

ESSAYS ON THE PHARMACEUTICAL INDUSTRY

by

Xiaobo Chen

A dissertation submitted to the Faculty of the University of Delaware in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Economics

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ABSTRACT

Essay 1: Strategic buying to keep competition in the market

I introduce a two-period dynamic model where a retailer transacts with two firms which produce a homogeneous product with different marginal costs. In this model, the firm with higher marginal cost would exit the market if price is below marginal cost. If the weak firm exits, the buyer faces a monopolist in the second period. To prevent this outcome, the buyer may intentionally purchase from the weak firm to keep it in the market. This behavior is called strategic buying. I analyze the conditions under which strategic buying will occur and responses of each firm to this strategic buying.

Essay 2: Empirical study: the effects of announcements during the drug approval process on the stock valuation of the corresponding pharmaceutical firms.

The purpose of this essay is to investigate which announcements during the new drug approval process impact the valuation of the related pharmaceutical company's stock using an event-study method over the period from 2004 to 2011. The results reveal extension of FDA review deadline, issuance of a complete response letter from the FDA, and approval of the first-time generics have negative influence on the stock price; public disclosure of advisory committee recommendation and approval of a new drug have significant positive impact on the related firm's stock returns; submission of a new drug application (NDA), acceptance of a NDA by FDA, resubmission of a NDA

and approval of new indication have no significant impact on the stock returns. Firm's leverage and profitability mitigate the influence of a single event, regardless of whether it is good or bad, on the stock returns; institutional ownership percentage decreases the impact of a good event on the stock value but has no significant relation to the impact of a bad event; firm size, diversification, R&D intensity and growth opportunity have no significant influence on abnormal returns associated with the FDA approval process.

ESSAY 1

STRATEGIC BUYING TO KEEP COMPETITION IN THE MARKET

Chapter 1

INTRODUCTION

This chapter introduces the first essay of this dissertation. The first essay investigates the practice of strategic buying in the pharmaceutical industry in order to maintain competition.

In recent years, retail markets have become increasingly concentrated. The formation of ever-larger multinational retailers, such as Wal-Mart and the quick spread of ever-larger store or outlet formats have shifted bargaining power from manufactures to retailers and boosted interest in countervailing-power. According to Galbraith (1952), sizable and powerful retailers are able to obtain more favorable trade terms from their suppliers. The growing dominance of big-box retailers has weakened many small or medium-size retailers and attracted the attention of antitrust policy makers.

On the other hand, there is some evidence that instead of eliminating competition in the market, powerful retailers or consumers sometimes purchase from less preferable sellers (in price or in quality) or intentionally purchase excessively to maintain competition in the wholesale market. This behavior is called *Strategic Buying*. As Clark and Polborn (2011) note, “if a buyer can potentially influence whether a seller stays in a market, it may purchase from this seller even if it would

otherwise prefer the product of one of its competitors who is less likely to exit the market.”¹

Strategic buying is often observed in government. Delaware state government is in the process of passing a code that requires each state agency to make at least 15% of their purchases from minority, women, or veteran businesses. The purpose of this code is to protect these relatively vulnerable businesses from larger competitors. The Hunan government in China recently purchased tons of steel from its local company for new bridge construction. Even though they didn't speak it explicitly it is known that they are strategically supporting local businesses, especially heavy industries, to avoid relying on out-of-state resources. Clark and Polborn also note that Britain's Ministry of Defense “appropriate sovereignty” concept is strategic buying.

Strategic buying also occurs in the generic pharmaceutical industry. The generic pharmaceutical industry is characterized by a small number of large manufacturers such as Teva, Actavis and Sandoz, along with smaller manufacturers. Due to FDA regulations, entry into the industry is difficult. Thus, retail drugstores are very cautious to keep competition in the market to prevent them from locking in a monopoly supplier.

In practice, the main purpose of strategic buying is to prevent seller exit in order to keep competition in the market. There is another possible reason for strategic buying is to keep variety in the market when the buyers are not sure their consumers'

¹ Clark and Polborn (2011)

future preferences but have not enough power to influence their preferences. The latter one often happens in small scale, such as small grocery stores or gas stations.

This essay is interested in the former purpose of keeping competition in the market. I model strategic buying in the pharmaceutical industry by a drugstore that purchases from two pharmaceutical manufacturers producing a homogeneous (generic) drug with different constant marginal costs. This drugstore does business with these two firms in two periods. I find that when the difference in marginal cost between two manufacturers is not big, the drugstore is willing to practice strategic buying. The less the difference the more willing the drugstore is to buy strategically. The demand in the downstream market also influences strategic buying. The tendency to engage in strategic buying increases with an increase in the demand. Increasing fixed cost would deter the drugstore from buying strategically. When the difference between the two manufacturers is big enough or the demand in the downstream market is small enough, the drugstore has no incentive to implement strategic buying at all. Once the decision to implement strategic buying has been made, the strong firm may have an incentive to take action to prevent this from happening. If it is not much stronger than the weak firm, especially when the price weak firm charges is relatively small.

My investigation of strategic buying is organized as follows. Chapter 2 reviews the literature on buyer power, chapter 3 introduces the model and analyzes the results from the model, and concluding remarks are presented in chapter 4.

Chapter 2

LITERATURE REVIEW

In this section I would review previous articles on buyer power. The articles studying buyer power focus on two fields. In the earlier papers they emphasize on the buyers' ability to bargain with suppliers to achieve lower price or more favorable trade terms. In the recent papers they move their attention on the buyers purchasing strategies to maintain competition in the market, which is an intertemporal consideration.

2.1 Bargaining Power

2.1.1 Monopsony Power

When there is perfect competition among suppliers and the normal selling price of a supplier is a competitive price the buyer has monopsony power. The textbook analysis argues that monopsony power leads to a wealth transfer from the seller to the buyer and causes an efficiency loss no matter whether there is competition in the downstream market (the final consumption market) or not.

Shaffer (1991) presents a model where duopoly retailers face competitive suppliers who have constant marginal costs to analyze slotting allowance and resale price maintenance. In the model, the suppliers compete to obtain shelf space by slotting allowance and resale price maintenance and the retailers use their buyer power to mitigate competition in the downstream market. Shaffer finds that competition

among suppliers gives retailers the ability to dictate terms of contracts between the retailers and the suppliers favoring the retailers. Slotting allowance permits the retailers to extract profits from the suppliers without decreasing the price in the downstream market. And resale price maintenance allows the retailers to commit contractually to higher prices in the downstream market, which eliminates their incentive to price aggressively in the downstream market. Obviously, these two applications would undermine the welfare of consumers.

2.1.2 Countervailing Power

When an upstream market is dominated by a small number of suppliers with market power the buyer power is called countervailing power. Countervailing power attracts more and more attention with the growing dominance of ‘Big-Box’ retailers and the increase in concentration in retail markets.

Dobson and Waterson (1997) suggest that the role of concentrated retailers not only may be as the consumer’s agent negotiating with suppliers and passing on savings to consumers but also could be powerful as sellers to control the final price. They examine the effects of increased concentration at the retail level on final prices and economic welfare within a market with a monopolistic supplier and N symmetric retailers differentiated by their retail services. They find that consumer welfare increases with retailer substitutability. Two perfectly substitutable retailers in the market is ideal, where the retailers have buying power to negotiate with the supplier and they don’t have market power in the final market which is perfectly competitive. Moreover, they also note that the supplier could change this ideal case by only trading

with one retailer and charging a franchise fee to drain the monopoly surplus from the retailer. This outcome would reduce social welfare.

The model used by Chen (2003) is more realistic than that used by Dobson and Waterson (1997). Chen uses a model with a monopolistic supplier who sells to a group of downstream retailers consisting of a dominant firm and a competitive fringe to examine the effects of an increase in the amount of countervailing power possessed by the dominant retailer on consumer prices and economic welfare. This model allows for two-part tariffs in the contracts between the supplier and the retailer to demonstrate how the retailer can share profits with its supplier. In contrast to the conclusion in Dobson and Waterson, Chen finds that an increase in the countervailing power of the dominant retailer leads to a reduction in the retail price and consequently an increase in consumer surplus. However, fall in the retail price does not result from a dominant retailer passing on cost savings to consumers but from a supplier offsetting the reduction in its profits by reducing its wholesale price to fringe retailers to increase its sales. This paper also demonstrates the importance of competition on improving economic efficiency. By raising the number of the fringe retailers the efficiency loss due to countervailing power could be offset by the gain in consumer surplus.

Erutku (2005) modifies Chen's model by introducing strategic interactions as well as product differentiation. In the model, a dominant national retailer competes with a local retailer in m local markets. Instead of setting that the dominant firm is able to extract a larger share of the maximum joint profit with the supplier the model assumes the dominant firm is able to obtain a discount off the listed wholesale price

set by the supplier. The conclusions in this paper contrast with those from Chen. With the assumption that all retailers remain active in the market, this paper finds the wholesale price and the retail price charged by local retailers are non-monotonic in the degree of countervailing power of the national retailer whenever the national retailer and local retailers are not perfectly substitutable. The wholesale price and the retail price of local retailers are initially increasing in the degree of countervailing power of the national retailer, attain a maximum and then are decreasing in the degree countervailing power. Moreover, economic welfare is non-decreasing with the degree of buying power of the national retailer regardless of the degree of product differentiation or the market share of the national retailer.

So far, the papers I reviewed focus on the effect of countervailing power on prices and thus its consequence in consumer surplus. However, in addition to the effect on prices, countervailing power may influence the product or service variety and the supplier's innovation or investment incentive. The papers I review next focus on this aspect.

