

## RESEARCH SUMMARY

# Pharmaceutical Development and the Approval Process: How FDA Review Times Affect Drug Company Decision-Making

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When making investment decisions, drug manufacturers must take into account a multitude of factors, including the expected length of time the FDA will take to approve their products. Anna Chorniy, James Bailey, Abdulkadir Civan, and Michael Maloney examine the significance of this factor in “[Regulatory Review Time and Pharmaceutical R&D](#).”

In the United States, all newly developed drugs undergo a lengthy FDA review process. These regulatory delays are costly for both patients and drug manufacturers. Analysis of the review times of drugs approved between 1999 and 2005 shows that manufacturers are less likely to develop drugs in disease categories where the FDA, on average, takes longer to review their applications, thus reducing expected profits.

### FDA BALANCING ACT: SPEED VERSUS SAFETY

The FDA faces a tradeoff between preventing the entry of unsafe drugs to the market and facilitating the entry of safe and effective drugs. If the agency applies stringent rules on safety and efficacy, many patients will be unnecessarily deprived of potentially successful treatment. On the other hand, if the rules are loose, unsafe and ineffective drugs are likely to enter the market and cause potentially fatal damage. The FDA must find a balance between the two.

### HOW SENSITIVE ARE FIRMS TO REGULATORY DELAY?

- The average review time for drugs approved after 1999 is 466 days, or about 1.3 years.
- There is wide variation in how quickly drugs are approved. It can take anywhere from 46 days to 1,827 days for a drug to complete the review process.
- A doubling of the review length is associated with approximately six fewer drugs in the development pipeline in that disease category.
- Approximately two and a half additional months of the review process result in one fewer drug in development.

### THE BENEFITS OF REDUCED REVIEW TIME FOR FIRMS AND PATIENTS

- Beneficial drugs enter the market sooner.
- Patients have access to those beneficial drugs earlier.

- Pharmaceutical companies can start marketing earlier and thereby improve cash flow.
- Gaining earlier market access can affect manufacturer profit substantially.
- New R&D and additional novel drug introductions may result.