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Editorial

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A Primer on Potential Economic Causes for the Current Failure of the Development of Disease-Modifying Treatments for NDDs

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Neurodegenerative diseases (NDDs) occur when nerve cells in the brain or peripheral nervous system lose function over time and ultimately die. The risk of being affected by a neurodegenerative disease increases drastically with age. With increasing life expectancy, neurodegenerative diseases have become an increasingly present part of today's society. The absence of a cure for NDD implies a high burden to the individual patient but also a tremendous cost to society. While the development of disease-modifying treatments for NDDs may present intrinsic hurdles, existing economic research provides arguments why other explanations for the absence of causal therapies may play a role. Notably, economic science can shed light on the incentives for investing in the development of causal treatments.

Incentives for research and development (R and D) follow a simple mechanism. Every R and D investment influences the return if R and D is successful, an innovation occurs and a drug can be sold. A rational, forward-looking investor will invest in R and D if and only if the expected returns surpass investment cost.

We subsequently present three factors that influence expected returns and therefore directly affect the incentive to invest in R and D.

Innovation inhibiting effect of an already existing drug portfolio

Pharmaceutical companies typically produce a portfolio of drugs. The company's expected returns will therefore consist of the payoff stream generated by the entire portfolio. It may be possible that these payoff-streams are not independent of each other. This is in particular the case, if the drugs are substitutes, i.e., the same disease can be treated (albeit possibly in different phases of the disease). This suggests that a company will evaluate the payoff stream of a new drug by also taking into account the effect of the new drug on its existing payoff streams.

If a new drug renders an old one obsolete, for instance because of its superiority in terms of efficacy, tolerability or due to an easier route of administration, the new drug will "cannibalise" the profits that a company made with the old drug prior to the invention of the new one. This likely affects incentives to innovate: A company's incentive to invest in R and D decreases the higher profits from existing drugs are that might become obsolete if a new drug is successfully developed. This effect may, for instance, be present in the market for Parkinson's Disease (PD) medication. One of the main drugs used to cure symptoms of PD is Levodopa. Levodopa has first shown to cure symptoms of PD in the early nineteen sixties and still accounts for a total revenue of several billion US$ today. Moreover, firms' incentives to innovate towards a causal treatment for PD may further be hampered by the high profits that firms accrue with direct medial costs for PD as well as follow up costs for other medication and health care interventions, that are estimated to be around US$ 25 billion.

Regulatory mechanisms, such as price control and health insurance distort companies' incentive to innovate

Price controls likely affect a company's expected returns if the regulation forces the company to set a price that is different from the price the company would set in the absence of the regulation. To determine the effect of price controls on the incentive to invest in R and D, it is necessary to consider the profit loss for the innovating company given a specific price regulation scheme. This is illustrated by the following example: A company has the choice to invest either in the development of a first causal treatment for a specific NDD that is considered to be a large innovation or into a small innovation such as a further symptomatic treatment. It is assumed that the large innovation can potentially be marketed at a high price compared to the small innovation. If the price regulation consist of disproportional price reductions, the large innovation will face more stringent price regulation than the small innovation. As expected revenue will decrease more strongly for the large innovation. This can lead to a shift of R and D investments towards the small innovation.

Another regulation that could influence incentives of investing into R and D are health insurance schemes. These schemes often ensure that patients do not need to pay the full price for a specific drug, but rather pay a fixed or proportional co-payment. Consequently, health insurance increases a patient's demand for a given drug because they do need to pay less than without the insurance. In this simple case, insurance causes an increase of companies' incentive to innovate. All in all, regulation schemes seem to have diverse effects on incentives to innovate, indicating that whether a company focuses on small or large innovations depends on the exact price regulation mechanism.

The effect of patent protection on innovation incentives

Another factor that shapes a company's future returns on investments are patents. The fundamental idea of the patent system is to increase incentives for new innovations by awarding the successful inventor with a period of exclusivity. This market exclusivity typically implies reduced competition and hence higher returns. All else equal, the longer the period of market exclusivity, the higher the incentives for innovation. The effective patent period is determined by the moment a patent is filed. Patents for new drugs are often filed while still in the development phase. Companies thus forgo a

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longer period of the effective patent period to reduce the risk of losing out on a patent because a competitor might also develop a similar drug.

The patent system in the US provides a baseline period of patent protection of 20 years. It, however, grants innovators an extension of half of the time spent in clinical trials plus the full time spent in the review period. This extension can be up to 5 years but total market exclusivity from the point of marketing approval cannot be longer than 14 years. Time spent in pre-clinical trials cannot be recovered. Because the development of drugs intended for long-term use, such as treatments for NDDs, usually require longer clinical programs, this decreases the effective patent periods if such drugs are successfully developed. For this reason it might be that companies' incentives to invest in R and D are tilted towards smaller innovations.

Discussion

We provided a short insight into some possible economic explanations for the absence of disease-modifying treatments for NDDs. We discussed the innovation inhibiting effect of an already existing drug portfolio. Moreover, we demonstrated that different regulatory mechanisms in essence price controls and health insurance, as well as patent protection, directly influences companies' incentives to innovate. A potential avenue for further research is to test above hypotheses empirically.

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Conflict of Interest

The author declares that there is no conflict of interest.

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