Inderst and Shaffer (2007) analyze the impact of a cross-border retail merger on the consolidated retailer's choice of products and on the suppliers' choices of how differentiated to make their products. They set up a model where two suppliers produce a differentiated good with symmetric and constant marginal costs of production. Both goods can be sold in two independent markets in which the respective retailers act as monopolists. To describe cross-border trade, they assume each retailer in each market would stock at most one of the two goods, and consumers'

preferences or brand recognition in each market are different so that each market carries a different good before a merger. This paper finds that if the suppliers have sufficiently strong power before a merger, which means each supplier's product is well suited to a particular market (their products are sufficiently differentiated), the consolidated retailer will be strictly better off by committing to one-source purchase which will decrease the product variety. And if the merger and solo-sourcing strategy is anticipated by the suppliers they would be induced to produce less differentiated products to accommodate preference of both markets which in turn reduces product diversity further. The reduced product diversity would decrease consumers' welfare and economic efficiency.

Battigalli, Fumagalli and Polo (2007) model a bargaining protocol in a non-cooperative setting which includes two independent retailers and a monopolistic supplier in the market to analyze the sources of buyer power and the effect of buyer power on the supplier's incentive to invest in R&D to improve the quality. They examine the sources of buyer power in two sides. One is on the demand side where it finds the degree of substitutability between retailers could influence the retailers' rivalry. When the degree of substitutability between retailers increases, buyer power decreases and the producer has more incentive to improve the quality which, in turn, increases total profits and producer profits. Final consumers would benefit from the quality improvement and consumer surplus and total welfare increase. The other effect is on the supply channel where the steepness of the marginal cost curve in an increasing marginal cost condition impacts the rivalry as it makes the two retailers

compete for a scarce input at the production stage. The paper shows a steeper marginal cost curve leads to a larger share of surplus left to the producer. At last, this paper combines these two channels together by showing that a condition where increase in rivalry (increase in the steepness of the marginal costs curve in a certain range of substitutability) leads to quality improvement, and increased industry profits and total welfare which not only benefits the producer but benefits the retailers.

Inderst and Wey (2007) and Montez (2007) analyze how size discounts can arise and how the formation of buyer power can influence supplier's investment strategies when suppliers have strictly convex costs or have capacity constraints. Inderst and Wey finds that facing larger buyers, the supplier cares more about reducing incremental production costs at high volumes and more about reducing the loss in revenues that might arise from a disagreement with a large buyer. Therefore, the presence of larger buyers may stimulate incremental investments, but it may stifle non-incremental investment including new product development and entry. Montez extends Inderst and Wey's analysis by focusing on a continuous investment choice and accounting for the problem of producer's opportunism in related output markets. This paper suggests a nonmonotonic relationship between downstream horizontal integration and the upstream equilibrium capacity: horizontal mergers induce a higher upstream capacity if the cost of capacity is low and a lower upstream capacity if the cost is high. Inderst and Wey (2011) investigate how the exercise of buyer power resulting from differences in buyer size affects the suppliers' incentives to become more cost efficient. They consider a model of bilateral bargaining where a supplier

produces a homogeneous final good at constant marginal cost and sells it in multiple independent markets, in each of which at least two competing buyers are active. They assume each bilateral negotiation result is not observable to other buyers and that buyers bargain with an outside option. (Buyers can more credibly threaten to integrate backwards). Unlike the conclusion in Battigalli, Fumagalli and Polo from a standard hold-up perspective that the suppliers' incentives to invest are stifled by the exercise of buyers' power, this paper finds the presence of a powerful buyer creates incentives for suppliers to lower marginal cost to decrease the value of the buyer's alternative supply options and the incentives are stronger as buyers are larger.

Ellison and Snyder (2010) conduct an empirical study to test whether supplier competition is necessary for buyer-size discounts to emerge in the pharmaceutical industry. They use data on average wholesale prices charged by manufactures to U.S. drugstores and Hospitals and HMO's for all prescription antibiotics from January 1992 to August 1996. The data allow for variation in both buyer size (e.g., chain store vs independent store) and intensity of supplier competition (e.g., on-patent antibiotics vs off-patent with one or more generics) to isolate the effect of size and suppliers' competition on the prices. Ellison and Snyder run a regression where the dependent variable is a difference in log price between chain and independent stores or between drugstores and hospitals or HMO's and the dependent variables are a set of dummy variables, including ONPAT, OFFPAT×BRANDED, OFFPAT×GENERIC×ONEGEN, and OFFPAT×GENERIC×MULTGEN, to focus on the interaction between a buyer's size and intensity of suppliers' competition. They

find that ability to substitute is a more significant source of countervailing power in the wholesale market for antibiotics than buyer size. In the regression examining the difference in prices paid by chain and independent drugstores, the coefficient on ONPAT is small and insignificant, suggesting that large buyers are not able to extract any discount at all in the antibiotics market when facing a monopoly supplier. For the off-patent branded drugs, chains receive a small (0.3%) but statistically significant discount and the discount for the single generics is larger (1.7%), but only marginally significant. This evidence suggests that when market supply becomes slightly more competitive, larger buyers are able to extract small discounts from the sellers relative to small buyers. The results of the regression comparing the prices paid by drugstores with those paid by hospitals further confirm the importance of supplier competition to sizable buyers receiving discounts. All coefficients in this regression are highly significantly negative which corresponds to the fact that hospitals have more substitute opportunities than drugstores. The smallest discounts occur for on-patent drugs and discounts are steeper for off-patent drugs both for single generics and for multiple generics.

2.2 Strategic Buying

If powerful buyers continue exercising their power to bargain for lower prices, or only purchase from suppliers with lower prices, higher quality or any feature they prefer, they would eventually help these superior suppliers gain dominant or even monopolistic power in the market by indirectly eliminating other suppliers from the upstream market, which in turn jeopardizes the buyer's surplus in the long-run.

Therefore, to maintain competition in the market powerful buyers try to prevent some suppliers from exiting by buying products or services from them on purpose, even though it might not be their optimal choices in the short term. In recent years, more and more studies have explored this strategic buying behavior.

Actually, Romano (1991) already realized that consumers would consume excessively to keep their favorite sellers in business when they worry that the sellers might exit the market if the consumption is not sufficient. He sets up a market where there are n identical consumers and a firm whose average cost is everywhere above demand to rationalize the excessive consumption. He shows that there is often Nash equilibrium in consumption beyond consumers' demand to keep the firm in business and to protect consumers' surplus. If consumers know the firm's cost there are multiple equilibria, but if the information is incomplete the multiple equilibria disappear.

The most related article to my paper is Clark and Polborn (2011). Clark and Polborn observe "strategic buying" behavior in some public sectors, such as UK's defense department and government agency for prison services. They also believe such behavior exists in private sectors, such as the market for regional jets. They argue that "strategic buying" is much more likely to happen in markets where one or a few buyers purchase big-ticket items than in the markets in which each buyer makes up only a negligible share of the market. They develop a two-period dynamic oligopoly model in which a seller may exit the market when demand for its product is insufficient to examine how the incidence of strategic buying depends on market

parameters and how sellers take advantage of strategic buying to price their products in the first period. They assume two sellers each produce a single variety of a product at zero marginal cost; N buyers each have a unit demand for the good in each of two periods; each seller decides whether to stay in the market or not based on its first-period revenue at the beginning of the second period. Because there are multiple buyers and all buyers benefit if both sellers survive in the second period, the strategic buying in this paper is a public good and generates a free-rider problem.

In the first analysis, Clark and Polborn assume the sellers' prices are exogenous and the same. In this situation, they predict that large buyers may intentionally purchase something that is not optimal for them in the short run, but will be better off in the long run if they were not myopic. They propose that the extent of strategic buying is strictly increasing in the individual benefit of having more sellers on the market in the second period. They also point out that strategic buying is underprovided as a result of a public good attribute. Moreover, they find a nonmonotonic relation between the number of buyers (N) in the market and the incidence of strategic buying: when N is small, an increase in N makes each buyer more likely to engage in strategic buying; when N is large, an increase in N could decrease the extent of individual strategic buying as each buyer is less likely to be pivotal to the survival of sellers. Furthermore, the increase in the number of customers required to prevent the sellers from exiting (n) makes the critical number even harder to reach, as a result, it decreases each buyer's incentive to engage in strategic buying.

In the second analysis, Clark and Polborn relax the assumption that the sellers' prices are exogenous in the first period which allows the sellers to manipulate their prices in the presence of strategic buyers. The paper first considers the situation in which the equilibrium of R/p is not near or at a boundary so that marginal changes of prices of both sellers do not change n for both sellers. They find that the more buyers would benefit from more sellers in the second period, the higher prices sellers charge in the first period, which they call a strategic buying effect. On the other hand, an increase in the profits to a seller from being a monopolist in the second period could result in a lower price charged in the first period, which they call a predatory price effect. Whether a change in market parameters (v, N, n, β) would increase or decrease equilibrium prices depends on whether the strategic buying effect is larger than the predatory price effect. The paper develops a numerical example to illustrate the case where the revenue constraint is such that small price changes affect the number of customers a seller needs for survival. It suggests that in this example both sellers and buyers are better off when the revenue constraint is sufficiently low and total profits of a seller in two periods are lower when there is a survival constraint than when there is not so that sellers might prefer to commit to prices for both periods to remove the motivation to predatory price. It also notes that, in this particular example, the buyers could be better off if they ex ante commit to not buy strategically.

