What Determines the Duration of BLA Approvals

Yupeng Li, PhD
Rowan University

Abstract

The Biologics License Application (BLA) approvals differ significantly from NDA by nature, and progressed in a surprising speed. To better understand this quickly emerging field of compounds, the effect of firm size and lobbying behaviors on the approval speed merits investigation. Overall, I investigate the role that different factors play in affecting the approval speed for BLAs, and find that (1) priority review status help reduce the waiting period; (2) firm size does not reveal statistically significant effects in the approval process; (3) lobbying strategies do not have significant effects; (4) past experience with does help reducing the approval duration when firms apply for BLA approvals.

Introduction

To legally market a new drug in the United States, the applicant will need to receive approval from FDA under either the New Drug Application (NDA) or Biological License Application (BLA). Even though NDA approval have long been regarded as the major indicator of success among pharmaceutical companies, the fast-growing market of biological products also draws attention from both the drug developers and the regulators.

It is FDA’s goal to improve communication between applicants and FDA review teams, to improve transparency of reviews, and improve efficiency and effectiveness of reviews. Thus, the duration of review cycles become a very important metric to assess the overall smoothness among NDA and BLA applications. Both FDA and the Government Accountability Office [1] have provided PDUFA performance reports as program assessment, among which they find some important metric to assess the overall smoothness among NDA and BLA applications.

Methods and Materials

This paper focuses on the BLA approvals ranging from year 2013 to 2020. The BLA duration data is obtained from CDER NME drug and original BLA calendar year approval reports by FDA, cross validated from Purple Book [3], and compilation dataset [4] of NME and BLA approvals. The firm level information is obtained from COMPUSTAT database. The annual lobbying information on the firm level is familiar to observe shorter duration. There is no evidence on the impact of firm’s size advantage in rent-seeking; also, potentially easier enrollment of priority designations are not significantly different by firm size. In addition, Figure 4 shows that the proportion of special designations are not significantly different by firm size. In addition, Figure 4 demonstrates that, although larger firms spend greater amount in lobbying compared to smaller competitors, the relative ratios of lobbying over scale (lobbying intensity) tend to share similar fashion across all sizes. Further, despite that larger firms have wider coverage of various therapeutic classes, no evidence suggest a significant approval speed benefit from a specific therapeutic class.

Discussion

Firm size may have a confounding effect on other factors, for instance, the deep-pocket advantage in rent-seeking; also, potentially easier enrollment of priority programs due to agency familiarity. Figure 3 shows that the proportion of special designations are not significantly different by firm size. In addition, Figure 4 demonstrates that, although larger firms spend greater amount in lobbying compared to smaller competitors, the relative ratios of lobbying over scale (lobbying intensity) tend to share similar fashion across all sizes. Further, despite that larger firms have wider coverage of various therapeutic classes, no evidence suggest a significant approval speed benefit from a specific therapeutic class.

Conclusions

Regression results show that priority review status always plays a significant and positive effect in accelerating the speed of approval. Firms with better regulatory familiarity observe shorter duration. There is no evidence on the impact of firm’s lobbying behavior, nor is there evidence of scale advantage from the regression results. The results are quite consistent with the literature. The findings suggest that FDA decision-makings may not be influenced by firm lobbying or size, but that past approval experience works better in securing a faster review process for the new BLA applications.

References

2. FDA. Prescription drug user fee amendments, 2021.
4. FDA. Compilation of CDER new molecular entity (NME) drug and new biologic approvals, 2021.