

The Announcement Effects of New Drug Approval on Pharmaceutical Stock Returns

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Abstract

New drug development in discovering new molecular entities (NMEs) is unquestionably a very costly investment for pharmaceutical companies with no guarantee of clinical testing and commercial success. Since technical risk and market risk in new drug development are nontrivial, the NME approval for marketing introduction must be breaking favorable news for a pharmaceutical company, thus leading to a great increase in its stock prices and returns after the approval date is announced by the FDA. For example, since the announcement of drug approval of Viagra, the first oral pill to treat male's impotence and manufactured by Pfizer Pharmaceuticals, Pfizer's stock price increased by 32.06% in a year, while the S&P 500 index only grew by 12.26% at the same time period.

The main purpose of the study is to investigate the announcement effects of drug approval on biochemical or pharmaceutical stock returns. Since empirical evidence suggested that stock markets appear to indicate weak-form efficient, this means that the drug approval announcements may result in abnormal returns on pharmaceutical stocks. For this research purpose, an event study based on an extensive sample of U. S. pharmaceutical data is conducted to explore the announcement effects on stock returns. We define the announcement dates of new drug approval as the events of concern. For the study, nearly 200 U.S. FDA approval data sets for the period of 1998-2004 are collected.

This research is the first study in the world to explore the effects of new drug announcements on abnormal returns on the biotech/pharmaceutical stocks. Preliminary study on abnormal returns has been conducted in progress and the announcement effects on pharmaceutical stock returns seem to exist. The expected contributions, after the completion of the study, are two-fold. First, we shall find how new drug approvals impact on the pharmaceutical industry. Since the announcement effects are considered to be market anomalies even in an efficient stock market, we can verify the extent of market efficiency in the U. S. Second, the findings may have important economic content in pharmaceutical investments. If the announcement effects on stock returns exist, investors can buy pharmaceutical stocks after the companies submit the drug review applications with reasonable review time considered, and then make a profit. Should the announcements not exist, investors need not waste time to "guess" when the drug approval announces, but focuses on normal profits from cash flows analysis of drug commercialization.

Keywords: New Drug Approval, Announcement Effect, Abnormal Returns, Event Studies, Efficient Market Hypothesis

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I. Introduction

New drug development in discovering new molecular entities (NMEs) is unquestionably a very costly investment for pharmaceutical companies with no guarantee of clinical and commercial success. According to a survey study conducted by Parexel's International Corporation, the overall research and development investment costs by research-based pharmaceutical in the U. S. have soared about 21 times from \$1.5 billion in 1980 to \$31.4 billion in 2005. With such considerable investments, the technical risks in new drug development are also incredibly substantial. In general, pharmaceutical investments in new drug development can be divided into three different stages, which are the stage of substance discovery research, that of clinical testing, and that of market introduction. The complete R&D process for developing new drug is exhibited in Figure 1.² If new drug development should fail in any R&D stage, pharmaceutical investments would become sunk costs immediately. DiMasi et al. (1991) reported that only 20-25% of NMEs tested in the clinic under the U. S. investigational new drug application (IND) obtain the marketing approval of the U. S. Food and Drug Administration (FDA). The approval rate became more favorable as the NME got closer to the final stage in the R&D process.

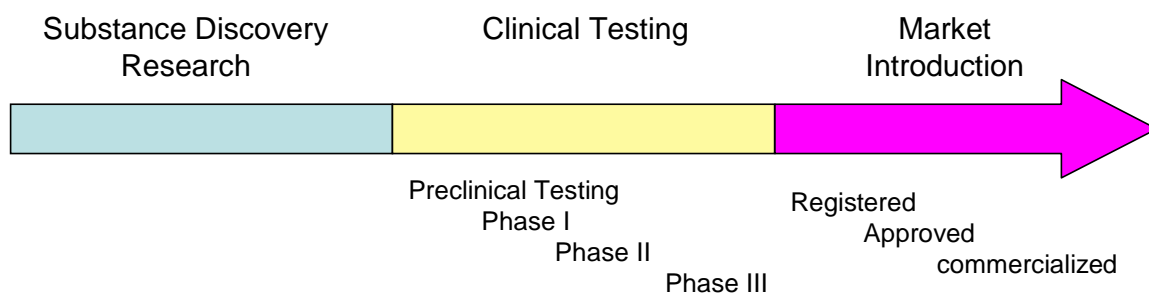


Figure 1. Typical R&D Process for New Drug Development

Although technical risk in developing NMEs is substantial, market risk of the R&D process is also significant in terms of pharmaceutical sales growth. Figure 2 demonstrates

² Refer to Perlitz et al. (1999) for discussions on pharmaceutical R&D process.

that global sales growth of the U. S. research-based companies are extremely fluctuating in the period from 1980 to 2005. In addition, drug sales growth is also indicated a quite diversified result for top 10 global pharmaceutical companies in 2005, as exhibited in Figure 3.³ For example, Roche Co. reached an unprecedented historical sales growth of 25.70%, while the U. S. giant, Merck, had a decline of -4%.