Based on the conclusion of their analysis, Clark and Polborn provide some managerial implications to both buyers and sellers. Sellers can take advantage of strategic buying by raising their prices as this lowers the price elasticity of the demand;

and their advertisements could not only focus on the differentiation of their products but also on the willingness of buyers to pay because in strategic buying situation buyer valuations matter. For buyers, even though they might be better off by ex-ante committing to not buy strategically they may be locked in to a supplier in the long-run.

Lewis and Yildirim (2002) examine the market equilibrium arising from repeated competition between suppliers to characterize the buyer's strategic process in managing learning among suppliers to reduce its overall purchase cost over times. They use a model in which a procurer purchases exactly one unit of a good or service from one of the two suppliers each period for infinitely recurring periods. They assume producers learn by experience so that they face decreasing marginal cost, and information in the market is incomplete as each seller observes its cost privately. The single procurer trades off between the advantage of learning by doing and a future reduction in competition when one supplier becomes dominant. They find if the future is very important, which means the discount rate is close to 1, the procurer facilitates learning by favoring the more expensive supplier; if the discount rate is small, the procurer is more likely to select the leading producer each period and probably tip to one supplier eventually. When learning economies are sufficiently small the procurer maintains market competition by diversifying its purchases between the two suppliers; when learning economies are large the procurer ends up only purchasing from the leading supplier. With regard to policies which the procurer makes to affect the learning rate of suppliers, the paper points out that the buyer prefers information sharing only when the gap between the two suppliers is big, and rotating procurement

managers would lead to a greater chance of market dominance by the leading seller. However, this paper only focuses on the buyer's behavior and not on possible strategies between the two suppliers.

Anton, Biglaiser and Vettas (2012) analyze a dynamic oligopolistic model for durable goods where sellers have capacity constraints and buyers are likely to buy strategically to solve for equilibrium capacity choices and pricing strategies and the buyer's best choices in equilibrium. In their model, there are two incumbents and many potential entrants on the seller side and a buyer in the market, who interact over two periods. The buyer has value for 3 units of the product over the lifetime. The product is perfectly homogeneous and perfectly durable which means when the buyer purchases a unit of the product in the first period it would generate utility in the second period as well as in the first period. The marginal cost to produce the product is zero. As this paper takes capacity constraints into account, it would hurt the seller if the buyer purchases from it in the first period rather than favoring the seller, which is reverse to other articles. This paper suggests that the sellers are worse off if the buyer commits to make all his purchases at once, effectively collapsing the game into a one-shot interaction, or commits to not buy strategically. Moreover, the buyer has an incentive to vertically integrate with one of the sellers. Furthermore, this paper shows that the optimal capacity choice for the sellers in equilibrium is (2, 2).

The last three papers reviewed above are the most related papers analyzing strategic buying behavior. These three papers share the same assumption that the goods or services are sold directly to consumers. However, in reality, especially in the

pharmaceutical industry prescription drugs are not directly sold to patients at all. Patients need a physician's prescription and go to a pharmacy to get their prescription filled. Therefore, my paper studies strategic buying at the retail level. Demand of retailers is not exogenous but is decided by the demand function in the downstream market. Table 1 summarizes the models in these three papers as well as in my paper.

My model is described in detail and the results are analyzed in the next chapter.

Table 1 Summary of different models on strategic buying

Lewis and Yildirim (2002)	Clark and Polborn (2011)	Anton, Biglaiser and Vettas (2012)	This Paper
<ul style="list-style-type: none"> • Infinite-horizon game • Single buyer purchasing exactly one unit of a good each period • Two suppliers produce a good with decreasing marginal cost (learn by going) • Products are perfectly homogeneous • Incomplete Information • No interaction between suppliers 	<ul style="list-style-type: none"> • Two periods • $N (N \geq 2)$ buyers with one unit good demand each period • Two sellers produce differentiated products at zero marginal cost • Products are heterogeneous • Complete Information • Sellers decide whether exit or not at the beginning of the second period 	<ul style="list-style-type: none"> • Two periods • Single buyer purchasing 3 units of product in total over two periods but only buying at largest 2 units in the first period • Two incumbent sellers with capacity constraints and zero marginal cost and a large number of potential entrants • Products are perfectly homogeneous and perfectly durable • Sellers decide their capacity at the beginning of each period 	<ul style="list-style-type: none"> • Two periods • Single retailer • The demand of the retailer is decided by the demand function in downstream market • Two suppliers with different constant marginal costs • Products are perfectly homogeneous • Complete information • Sellers decide whether exit or not at the beginning of each period

Chapter 3

MODEL

According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and pharmacodynamic properties. By extension generics are considered (by the FDA) identical in dose, strength, route of administration, safety, efficacy, and intended use.² Therefore, consider one drugstore purchasing a generic drug from two pharmaceutical manufacturers producing an identical product with different marginal costs. Assume the two pharmaceutical firms engage in Bertrand competition. I only consider two periods and for simplicity the discount rate is 1. Moreover, I assume the market is perfect and efficient, so all market participants know one another's technology, cost and price and could respond to the market very quickly. In addition, exit is costless, and each firm could make an exit decision at the beginning of each period based on the demand for its product. The two firms have no capacity constraint.

Downstream market demand in each period $j = \{1,2\}$ is assumed to be

$$P_j = k - (x_{1j} + x_{2j}) \quad (j = 1,2) \quad (1)$$

P is market price, x_1 is the demand for firm 1 and x_2 is the demand for firm 2.

² Wikipedia

The buyer's profit function for each period is

$$\pi_{bj}(x_{1j}, x_{2j}) = P_j(x_{1j} + x_{2j}) - p_{1j}x_{1j} - p_{2j}x_{2j} \quad (j = 1,2) \quad (2)$$

where p_1 is the price firm 1 charges and p_2 is the price firm 2 charges.

Each firm i 's cost function for each period j is

$$C_{ij} = c_i x_{ij} + f \quad (i, j = 1,2) \quad (3)$$

where c_i is the marginal cost of firm i and f is the fixed cost; and firm i profit in period j is

$$\pi_{sj} = p_i x_{ij} - C_{ij} \quad (i, j = 1,2) \quad (4)$$

In the model, I suppose $k > c_2 > c_1$ to ensure the drugstore will always purchase from at least one of the pharmaceutical firms.

The interactions between the two pharmaceutical firms and between these firms and drugstore at the beginning of each period are as follows. First, the two pharmaceutical firms set their prices to maximize their overall profits. Second, the drugstore maximizes its total profit by choosing its optimal demand for each firm at the prices set by both firms. Third, given the drugstore's demand, the two pharmaceutical firms decide whether they exit or not.

3.1 No Strategic Buying

If the drugstore is myopic in the first period, it only purchases from the firm with the lower price, which results in monopoly in the second period.

Since I assume $c_1 < c_2$, firm 1 is able to price its product a little bit lower than firm 2's price to beat firm 2 out of business so that it can gain monopoly power in the second period. Therefore, if firm 1 prices to eliminate firm 2, the equilibrium price for

firm 1 in the first period is equal to or less than the marginal cost of firm 2. If the drugstore is myopic it would buy no product from firm 2 at all, thus firm 2 would exit the market immediately. As a result, the drugstore only does business with firm 1 in both periods because firm 2 has exited the market at the beginning of the first period.

The buyer's problem turns out to be

$$\max \pi_b(x_{11}, x_{12}) = \pi_{b1} + \pi_{b2} = (P_1 - p_{11})x_{11} + (P_2 - p_{12})x_{12}$$

Subject to

$$P_j = k - x_{1j} \quad (j = 1, 2)$$

Solving for the first-order condition generates the buyer's optimal demands (x_{11}, x_{12}) ,

$$x_{11} = \frac{k-p_{11}}{2}, x_{12} = \frac{k-p_{12}}{2} \quad (5)$$

Firm 1's problem is

$$\max \pi_s(p_{11}, p_{12}) = \pi_{s1} + \pi_{s2} = (p_{11}x_{11} - C_{11}) + (p_{12}x_{12} - C_{12})$$

subject to

$$p_{11} \leq c_2,$$

$$C_{1j} = c_1x_{1j} + f \quad (j = 1, 2), \text{ and}$$

$$x_{11} = \frac{k-p_{11}}{2}, x_{12} = \frac{k-p_{12}}{2}$$

Taking derivative of π_s with respect to p_{11} and p_{12} yields the optimal prices for firm

1 of

$$p_{11} = p_{12} = \frac{k+c_1}{2}$$

Case A: if $k + c_1 \geq 2c_2$, then $p_{11} = c_2$

Substituting $p_{11} = c_2$ and $p_{12} = \frac{k+c_1}{2}$ into (5) yields,

$$x_{11} = \frac{k-c_2}{2}, x_{12} = \frac{k-c_1}{4} \quad (6)$$

Using (6) $p_{11} = c_2$ and $p_{12} = \frac{k+c_1}{2}$ in the buyer's and firm1's profit functions,

maximum profits without strategic buying in case A are

$$\begin{aligned} \pi_b &= \pi_{b1} + \pi_{b2} = (P_1 - p_{11})x_{11} + (P_2 - p_{12})x_{12} \\ &= (k - x_{11} - p_{11})x_{11} + (k - x_{12} - p_{12})x_{12} \end{aligned} \quad (7)$$

$$\begin{aligned} \pi_s &= \pi_{s1} + \pi_{s2} = (p_{11} - c_1)x_{11} - f + (p_{12} - c_1)x_{12} - f \\ &= (c_2 - c_1)\frac{k-c_2}{2} + \frac{(k-c_1)^2}{8} - 2f \end{aligned} \quad (8)$$

Case B: If $k + c_1 < 2c_2$, then $p_{11} = p_{12} = \frac{k+c_1}{2}$

$$x_{11} = x_{12} = \frac{k-p_{11}}{2} = \frac{k-c_1}{4} \quad (9)$$

Using (9) and $p_{11} = p_{12} = \frac{k+c_1}{2}$ in the buyer's and firm 1's profit functions, total

profits without strategic buying in case B are

$$\pi_b = \pi_{b1} + \pi_{b2} = 2\pi_{b1} = 2(P_1 x_{11} - p_{11} x_{11}) \quad (10)$$

$$\pi_s = \pi_{s1} + \pi_{s2} = 2\pi_{s1} = 2(p_{11} x_{11} - c_1 x_{11} - f) = \frac{(k-c_1)^2}{4} - 2f \quad (11)$$

3.2 Strategic Buying

Strategic buying only occurs in the first period as in the last period it's not necessary for the drugstore to worry about maintaining competition in the future. The equilibrium in the second period under strategic buying would be exactly the same as the equilibrium in the first period under no strategic buying.

