace, yet even at full throttle, this process routinely takes 10-15 years. Every year in development means one less year of patent protection.

Time also hurts patients. As was the case with the statins, the new class of cancer drugs called tyrosine kinase inhibitors. Imatinib (Gleevec), was the first game changing drug in this class. It is now known that 95 percent of patients (1) with Chronic Myelogenous Leukemia (CML) will be alive in eight years. Prior to Gleevec, that number was 3-5 years. During the decade it took to establish these data, who knows how many patients could have benefitted from this knowledge.

Taking a broader look at the issue, Popovian says, "We all know that a small number of patients are under tremendous financial pressure like never before. However, we need to put the price tag of medicines within the larger context of long term savings as well as economic and social value."

You can read his essay in its entirety [here](#) [2].

COPYRIGHT © 1978-2016 BY THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

Source URL: <https://www.acsh.org/news/2016/07/15/for-drug-companies-time-is-of-the-essence>

Links

[1] <https://morningconsult.com/>

[2] <https://morningconsult.com/opinions/drug-development-time/>