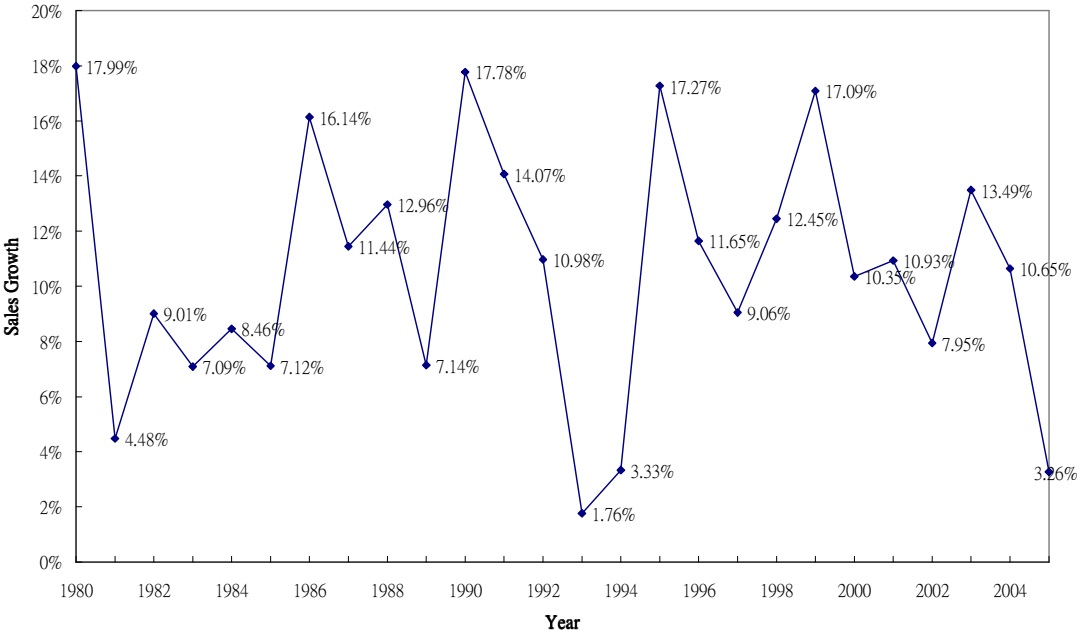


Figure 2. Global Sales Growth of U. S. Research-Based Companies

³ Data source: *Paraxel's Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007* (2006), Paraxel International Corporation.

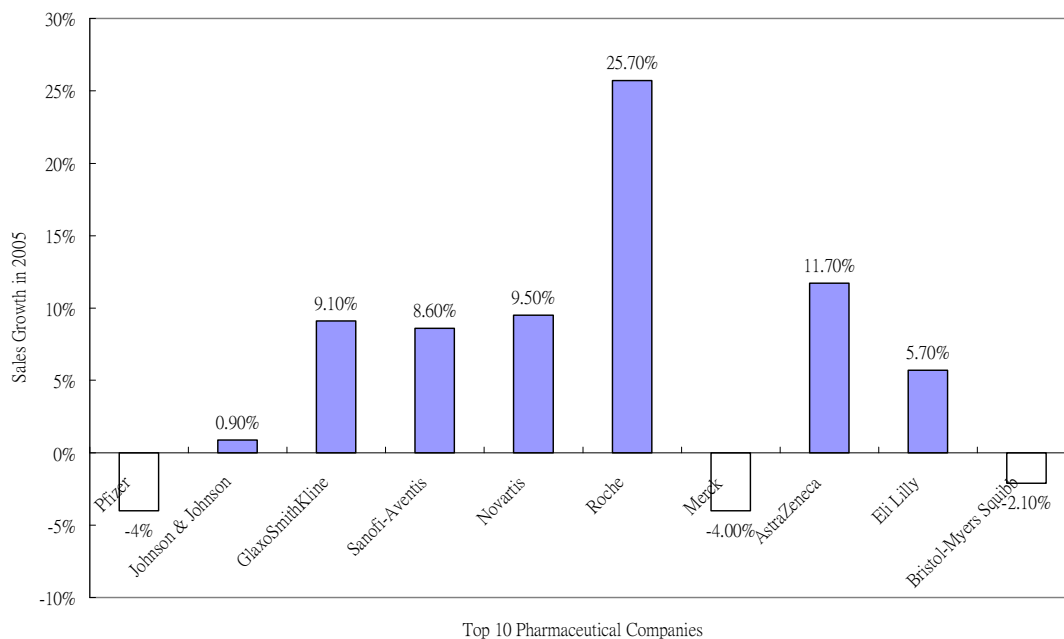


Figure 3. Drug Sales Growth of Top 10 Global Pharmaceutical Companies in the Year of 2005