3.2.1 Case A: $k + c_1 \geq 2c_2$

With strategic buying the drugstore intentionally purchases enough from firm 2 to keep it in business even though firm 2 may charge more than firm 1 for the identical drug. The amount the buyer would purchase from firm 2 will be just enough to cover firm 2's total cost.

This case is considered using backward induction. In the second period, if both firms exist in the market by the end of the first period the equilibrium price the buyer would be charged is c_2 by firm 1 and firm 2 will exit the market at the beginning of the second period. This is the same as the outcome in the first period when there is no strategic buying.

Therefore, the equilibrium in the second period is

$$\widetilde{p}_{12} = p_{11} = c_2$$

$$\widetilde{x}_{12} = x_{11} = \frac{k-c_2}{2}$$

$$\widetilde{\pi}_{b2} = \pi_{b1} = \left(\frac{k-c_2}{2}\right)^2$$

As I noted above, under strategic buying, in the first period the drugstore intentionally purchases from firm 2 in order to keep firm 2 in the market so that firm 1 could not implement monopoly pricing in the second period. The amount the drugstore will buy from firm 2 would be just enough for firm 2 to break even, which means

$$\widetilde{p}_{21}\widetilde{x}_{21} = c_2\widetilde{x}_{21} + f \text{ or}$$

$$\widetilde{x}_{21} = \frac{f}{\widetilde{p}_{21}-c_2}$$

The buyer's problem in the first period is

$$\begin{aligned}
\max \widetilde{\pi}_{b1}(\widetilde{x}_{11}) &= [(k - (\widetilde{x}_{11} + \widetilde{x}_{21}))(\widetilde{x}_{11} + \widetilde{x}_{21}) - \widetilde{p}_{11}\widetilde{x}_{11} - \widetilde{p}_{21}\widetilde{x}_{21}] \\
&= \left[k - \left(\widetilde{x}_{11} + \frac{f}{\widetilde{p}_{21} - c_2} \right) \right] \left(\widetilde{x}_{11} + \frac{f}{\widetilde{p}_{21} - c_2} \right) - \widetilde{p}_{11}\widetilde{x}_{11} - \widetilde{p}_{21} \frac{f}{\widetilde{p}_{21} - c_2}
\end{aligned} \tag{12}$$

Taking the derivative of $\widetilde{\pi}_{b1}$ on \widetilde{x}_{11} , the buyer's optimal demand on firm 1 is

$$\widetilde{x}_{11} = \frac{k - \widetilde{p}_{11}}{2} - \frac{f}{\widetilde{p}_{21} - c_2} = \frac{k - \widetilde{p}_{11}}{2} - \widetilde{x}_{21}. \tag{13}$$

Firm 1's problem in the first period is

$$\max \widetilde{\pi}_{s1}(\widetilde{p}_{11}) = \widetilde{p}_{11}\widetilde{x}_{11} - c_1\widetilde{x}_{11} - f \tag{14}$$

Substituting (13) into (14) and solving for the first-order condition, the optimal price firm 1 would charge is

$$\widetilde{p}_{11} = \frac{k + c_1}{2} - \widetilde{x}_{21} = \frac{k + c_1}{2} - \frac{f}{\widetilde{p}_{21} - c_2} \tag{15}$$

Substituting (15) into (13), the buyer's optimal demand is

$$\widetilde{x}_{11} = \frac{k - c_1}{4} - \frac{\widetilde{x}_{21}}{2} = \frac{k - c_1}{4} - \frac{1}{2} \frac{f}{\widetilde{p}_{21} - c_2} \tag{16}$$

The buyer's maximum profit in the first period is calculated by plugging (16) and (15) into (12), which yields

$$\widetilde{\pi}_{b1} = \left(\frac{k - c_1}{4} \right)^2 + \frac{3}{4} k \widetilde{x}_{21} + \frac{1}{4} c_1 \widetilde{x}_{21} - \frac{3}{4} \widetilde{x}_{21}^2 - \widetilde{p}_{21} \widetilde{x}_{21}. \tag{17}$$

Therefore, the total profit of the drugstore is

$$\widetilde{\pi}_b = \widetilde{\pi}_{b1} + \widetilde{\pi}_{b2} = \left(\frac{k - c_1}{4} \right)^2 + \left(\frac{k - c_2}{2} \right)^2 + \frac{3}{4} k \widetilde{x}_{21} + \frac{1}{4} c_1 \widetilde{x}_{21} - \frac{3}{4} \widetilde{x}_{21}^2 - \widetilde{p}_{21} \widetilde{x}_{21}. \tag{18}$$

Comparing (7) with (18) I have

Proposition 1: If $\widetilde{p}_{21} \in [\widetilde{p}_{21}^{min}, \widetilde{p}_{21}^{max}]^3$, the buyer will buy strategically; the buyer's profit is maximized at $\widetilde{p}_{21} = \widetilde{p}_{21}^*$ ⁴.

It is seen that if f is so big that the term inside the square root is negative $((3k + c_1 - 4c_2)^2 - 48f < 0)$, there will not be any price firm 2 could charge to induce the buyer to engage in strategic buying. Intuitively, if f is large, the buyer has more incentive to concentrate its purchase on a single firm to bring average cost down. When the buyer chooses to buy strategically, it not only incurs the higher marginal cost of firm 2, splitting its demand across the two firms implicitly doubles the fixed cost. If the fixed cost is sufficiently large, the buyer's incentive to take advantage of scale economies by concentrating its purchase in a single firm dominates the incentive to maintain competition in the market, and the buyer won't buy strategically.

From another standpoint, as k or c_1 increases, or as c_2 decreases, the term inside square root is more likely to be positive and it is more likely that a solution to \widetilde{p}_{21} exists and strategic buying will occur in equilibrium. A larger k indicates the demand for the drug in the downstream market is high, which gives the buyer more freedom or power to allocate its demand between firm 1 and firm 2. If the demand is

$$^3 \widetilde{p}_{21}^{min} = \frac{1}{8} [(3k + c_1 + 4c_2) - \sqrt{(3k + c_1 - 4c_2)^2 - 48f}],$$

$$\widetilde{p}_{21}^{max} = \frac{1}{8} [(3k + c_1 + 4c_2) + \sqrt{(3k + c_1 - 4c_2)^2 - 48f}].$$

$$^4 \widetilde{p}_{21}^* = \frac{(3k+c_1+4c_2) \pm \sqrt{(3k+c_1-4c_2)^2 - 96f}}{8}$$

large the buyer only needs to sacrifice a small portion of its profit in the first period to keep the weak firm (firm 2) in the market, so it will be more willing to implement strategic buying. As c_1 increases or c_2 decreases, or as the difference between c_1 and c_2 shrinks, the advantage of firm 1 over firm 2 decreases, the loss the buyer should bear by buying from the higher marginal cost product reduces, thus, the buyer would have more and more incentive to take advantage of its power to practice strategic buying.

I also find that the condition for the optimal situation should be more restricted since f which satisfies the condition to lure the buyer to buy strategically may not be necessary to satisfy the condition to reach the maximum profit. In the optimal condition f should be much less than the f in the just taking-action situation. The optimal prices suggest the buyer could negotiate with the weak firm about the price to achieve its biggest profit without making the weak firm worse-off once it decides to buy strategically. As for the weak firm it has two choices of the optimal prices and it is indifferent to these two choices in the profit perspective. However, if it chooses the lower one it can sell more to the buyer which in turn raises its market share and improve its customer recognition. Therefore, if firm 2 cares about its brand it should choose the lower price.

