

Competition and Attrition in Drug Development

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With less than 10% of new drugs reaching the market, the drug development process is notorious for having a high attrition rate. While scientific considerations about safety and efficacy explain much of this attrition, pharmaceutical firms also withdraw drugs for strategic reasons. Disentangling these two sources of attrition is necessary to predict how government policies will impact the number of drugs that reach consumers. There are three main contributions of this research. First, for each disease, I estimate the proportion of drug withdrawals that are strategic rather than scientific. Second, I analyze how these two sources of attrition interact to determine the number of medicines that reach the market. Third, I quantify how policies in drug development affect the rate of innovation.

To this end, I develop a dynamic model of pharmaceutical R&D in the U.S. The model features four stages: early trials, late trials, regulatory review, and commercialization. After the first stage a drug can be deemed unsafe, and after the second stage it can be deemed ineffective. These clinical failures happen with disease-specific probabilities that I estimate. Upon such failure, the firm must discontinue the drug. Otherwise, the firm can promote the drug to the next stage, but may still choose not to after weighing the development costs against the expected profit given current and potential future competition.

To estimate the model, I use data on R&D pipelines of pharmaceutical firms, which provides the timing of all the development milestones for every investigational drug in the last 20 years. I supplement this dataset with epidemiological data (to parameterize disease-specific market sizes) and clinical trials data (to parameterize the probabilities of scientific terminations). Intuitively, higher expected profitability means that withdrawals are more likely from science than strategy, so focusing on diseases with large markets helps identify scientific attrition. Variation in competition over time within markets helps identify strategic attrition parameters.

My estimates suggest that while strategic terminations account for 8.4% of attrition, there are sizeable differences across diseases: from 5.5% for pulmonary disease to 34.8% for myelodysplastic syndrome. Strategic considerations are more prevalent following early trials, on average accounting for 9.3% of discontinuations versus 1.2% after late trials. A regulatory change that decreases the probability of clinical failure in early trials by 10 percentage points is predicted to increase the rate of new drug launches by 20%, while the same change instead applied to late trials would result in a 30% increase. The discrepancy is partially explained by differences in how strategic withdrawals across the two stages change in response to fewer competitors being disqualified. Finally, I show that even large subsidies for clinical trials only minimally affect the rate at which new drugs reach the market.

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