If technical risk and market risk in new drug development are nontrivial, then the NME approval for marketing introduction must be breaking news for a pharmaceutical company, thus leading to a great increase in its stock prices and returns after the approval date is announced. For example, Viagra, the first oral pill to treat male’s impotence and manufactured by Pfizer Pharmaceuticals, was approved to commercialize into the market by the FDA in March 1998. Since the announcement of drug approval, Pfizer’s stock price increased by 32.06% in a year, while the S&P 500 index only grew by 12.26% at the same time.

The main purpose of the study is to investigate the announcement effects of drug approval on biochemical or pharmaceutical stock returns. Based on the efficient market hypothesis, we consider the announcements of drug approval as market anomalies. If stock markets should be semi-strong form efficient or above, the drug approval announcements would cause no abnormal returns on pharmaceutical stocks. Since empirical evidence suggested that stock markets appear to indicate weak-form efficient, this means that the drug approval announcements may result in abnormal returns on pharmaceutical stocks. For this research purpose, we intend to conduct an event study based on an extensive sample of U. S. pharmaceutical data to the announcement effects on stock returns.

II. Literature Review

Event studies have long been considered to be the major popular research paradigm for testing semi-strong form market efficiency and information contents. The early applications of event studies were proposed by Ball and Brown (1968) and Fama et al. (1969), both of which investigated how the arrival of new accounting information resulted in abnormal returns. Ball and Brown considered the influence of company's earning announcements on stock returns while Fama et al. examined how quickly and correctly the market reacts to the announcement of stock splits. There are more studies⁴ assessing the impact of accounting disclosures on shareholders' returns in a number of industries.

More complete surveys on event studies were discussed by Bowman (1983) and Henderson (1990). Bowman's study focused on understanding the research procedure of conducting event studies. Henderson, on the other hand, explored how an effective event study can be conducted in a systematic manner to identify the announcement impact on stock returns.

In addition, there are a number of studies examining the announcement effect of company merger on stock performance. For example, Travlos (1987) and Brown and Ryngaert (1991) found that the payment method in a merger is a nontrivial issue on the stock performance of bidding firms. If the acquiring firm adopts stock swaps in a merger, the target company may have statistically significant in negative abnormal returns. By contrast, the cash-payment effects on positive abnormal returns are statistically insignificant. Although there are sufficient researches using event studies on the announcement effects, this study is the first one to investigate the drug approval announcement effects on stock returns.

III. Research Methodology

To investigate the announcement effects of NCE's approval in the pharmaceutical industry, we apply traditional methodology of event studies. Event study has long been considered to be the major research method for testing semi-strong efficient market hypothesis. As the first step to conduct event studies, we collect the announcement dates of all the "events", which are defined as the approval dates of new drugs approved by U. S. Food and Drug and Administration (FDA). The second step of event studies is to determine the estimation period, in which we build up an expectation model to estimate normal stock returns unaffected by the announcement event, and the event period (or event window), in which we compute abnormal returns by differencing realized returns from normal returns.

⁴ These studies are Sprecher and Pertl (1983), Davidson, Chandy, and Cross (1987), and Lacey (1988).

The timeline of event studies is shown in Figure 2.

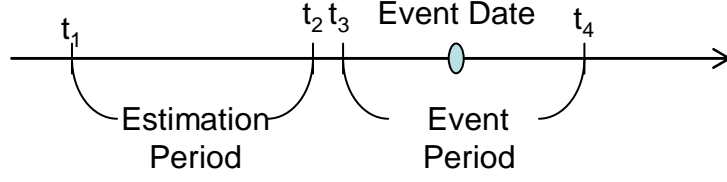


Figure 2. Timeline of Event Studies

According to literature, there are three different ways to calculate normal returns, mean-adjusted return model, market-adjusted return model, and risk-adjusted return model (also known as capital asset pricing model, CAPM). In this study, we adopt the commonly applied CAPM to estimate normal returns as follows:

$$E(\hat{R}_{it}) = \hat{\alpha} + \hat{\beta}R_{imt}, \quad (1)$$

where $E(\hat{R}_{it})$ is company i 's expected normal return at time t ,

$\hat{\alpha}$ and $\hat{\beta}$ are the ordinary least square (OLS) parameters,

R_{imt} is company i 's market return at time t , and

t stands for the estimation period and $t \in [t_1, t_2]$.