Proof of proposition 1:

$$\text{Let } \alpha = \frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21} \geq 0 \quad (19)$$

By rearranging (19) I have

$$\widetilde{x}_{21} = \frac{f}{\widetilde{p}_{21} - c_2} \leq k + \frac{1}{3}c_1 - \frac{4}{3}\widetilde{p}_{21} \quad (20)$$

Solving (20) for \widetilde{p}_{21} yeilds

$$\frac{3}{4}\widetilde{p}_{21}^2 - \left(k + \frac{1}{3}c_1 + \frac{4}{3}c_2\right)\widetilde{p}_{21} + (kc_2 + \frac{1}{3}c_1c_2 + f) \leq 0, \text{ which implies}$$

$$\widetilde{p}_{21}^{min} \leq \widetilde{p}_{21} \leq \widetilde{p}_{21}^{max}$$

where

$$\widetilde{p}_{21}^{min} = \frac{1}{8}[(3k + c_1 + 4c_2) - \sqrt{(3k + c_1 - 4c_2)^2 - 48f}],$$

$$\widetilde{p}_{21}^{max} = \frac{1}{8}[(3k + c_1 + 4c_2) + \sqrt{(3k + c_1 - 4c_2)^2 - 48f}].$$

If firm 2 decides to stay in the market, its price cannot be less than its marginal cost c_2 ($\widetilde{p}_{21} \geq c_2$). Comparing \widetilde{p}_{21}^{min} with c_2 identifies the lowest boundary of \widetilde{p}_{21} to motivate the buyer to make the strategic buying decision.

Suppose $f = 0$,

$$\begin{aligned} \widetilde{p}_{21}^{min}(f = 0) &= \frac{1}{8}[(3k + c_1 + 4c_2) - \sqrt{(3k + c_1 - 4c_2)^2}] \\ &= \frac{1}{8}[(3k + c_1 + 4c_2) - |3k + c_1 - 4c_2|] \end{aligned} \quad (21)$$

Since $k + c_1 \geq 2c_2$ and $k > c_2 > c_1$, then $3k + c_1 > 2k + 2c_1 \geq 4c_2$, that is $3k + c_1 - 4c_2 > 0$, (21) implies

$$\widetilde{p}_{21}^{min}(f = 0) = \frac{1}{8}(3k + c_1 + 4c_2 - 3k - c_1 + 4c_2) = c_2 \text{ is a sufficient condition}$$

for $\widetilde{p}_{21}^{min} > c_2$.

Because $\frac{\partial \widetilde{p}_{21}^{min}}{\partial f} > 0$, \widetilde{p}_{21}^{min} is increasing with respect to f , I have $\widetilde{p}_{21}^{min} >$

c_2 , when $f > 0$.

I am also interested in what price for firm 2 provides the buyer the most additional profit form strategic buying compared to no strategic buying.

Therefore, I solve for α 's first order condition in \widetilde{x}_{21} :

$$\begin{aligned} \frac{d\alpha}{d\widetilde{x}_{21}} &= \frac{d(\frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21})}{d\widetilde{x}_{21}} \\ &= \frac{3}{4}k + \frac{1}{4}c_1 - \frac{3}{2}\widetilde{x}_{21} - \widetilde{p}_{21} = 0 \end{aligned} \quad (22)$$

Substituting $\widetilde{x}_{21} = \frac{f}{\widetilde{p}_{21} - c_2}$ into (22) and solving for \widetilde{p}_{21} yields

$$\widetilde{p}_{21}^* = \frac{(3k+c_1+4c_2) \pm \sqrt{(3k+c_1-4c_2)^2 - 96f}}{8}$$

As we know

$$\widetilde{p}_{21}^{min} < \frac{(3k+c_1+4c_2) - \sqrt{(3k+c_1-4c_2)^2 - 96f}}{8} \text{ and } \widetilde{p}_{21}^{max} >$$

$\frac{(3k+c_1+4c_2) + \sqrt{(3k+c_1-4c_2)^2 - 96f}}{8}$, the greatest points could be achievable under the

condition when the buyer would buy strategically. \square

Above, I analyze the conditions when the buyer has incentive to buy strategically. An interesting question is whether, under these conditions, firm 1 would accept the buyer's decision and make its best choices based on the buyer's behavior or whether firm 1 might react in a way that deters the buyer from buying strategically. I will discuss the possibilities in the following content.

3.2.1.1 Firm 1 Has No Action

Assume firm 1 takes no action to deter strategic buying and makes its own optimal pricing decision given that the buyer's demand for firm 2 $\widetilde{x}_{21} = \frac{f}{\widetilde{p}_{21} - c_2}$.

Substituting (15), (16) into (14) yields the maximum profit of firm 1 in the first period

$$\widetilde{\pi}_{s1} = \widetilde{p}_{11}\widetilde{x}_{11} - c_1\widetilde{x}_{11} - f = \frac{1}{2}\left(\frac{k-c_1}{2} - \frac{f}{\widetilde{p}_{21}-c_2}\right)^2 - f$$

Substituting $\widetilde{x}_{12} = \frac{k-c_2}{2}$ and $\widetilde{p}_{12} = c_2$ into the firm 1's second period profit function

$$\widetilde{\pi}_{s2} = \widetilde{p}_{12}\widetilde{x}_{12} - c_1\widetilde{x}_{12} - f = \frac{k-c_2}{2}(c_2 - c_1) - f$$

Therefore, the total profit of firm 1 in the “no action” situation is

$$\widetilde{\pi}_s = \widetilde{\pi}_{s1} + \widetilde{\pi}_{s2} = \frac{1}{2}\left(\frac{k-c_1}{2} - \frac{f}{\widetilde{p}_{21}-c_2}\right)^2 + \frac{k-c_2}{2}(c_2 - c_1) - 2f \quad (23)$$

Subtracting (8), the total profit of firm 1 when there is no strategic buying, from (23)

$$\widetilde{\pi}_s - \pi_s = \frac{1}{2}\frac{f}{p_{21}-c_2}\left(\frac{f}{p_{21}-c_2} - k + c_1\right) \quad (24)$$

Under strategic buying we know that

$$\frac{f}{\widetilde{p}_{21}-c_2} \leq k + \frac{1}{3}c_1 - \frac{4}{3}\widetilde{p}_{21}$$

$$\text{and } \widetilde{p}_{21} \in [\widetilde{p}_{21}^{min}, \widetilde{p}_{21}^{max}] > c_2 > c_1.$$

So,

$$\frac{f}{\widetilde{p}_{21}-c_2} - k + c_1 \leq k + \frac{1}{3}c_1 - \frac{4}{3}\widetilde{p}_{21} - k + c_1 = \frac{4}{3}(c_1 - \widetilde{p}_{21}) < 0$$

Since $\frac{f}{p_{21}-c_2} > 0$ and $\frac{f}{p_{21}-c_2} - k + c_1 < 0$, it follows that $\widetilde{\pi}_s - \pi_s < 0$

Obviously, firm 1 is worse-off when the buyer buys strategically, so firm 1 has an incentive to take actions to prevent the buyer from buying strategically.

3.2.1.2 Firm 1 Takes Action

The way firm 1 can prevent the buyer from buying strategically is to set a price in the first period so that the buyer's total profit without strategic buying is greater than the total profit it would have if it buys strategically.

Proposition 2: Firm 1 will prevent strategic buying if and only if $\frac{(k-c_1)^2}{8} -$

$$\frac{1}{2} \left(\frac{k-c_1}{2} - \frac{f}{\widehat{p}_{21}-c_2} \right)^2 > \frac{k-c_2}{2} (c_2 - c_1) - (\widehat{p}_{11} - c_1) \frac{k-\widehat{p}_{11}}{2} \text{ at } p_{11} < c_2.$$

Proof of proposition 2:

The equilibrium in this scenario is the same as that in the situation when the buyer has no intention to buy strategically at all, except in this circumstance c_2 is not low enough for firm 1 to charge to beat firm 2 out of business.

Firm 1 sets its price \widehat{p}_{11} , and as I discussed before the equilibrium is

$$\widehat{x}_{11} = \frac{k-\widehat{p}_{11}}{2}, \widehat{p}_{12} = \frac{k+c_1}{2}, \widehat{x}_{12} = \frac{k-c_1}{4}$$

The total profit for the drugstore is

$$\widehat{\pi}_b = \left(\frac{k-\widehat{p}_{11}}{2} \right)^2 + \left(\frac{k-c_1}{4} \right)^2 \quad (25)$$

The total profit for firm 1 is

$$\widehat{\pi}_s = (\widehat{p}_{11} - c_1) \frac{k-\widehat{p}_{11}}{2} + \frac{(k-c_1)^2}{8} - 2f \quad (26)$$

If firm 1 wants to deter strategic buying it needs to choose a \widehat{p}_{11} so that $\widehat{\pi}_b > \widetilde{\pi}_b$. I compare (25) with (18) and get the condition that p_{11} should be at least less than c_2 ($\widehat{p}_{11} < c_2$), since $\alpha = \frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21} \geq 0$.⁵

Firm 1 will take action to prevent strategic buying if it will be better off by doing this. Therefore, I compare (26) to (23).

$$\text{Let } \beta = (\widehat{p}_{11} - c_1) \frac{k - \widehat{p}_{11}}{2}$$

when $\widehat{p}_{11} < c_2$, as $k + c_1 \geq 2c_2$

$$\frac{d\beta}{d\widehat{p}_{11}} = \frac{1}{2}(-2\widehat{p}_{11} + k + c_1) > 0$$

β is a strictly increasing function on $\widehat{p}_{11} < c_2$.

