Incentives for Long-Shot Pharmaceutical Innovation

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Pharmaceutical companies respond to regulatory and other incentives, such as market exclusivity for orphan drugs, by adapting their product pipelines, research and development (R&D) activities, and go-to-market strategies. Such portfolio adaptations are driven by short-term interests. This paper addresses the challenge of designing incentive-compatible incentives to promote R&D for precision and personalized medicine. When setting a minimum preclinical quality (or effectiveness) threshold, the social planner shapes the firm's incentives to invest in enhancing the translational value of preclinical studies, effectively solving a moral-hazard problem. We characterize the socially optimal and incentive-compatible outcomes, and incorporate the recent issues of biomarker-based drug discovery and development (DDD), pipeline-quality effects and value-based pricing into a unified framework. Finally, the model is extended to allow for multiple drugs where R&D spillovers form an integral part of the social planner's incentive-design problem.

The advent of health-related `-omics' technologies is transforming the (bio-) pharmaceutical drug discovery and development process, as well as firms' go-to-market strategies. A pharmaceutical firm can, for example with the aid of biomarkers, target specific patient subgroups and leverage those to demonstrate improved drug effectiveness relative to current standards of care. Using targeted techniques, the firm may better navigate the nexus of stakeholders: patients, providers, payers, regulator, and health-technology assessment (HTA) bodies. Focusing on the strategic interaction between firm and regulator, this paper provides the hitherto missing micro-foundations for the active use of regulation to improve R&D productivity in the pharmaceutical industry. Using a game-theoretic framework, we analyze the impact of regulatory approval thresholds (for the provision of market and/or data exclusivity) on the firm's incentives for inventive activity, taking into account the possible presence of biomarkers (with different incidence and accuracy), the degree of differentiation to extant drugs, and the consumer sentiment (beliefs) about the corresponding treatment success rate.

A number of influence parameters capture some of the trending patterns in the (bio-) pharmaceutical industry, such as patient stratification, biomarker-based drug discovery and development, and value-based pricing, which have thus far only been described via largely hypothetical scenario analyses. Because the underlying framework is fairly general, it can be easily adapted to specific markets and contexts. In the extension to a multidrug setting we allow for R&D spillovers, depending on how focused (or not) the firm's research efforts are (captured by the R&D precision). Based on the proposed model, we find that increased personalization can create more value to society in the presence of R&D spillovers. In addition, we show that the difference between the observed incentive-compatible outcome and the idealized socially optimal outcome critically depends on the difference between the private benefit and society's benefit. In our model, the private-social value balance is governed by the macroeconomic multiplier, the healthcare reimbursement rate, and the biomarker accuracy. Value-based pricing (or outcome-based pricing), which amounts to increasing the appropriable fraction of patient benefits, is a step towards reducing the spread between societal and private returns.

Finally, our model highlights the difficulty of achieving a first-best outcome with a single regulatory incentive—in particular the approval threshold—leading to a discussion of the additional influence parameters which correspond to additional interventions that may be put in place to ensure that the right drug is brought to the right patient at the right time. In this context, we derive some managerial insights with respect to regulatory and commercialization-related risk-management strategies.

Key Words

Incentive Contracting, Innovation in Healthcare, Long-Shot Investments, Moral Hazard, Orphan Drugs, R&D Incentives, Stratified Medicine