Thus, company i 's abnormal returns at time τ , expressed by $AR_{i\tau}$, can be computed by subtracting normal returns from realized returns as shown in Equation (2):

$$AR_{i\tau} = R_{i\tau} - E(R_{i\tau}) \quad (2)$$

where $R_{i\tau}$ is company i 's realized return at time τ , and

τ stands for the event period and $\tau \in [t_3, t_4]$.

Before we can conduct a statistical test of significance, we compare average abnormal returns,

\overline{AR} , in the estimation period and that in the event period. For a sample of n companies, average abnormal return is calculated as follows:

$$\overline{AR}_\tau = \frac{1}{n} \sum_{i=1}^n AR_{i\tau}, \quad \tau \in [t_3, t_4] \quad (3)$$

By definition, average abnormal return in the estimation period is expected to be zero and that in the event period is expected to be non-zero, conditional on the positive or negative influence on stock returns. Average abnormal return in the estimation period and that in the event period are shown in Equations (4) and (5), respectively:

$$E(\overline{AR}_t) = 0, \quad t \in [t_1, t_2] \quad (4)$$

$$E(\overline{AR}_\tau) \neq 0, \quad \tau \in [t_3, t_4] \quad (5)$$

In addition, we are also interested in cumulative abnormal return, CAR , due to the event:

$$CAR_{i\tau} = \sum_{\tau=t_3}^{t_4} AR_{i\tau}, \quad \tau \in [t_3, t_4] \quad (6)$$

For a sample of n companies, cumulative average abnormal return is calculated as follows:

$$\overline{CAR}_\tau = \frac{1}{n} \sum_{i=1}^n CAR_{i\tau} \quad (7)$$

For the reasons of statistical convenience and testing error reduction, Patell (1976) suggested to standardize AR and CAR into SAR and $SCAR$, both of which thus follow a unit normal distribution. SAR and $SCAR$ can be expressed by Equations (8) and (9), respectively:

$$SAR_{i\tau} = \frac{AR_{i\tau}}{\hat{S}_{it} \sqrt{1 + \frac{1}{t_2 - t_1 + 1} + \frac{(R_{im\tau} - \overline{R}_{imt})^2}{\sum_{j=t_1}^{t_2} (R_{imj} - \overline{R}_{imt})}}}, \quad t \in [t_1, t_2], \quad \tau \in [t_3, t_4] \quad (8)$$

$$SCAR_{i\tau} = \sum_{\tau=t_3}^{t_4} SAR_{i\tau} \quad (9)$$

where \hat{S}_{it} is standard deviation of AR in the estimation period,

$$\hat{S}_{it} = \sqrt{\frac{\sum_{t=t_1}^{t_2} (AR_{it} - \overline{AR}_i)^2}{t_2 - t_1 - 1}}, \quad (10)$$

\overline{R}_{imt} is average market return for company i at time t ,

$$\overline{R}_{imt} = \frac{1}{t_2 - t_1 + 1} \sum_{j=t_1}^{t_2} R_{imj}. \quad (11)$$

Thus, standardized AR and CAR for a given sample size in the event period, denoted by \overline{SAR} and \overline{SCAR} , respectively, can be re-expressed as follows:

$$\overline{SAR}_{\tau} = \frac{1}{n} \sum_{i=1}^n SAR_{i\tau}, \quad \tau \in [t_3, t_4] \quad (12)$$

$$\overline{SCAR}_{\tau} = \frac{1}{n} \sum_{i=1}^n SCAR_{i\tau}, \quad \tau \in [t_3, t_4] \quad (13)$$

After the standardized procedure, the testing statistic of significance, denoted by t_{SAR} , can be expressed as follows:

$$t_{SAR} = \frac{\overline{SAR}}{\sqrt{\sigma_{SAR}^2}} \quad (14)$$

It is important to note that traditional market model in Equation (1) is based on the homoskedasticity assumption. Since evidence has indicated that most stock return may have the property of heteroskedasticity, Bollerslev (1986) assumed the variance of the OLS residual term in Equation (1) to be an autoregressive moving average model, named a generalized autoregressive conditional heteroskedasticity (GARCH) model. In a GARCH(1,1) model,

the residual term at time t , ε_t , given the information set at time $t-1$, Ψ_{t-1} , is assumed to be a normal distribution with a conditional variance, h_t , that is:

$$\varepsilon_t | \Psi_{t-1} \sim N(0, h_t) \quad (15)$$

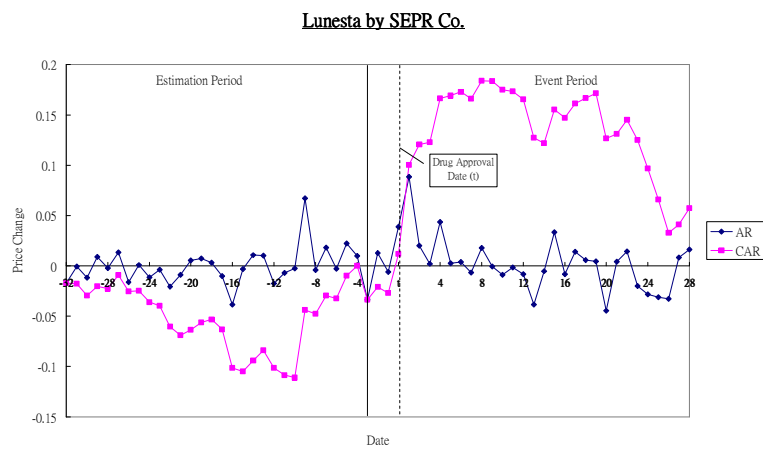
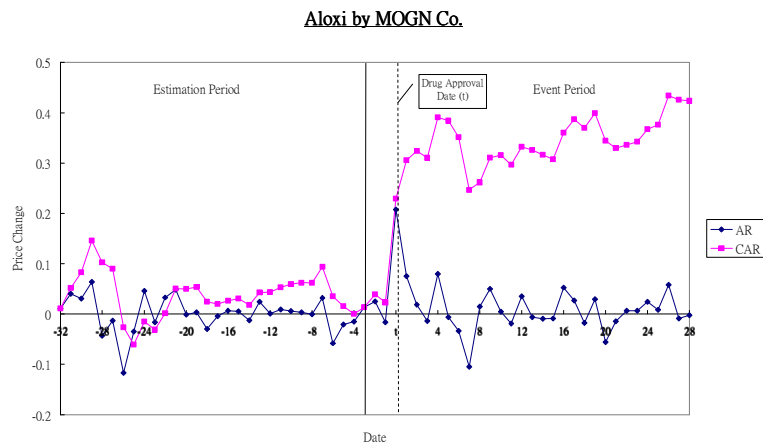
The process of residual's conditional variance is as follows:

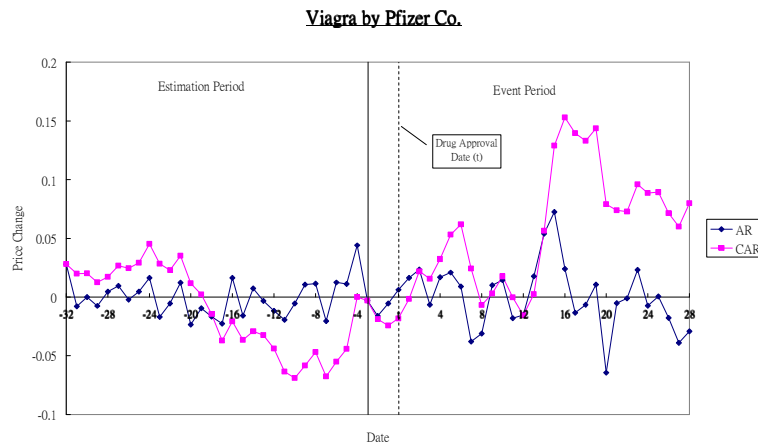
$$h_t = \gamma_0 + \gamma_1 h_{t-1} + \gamma_2 \varepsilon_{t-1}^2 \quad (16)$$

where γ_0 , γ_1 , and γ_2 stand for the coefficients in the GARCH(1,1) model.

IV. Data and Some Results

For this study, we will collect the





V. Expected Conclusion

The expected contributions, after the completion of the study, are two-fold. First, we shall find how new drug approvals impact on the pharmaceutical industry. Since the announcement effects are considered to be market anomalies even in an efficient stock market, we can verify the extent of market efficiency in the U. S. Second, the findings may have important economic content in pharmaceutical investments. If the announcement effects on stock returns exist, investors can buy pharmaceutical stocks after the companies submit the drug review applications with reasonable review time considered, and then make a profit. Should the announcements not exist, investors need not waste time to “guess” when the drug approval announces, but focuses on normal profits from cash flows analysis of drug commercialization.

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