Therefore, for any $\widehat{p}_{11} < c_2$,

$$\beta = (\widehat{p}_{11} - c_1) \frac{k - \widehat{p}_{11}}{2} < \frac{k - c_2}{2} (c_2 - c_1)$$

However,

$$\frac{(k - c_1)^2}{8} = \frac{1}{2} \left(\frac{k - c_1}{2} \right)^2 > \frac{1}{2} \left(\frac{k - c_1}{2} - \frac{f}{\widetilde{p}_{21} - c_2} \right)^2$$

Subtracting (23) from (26), the result is

$$\widehat{\pi}_S - \widetilde{\pi}_S = \left[\frac{(k - c_1)^2}{8} - \frac{1}{2} \left(\frac{k - c_1}{2} - \frac{f}{\widetilde{p}_{21} - c_2} \right)^2 \right] + [(\widehat{p}_{11} - c_1) \frac{k - \widehat{p}_{11}}{2} - \frac{k - c_2}{2} (c_2 - c_1)]$$

$$\text{If } \frac{(k - c_1)^2}{8} - \frac{1}{2} \left(\frac{k - c_1}{2} - \frac{f}{\widetilde{p}_{21} - c_2} \right)^2 > \frac{k - c_2}{2} (c_2 - c_1) - (\widehat{p}_{11} - c_1) \frac{k - \widehat{p}_{11}}{2}, \quad (27)$$

⁵ Set $\widehat{\pi}_b - \widetilde{\pi}_b = \left(\frac{k - \widehat{p}_{11}}{2} \right)^2 - \left(\frac{k - c_2}{2} \right)^2 - \left(\frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21} \right) > 0$

then $\widehat{\pi}_s - \widetilde{\pi}_s > 0$, and firm 1 has incentive to take action to prevent strategic buying. □

We can see that α is a quadratic function. When \widetilde{p}_{21} is very small (x_{21} is very big) or \widetilde{p}_{21} is very big (x_{21} is very small), α is very close to 0. In other words, the closer \widetilde{p}_{21} is to its boundary \widetilde{p}_{21}^{min} or \widetilde{p}_{21}^{max} , the closer α is to 0 and the less firm 1 needs to cut its price \widehat{p}_{11} below c_2 to ensure that strategic buying is not optimal for the buyer.

In the right side of (27), the closer \widehat{p}_{11} is to c_2 , the closer β is to $\frac{k-c_2}{2}(c_2 - c_1)$ and the closer $\frac{k-c_2}{2}(c_2 - c_1) - (\widehat{p}_{11} - c_1)\frac{k-\widehat{p}_{11}}{2}$ is to 0; (27) is more likely to be satisfied, so firm 1 would take action to deter strategic buying.

In the left side of (27), the bigger \widetilde{p}_{21} is, the less difference is between $\frac{(k-c_1)^2}{8}$ and $\frac{1}{2}\left(\frac{k-c_1}{2} - \frac{f}{\widetilde{p}_{21}-c_2}\right)^2$, thus the chance that (27) is satisfied decreases and firm 1 would be less likely to prevent strategic buying.

Proposition 2.1: When \widetilde{p}_{21} decreases, firm 1 is more likely to prevent strategic buying.

As discussed above, firm 2 should be willing to cooperate with the buyer on its price if it wants to stay in business. By choosing the optimal prices at which the buyer could achieve its biggest additional profit from strategic buying, firm 2 would make strategic buying more attractive to the buyer and increase the cost for firm 1 to take action to prevent it. In addition, moving away from the lowest boundary would reduce the chance that firm 1 would gain from taking action. Firm 2 faces a tradeoff between

a lower optimal price leading to higher market share but the risk that firm 1 will deter strategic buying, and a higher optimal price with lower market share but higher chance of strategic buying.

This does make sense intuitively. If firm 2's price is high the buyer only need to buy a few units from firm 2 to cover firm 2's cost, resulting in low market share of firm 2 and high market share of firm 1, which means firm 1 is sacrificing its high price to receive only a little more sales if it takes action. Therefore, firm 1 is less willing to prevent the buyer from strategic buying when firm 2's price is high. While when firm 2's price is low, the buyer needs to purchase a large amount from firm 2 to keep it in business so that firm 1's market share is relatively small. Under this situation firm 1 may just need to lower its price a little to attract the buyer from firm 2 to gain the whole market.

3.2.2 Case B: $k + c_1 < 2c_2$

In this case the buyer's behavior is the same in two periods. If the buyer buys strategically in the first period, it will buy strategically in the second period. The motive that the buyer buys strategically in this case is that the strategy can force firm 1 charge less.

The analysis and the results in the first period when the buyer buys strategically are the same as those in the case $k + c_1 \geq 2c_2$. I just rewrite the results here:

$$\widetilde{\pi}_{b1} = \left(\frac{k-c_1}{4}\right)^2 + \frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21}$$

$$\widetilde{\pi}_{s1} = \frac{1}{2} \left(\frac{k-c_1}{2} - \frac{f}{\widetilde{p}_{21}-c_2} \right)^2 - f$$

So, I have

$$\widetilde{\pi}_b = 2\widetilde{\pi}_{b1} = 2 \left(\frac{k-c_1}{4} \right)^2 + 2 \left(\frac{3}{4} k \widetilde{x}_{21} + \frac{1}{4} c_1 \widetilde{x}_{21} - \frac{3}{4} \widetilde{x}_{21}^2 - \widetilde{p}_{21} \widetilde{x}_{21} \right) \quad (28)$$

$$\widetilde{\pi}_s = 2\widetilde{\pi}_{s1} = \left(\frac{k-c_1}{2} - \frac{f}{\widetilde{p}_{21}-c_2} \right)^2 - 2f \quad (29)$$

Comparing (28) to (10), I can know that the buyer would take strategic buying only when $\alpha = \frac{3}{4} k \widetilde{x}_{21} + \frac{1}{4} c_1 \widetilde{x}_{21} - \frac{3}{4} \widetilde{x}_{21}^2 - \widetilde{p}_{21} \widetilde{x}_{21} \geq 0$, which is exactly the same condition as that in the case $k + c_1 \geq 2c_2$.

Thus, I retrieve the boundary of the range from the conclusion in the case $k + c_1 \geq 2c_2$, between which the buyer buys strategically:

$$\widetilde{p}_{21}^{min} = \frac{1}{8} \left[(3k + c_1 + 4c_2) - \sqrt{(3k + c_1 - 4c_2)^2 - 48f} \right],$$

$$\widetilde{p}_{21}^{max} = \frac{1}{8} \left[(3k + c_1 + 4c_2) + \sqrt{(3k + c_1 - 4c_2)^2 - 48f} \right].$$

Suppose $f = 0$,

$$\widetilde{p}_{21}^{min}(f = 0) = \frac{1}{8} \left[(3k + c_1 + 4c_2) - \sqrt{(3k + c_1 - 4c_2)^2} \right]$$

$$= \frac{1}{8} \left[(3k + c_1 + 4c_2) - |3k + c_1 - 4c_2| \right]$$

$$\widetilde{p}_{21}^{max}(f = 0) = \frac{1}{8} \left[(3k + c_1 + 4c_2) + \sqrt{(3k + c_1 - 4c_2)^2} \right]$$

$$= \frac{1}{8} \left[(3k + c_1 + 4c_2) + |3k + c_1 - 4c_2| \right]$$

Proposition 3: If $3k + c_1 - 4c_2 < 0$, that is $3(k - c_2) < c_2 - c_1$, the drugstore would never ever buy strategically.

Proof of Proposition 3:

$$\widetilde{p}_{21}^{max}(f = 0) = \frac{1}{8}(3k + c_1 + 4c_2 - 3k - c_1 + 4c_2) = c_2$$

Because $\frac{\partial \widetilde{p}_{21}^{max}}{\partial f} < 0$, \widetilde{p}_{21}^{max} is decreasing with respect to f . Thus, $\widetilde{p}_{21}^{max} < c_2$, when $f > 0$.

In the scenario discussed above, as firm 2 would never stay in business when its price is less than its marginal cost (c_2), it is impossible for firm 2 to charge a price lying between the range $[\widetilde{p}_{21}^{min}, \widetilde{p}_{21}^{max}]$ to inspire the buyer to buy strategically, which means the strategic buying would never happen in this situation. \square

Intuitively, $3(k - c_2) < c_2 - c_1$ indicates $c_2 - c_1$ is very large or $k - c_2$ is very small. Large difference between c_2 and c_1 suggests that firm 1 is much more efficient than firm 2 so that the loss the buyer bears resulting from intentionally buying from firm 2 to keep competition in the first period could not be made up by the gain from eliminating monopoly in the second period. Small $k - c_2$ implies k is small, which means the demand in the drug is small. The monopoly power comes from the monopoly firm could control the amount of the product in the market to control the price. If the demand in the market is already small it could be possible that the supply in monopoly exceeds the demand. Therefore, there is no or little loss for the buyer even though there is monopoly in the market and in turn there is no incentive for the buyer to buy strategically.

Proposition 4: If $3k + c_1 - 4c_2 > 0$, that is $3(k - c_2) > c_2 - c_1$, $\widetilde{p}_{21} =$

$[\widetilde{p}_{21}^{\min}, \widetilde{p}_{21}^{\max}]$ ⁶, the buyer buys strategically; when $\widetilde{p}_{21} = \widetilde{p}_{21}^*$ ⁷ the buyer's profit is the biggest in strategic buying.

Proof of Proposition 4:

$$\widetilde{p}_{21}^{\min}(f = 0) = \frac{1}{8}(3k + c_1 + 4c_2 - 3k - c_1 + 4c_2) = c_2$$

Because $\frac{\partial \widetilde{p}_{21}^{\min}}{\partial f} > 0$, $\widetilde{p}_{21}^{\min}$ is increasing with respect to f . Thus, $\widetilde{p}_{21}^{\min} >$

c_2 , when $f > 0$. □

Proposition 4.1: Firm 1 will prevent strategic buying if and only if $\frac{(k-c_1)^2}{8} >$

$$\left(\frac{k-c_1}{2} - \frac{f}{\widetilde{p}_{21}-c_2}\right)^2 - (\widehat{p}_{11} - c_1) \frac{k-\widehat{p}_{11}}{2} \text{ and } \left(\frac{k-\widehat{p}_{11}}{2}\right)^2 > \left(\frac{k-c_1}{4}\right)^2 + 2\left(\frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21}\right).$$

Proof of Proposition 4.1:

If firm 1 prevents strategic buying, the following two conditions must be satisfied:

$$\begin{aligned} \widehat{\pi}_b - \widetilde{\pi}_b &= \left(\frac{k-\widehat{p}_{11}}{2}\right)^2 + \left(\frac{k-c_1}{4}\right)^2 - 2\left(\frac{k-c_1}{4}\right)^2 - 2\left(\frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \right. \\ &\left. \widetilde{p}_{21}\widetilde{x}_{21}\right) = \left(\frac{k-\widehat{p}_{11}}{2}\right)^2 - \left(\frac{k-c_1}{4}\right)^2 - 2\left(\frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21}\right) > 0 \end{aligned}$$

$$\text{so, } \left(\frac{k-\widehat{p}_{11}}{2}\right)^2 > \left(\frac{k-c_1}{4}\right)^2 + 2\left(\frac{3}{4}k\widetilde{x}_{21} + \frac{1}{4}c_1\widetilde{x}_{21} - \frac{3}{4}\widetilde{x}_{21}^2 - \widetilde{p}_{21}\widetilde{x}_{21}\right) > 0$$

⁶ $\widetilde{p}_{21}^{\min} = \frac{1}{8}[(3k + c_1 + 4c_2) - \sqrt{(3k + c_1 - 4c_2)^2 - 48f}]$,

$\widetilde{p}_{21}^{\max} = \frac{1}{8}[(3k + c_1 + 4c_2) + \sqrt{(3k + c_1 - 4c_2)^2 - 48f}]$.

⁷ $\widetilde{p}_{21}^* = \frac{(3k+c_1+4c_2) \pm \sqrt{(3k+c_1-4c_2)^2 - 96f}}{8}$

and,

$$\widehat{\pi}_s - \widetilde{\pi}_s = (\widehat{p}_{11} - c_1) \frac{k - \widehat{p}_{11}}{2} + \frac{(k - c_1)^2}{8} - 2f - \left(\frac{k - c_1}{2} - \frac{f}{\widetilde{p}_{21} - c_2} \right)^2 + 2f > 0$$

$$\text{so, } \frac{(k - c_1)^2}{8} > \left(\frac{k - c_1}{2} - \frac{f}{\widetilde{p}_{21} - c_2} \right)^2 - (\widehat{p}_{11} - c_1) \frac{k - \widehat{p}_{11}}{2}$$

□

Chapter 4

CONCLUSION

The first essay explores a two-period dynamic model with one retailer and two firms which produce an identical product but with different constant marginal costs. The firm with higher marginal cost will exit the market if its revenue does not cover its cost. The analysis explains market conditions under which strategic buying is optimal, and how the two firms will respond to strategic buying. My results indicate that the smaller the cost advantage of firm 1 over firm 2 the greater the incentive for the retailer to buy strategically. The possible explanation is that when the technology or operation system or administration of firm 2, whatever makes its marginal cost higher than firm 1's, is close to firm 1, the price premium the retailer must pay to keep firm 2 in operation and maintain competition in the second period is small. Therefore, the retailer is more inclined to buy strategically to keep relatively weak firm in the market. The results also demonstrate that high fixed cost would deter the retailer from strategic buying. When the fixed cost is high enough, the incentive to concentrate purchases on a single firm to reduce the average cost dominates the incentive to keep competition in the market by splitting the demand to support firm 2. In addition, the results show an increase in demand in the downstream market could increase the retailer's willingness to buy strategically. My explanation on this is that the increase in demand gives the retailer more flexibility to split its demand between two firms. When

the retailer implements strategic buying, firm 1 would have an incentive to take action to deter his practice only if the rivalry between firm 1 and firm 2 is relatively severe (the difference in marginal cost is small). If the marginal cost of firm 2 is much higher than that of firm 1, firm 1 has no incentive to take any action. This makes sense as firm 1 could only gain much more from being monopoly in a market which would have been competitive if it doesn't take any action. Moreover, my results suggest that the better choice for firm 2 is to negotiate with the retailer for the optimal price so that it could make strategic buying more attractive to the retailer and raises the cost for firm 1 to take action.

The further study of this paper could go from relaxing the assumptions. Even though the generic drugs are 'identical' to the brand-name drugs, consumers could still have their different preferences generated by their brand loyalty, habits, geography or others. So, future study could focus on the heterogeneous products. On the other hand, the model in this paper assumes the market is perfectly informative and each participant knows others' movement very clearly before it makes its own decision. In reality, the market is not perfect so the probability may have to be involved in the study. In addition, further study could think about what would happen if the two firms could cooperate with one another. Last, some experiments could be conducted to test my conclusions.

ESSAY 2

EMPIRICAL STUDY: THE EFFECTS OF ANNOUNCEMENTS DURING THE DRUG APPROVAL PROCESS ON THE STOCK VALUATION OF THE CORRESPONDING PHARMACEUTICAL FIRMS

Chapter 5

INTRODUCTION

The pharmaceutical industry is a heavily regulated industry, where new drugs are subject to FDA approval. The FDA evaluates products for safety, efficacy and manufacturing quality. Furthermore, promotional messages must be limited to approved product characteristics. It is also a research-based industry investing about 17 percent of sales in R&D. The features of this industry require companies to invest in R&D. On one hand, the feature of one patent per product means original products after patent time lose market share rapidly as generics are introduced. The Hatch-Waxman Act (1984) made it easier and less costly for manufacturers to enter the market for generic drugs. Accordingly, pharmaceutical companies cannot grow continuously without continuous development and production of new drugs. On the other hand, medical needs of citizens always change and companies must produce blockbuster drugs and continue to do so to meet these needs and remain in good standing. Due to a combination of strict regulations including the difficulty in attaining new drug approval from the FDA, the expensive cost of intensive R&D involving money and time consuming clinical trials with uncertain outcomes, and the fierce competition from generics after expiration of patents, the valuation of the companies in this industry must be sensitive to the information related to these activities.

In spite of the broad interest in firms' R&D or innovations, the literature associating the process of a new product introduction to the sponsoring firm's stock valuation is limited, particularly in the pharmaceutical industry. Different from literatures focusing on the determinants of R&D expenditures (Hirschey, Skiba and Wintoki (2012)) or on the association between R&D spending and the firm's valuation or performance (Chan, Lakonishok and Sougiannis(2001); Eberhart, Maxwell and Siddique(2004)), this part of my dissertation makes contribution to our understanding of the pharmaceutical market by applying the traditional event-study method to empirically investigate whether announcements during a new drug approval process or the approval of the first-time generics influence the related firm's stock performance. The relevant announcements during a new drug approval process include submission of a new drug application (NDA), acceptance of a NDA by FDA, extension of the FDA review deadline, public disclosure of advisory committee recommendation, issuance of a complete response letter from FDA, resubmission of a NDA, and approval of a new drug application. In addition to submitting an application for a totally new drug, sometimes pharmaceutical companies apply for approval of new indications for their existing drugs to extend their patent to alleviate competition from generic drugs. I also examine the effect of approval of these new indications on the sponsoring firms' stock performance.

I construct the sample for each announcement mentioned above over the period from 2004 to 2011. The results reveal that extension of FDA review deadline, public disclosure of advisory committee recommendation, issuance of complete response

letter from FDA, approval of a new drug application and approval of the first-time generics have significant impact on the related firms' stock returns, while submission of a new drug application (NDA), acceptance of a NDA by FDA, resubmission of a NDA and approval of new indication have no significant impact on the stock returns. Among those events which have significant impact, significant negative abnormal returns are observed within a short time surrounding announcement of an extension of the FDA review deadline, issuance of a complete response letter from FDA, and approval of the first-time generics, which imply new drug development setbacks or large future profit losses; significant positive abnormal returns are observed within a short time surrounding public disclosure of an advisory committee recommendation, and approval of a new drug application, which indirectly or directly suggest new drug development success. The short-term abnormal returns support the efficient market hypothesis (EMH) that new information is absorbed quickly (efficiently) into market value of the firm. No sign reversal in the cumulative abnormal returns indicates that there is no overreaction to the events. The results are consistent when I partition my sample into big capital size, medium capital size and small capital size. Even though there are some different patterns of response in direction or in degree or in time frame to each event between the small capital group and the big capital group, most of the differences are statistically insignificant. In cross-sectional analysis on firm characteristic determinants of abnormal returns, I find the firm's leverage (total liability/total asset) and profitability (net income/total asset) significantly decrease the magnitude of negative abnormal returns in 'bad' events and institutional ownership

percentage, leverage and profitability significantly decrease the magnitude of positive abnormal returns in ‘good’ events.

The rest of paper is organized as follows. Chapter 6 is the literature review for event study, pharmaceutical industry and cross-sectional study; chapter 7 is the brief introduction of data and methodology; chapter 8 is empirical results and analysis; chapter 9 is the cross-sectional study of the determinants of excess returns; chapter 10 is the summary.

Chapter 6

LITERATURE REVIEW

Yu and Leistikow(2011) examine daily stock returns around one-day price declines of 10 percent or more for event stocks as well as their respective industry rivals to explore intra-industry contagion and the efficient market hypothesis. Abnormal return is the difference between actual daily return and the estimated daily return based on the Market Model. Cross-sectional average abnormal returns (ARs) of 41 trading days [-20, +20] and cumulative abnormal returns (CARs) for the [+1, +3] period and the [+4, +20] period are calculated and tested for statistical significance. They examine both the price movements of large cap(S&P 500) stocks for two periods, 1973-2006 and 1995-2006, and the price movements of small cap(S&P 600) stocks for 1995-2006 to see if the differences between them, noted by Cox and Peterson (1994), hold. Furthermore, they examine whether the post-event abnormal stock returns for the event firm and its rivals can be explained by prior event firm variables, net sales market share (MKTSHR), and the stock return correlation with its rival's stock return (CORR), and industry variables, including the degree of industry concentration (HHI) and the industry average stock return standard deviation (AVGSTD), as well as CAR for the [-20, 0] period (PRECAR). The results show the event firms' stock prices fall about 13 percent on the event day while their rivals' stock prices fall roughly only about a 30th as much. However, due to the number of

rivals, the dollar effect on the industry can be very large. Moreover, much of the rivals' stock price decline is delayed for a couple days, less so for the large cap stocks than for the small cap stocks, which is called as lag contagion. This prompts a feedback response upon the event firms' stocks that can be competitive with return reversal for a couple days [+1, +3], and a contagion over the longer [+4, +20] period in which the event firm's resumed stock price drops. The effect is less for large cap stocks than for small cap stocks. In addition, they find that the smaller the event, the smaller the event firm's pre-event market share, the more correlated the event firm and rivals' stock prices in the pre-event period, the less concentrated the industry, and the less risky the industry, the better the event firm's CAR is in the period [+4, +20], which confirms the intra-industry effect and feedback explanation for their results.

Savor (2011) examines how information affects the behavior of returns after significant stock price changes. The paper uses recommendation-issuing analyst reports as the proxy for the presence of public information and classifies those price shocks accompanied by newly released analyst reports as information-based and the remaining ones as not. It defines a firm's abnormal returns as its daily return in excess of its return predicted by a Fama French three-factor plus momentum model. Both regression analysis and calendar-time portfolios show no-information price events experience reversal, while information-based price events exhibit momentum, which means investors tend to underreact to relevant new information about a firm and overreact to other price movement factors (such as liquidity shocks). By incorporating headline-news based measures of information used in Chan (2003), Savor finds only

the presence of analyst reports results in drift even though the absence of information predicts reversal under both measures, suggesting analyst reports are more relevant to investors than newspapers. Then, Savor shows that investors can profit from the different market response to information released by analysts relative to other factors for price changes. It finds that long no-information losers and short no-information winners or long information-based winners and short information-based losers can earn annualized abnormal return of 20% or 16% over 20 trading days, both of which are substantially higher for shorter holding periods. Furthermore, Savor finds that the content of analyst reports matters. When the recommendations of the reports are consistent with the direction of the price movement, Savor documents a momentum; when the recommendations of the report contradict the price movement the paper finds reversals. Finally, Savor's results show stronger correlation between information-based price moves and future earnings shocks than no-information ones. All of the results and conclusions in this paper are robust by inclusion of various controls, different post-event horizons and various methods of calculating abnormal returns.

Fama, Fisher, Jensen and Roll (1969) examine security return behaviors of 940 splits occurring on the New York Stock Exchange from January, 1927, through December, 1959 to see whether there is "unusual" return behavior on a split security in the months surrounding the split and to what extent this unusual behavior can be accounted for by the relationship between splits and dividend changes. This paper finds that the estimated residuals from the regression of the adjusted security returns

on the general market returns could reflect the unusual return behaviors. The market realizes the association between stock splits and dividend increases and it incorporates the implication of a split into the price of a share at least by the end of the split month but most probably almost immediately after the announcement date, which is evidence of market efficiency. Moreover, this paper shows that the split causes price adjustment only to the extent that it is associated with changes in the anticipated level of future dividends. Last, the paper shows there is no extra return for investors using a split unless they have access to inside information concerning the split.

Brown and Warner (1980) randomly select and assign 250 samples of 50 securities and event dates to simulate a situation where event dates for different securities are not clustered. They find the differences in frequency of picking up present abnormal performance and in the power of the test between methodologies based on Mean Adjusted Returns, Market Adjusted Returns, and Market and Risk Adjusted Returns are quite small. However, when event dates are clustered in calendar time, the Mean Adjusted Returns method performs very poorly compared to Market Adjusted Returns and Market and Risk Adjusted Returns. Within the class of methodologies which adjust for market factors the differences between them are small when no risk clustering exists, regardless of whether or not there is event-date clustering; with systematic risk clustering, the Control Portfolio method is much less likely to spot a given level of abnormal performance than either a one-factor or a two-factor model. Moreover, this paper finds no evidence that the use of the Value-Weighted Index increases the power of the tests compared to the use of the Equal-

Weighted Index, and improper use of the Value-Weighted Index could cause considerable problems. Non-parametric tests did not improve the results found using a parametric test. Furthermore, this paper suggests that when the exact event time is uncertain studying the event over a longer period may be better; when the distribution of the time of abnormal performance is not sure, it is dangerous to merely check a CAR plot or the estimated level of abnormal performance. In conclusion, this paper points out that there is no evidence that more complicated methodologies convey any benefit beyond a simple, one factor market model, and might make the situation worse-off.

Brown and Warner (1985) randomly select 250 samples of 50 securities from the population of all securities whose daily returns are available in CRSP and randomly assign an “event- date” to each and use simulation procedures to examine how the particular characteristics of daily stock return data (such as non-normality, non-synchronous trading, autocorrelation and variance increase) affect event study methodologies. The paper finds the non-normality of daily returns has no obvious impact on event study methodologies, even if the sample is very small or event dates are clustered. Various methods measuring excessive returns have similar power with daily data. It also shows that using procedures other than OLS to estimate the market model with daily returns convey no clear-cut benefit in detecting abnormal performance, which applies to samples having trading frequencies systematically different from average. Moreover, the paper indicates the benefit from autocorrelation adjustments tend to be limited. It only has small but notable improvement in test

statistic specification in two special instances, when using a Mean Adjusted Return method with clustering or when samples are concentrated in AMEX. Furthermore, the paper finds that when event dates are not clustered, the gain from procedures assuming independence is substantial. Finally, this paper illustrates how variance increases in daily data can cause hypothesis test under standard event study procedures to become misspecified, and one of their proposed ways to address this problem is to partition the sample based on the effect of the event, such as whether the event is ‘good news’ or ‘bad news’.

Hirshleifer, Lim and Teoh (2009) use quarterly earnings announcement data from the CRSP-Compustat merged database and I/B/E/S from 1995-2004 to test directly whether competing signals could distract investors, causing market prices to underreact to relevant news. They perform univariate analysis and multivariate regression which controls for other possible determinants, such as firm characteristics, to examine how the number of earnings announcement by other firms affects a firm’s volume, announcement period return, and post-event return reaction to an earnings surprise. Their results are consistent with the investor distraction hypothesis. The paper shows that the larger number of competing announcements by other firms, the weaker is the announcement date price reaction to a firm’s own earning surprise, the lower is the transaction volume reaction is and the stronger subsequent post-earnings announcement drift is. These facts can be exploited by a trading strategy to make profit. Moreover, this paper finds that unrelated announcements have a stronger distraction effect on investors than related announcements; big surprises distract

investors much more strongly than small surprises; small firm announcements are more distracting than big firm announcements. Nevertheless, there is weak evidence that the distraction effect is weaker among firms with big market capitalizations or greater analyst following or institutional ownership; there is weakly stronger distracting effect of positive earnings surprises than negative earnings surprises on announcement period return, though no evidence shows asymmetry of the distraction effect in post-event drift.

Cornett, Tanyeri and Tehranian(2011) uses the sample of public and private nonfinancial U.S.-based enterprise mergers that transfer control rights from the target to the bidder announced between July 1, 1979 and December 31, 2004 from the Security Data Company's US Mergers and Acquisitions database and the sample of non-financial U.S.-based non-merging firms between 1979 and 2004 from the CRSP-COMPUSTAT combined database. They first perform multinomial Logit analysis by incorporating multiple merger motives to investigate the extent to which investors anticipate bidder and target firm merger candidacy. Second, they run various regressions to examine the effect of investor expectations on both bidder and target candidacy, on stock price responses to merger announcements. The results show the multinomial models used in this paper correctly estimate that bidders are more likely to propose bids than nonbidders and that targets are more likely to receive bids than nontargets, though the models do not do as well in predicting target candidates as they do in predicting bidder candidates. When the paper takes into account the different degree of predictability in bidder and target candidates, the difference between bidder

firm and target firm 3-day cumulative abnormal return around a merger announcement decreases significantly, which supports the hypothesis that to some extent the asymmetry in investor prediction of bidders and targets causes disparity in bidder and target cumulative abnormal returns around the announcement period.

Pindado, Queiroz and Torre(2010) demonstrate that firms value is positively dependent upon residual income and R&D spending and study how firm characteristics (including firm size, firm growth, free cash flow, market share, external financial dependence, labor intensity and capital intensity) affect market valuation of R&D spending. They use data for companies from Eurozone countries for which information is available for at least six consecutive years from 1986 to 2003 in the international database Worldscope. All the models in their paper are estimated by the GMM to eliminate individual heterogeneity and two or three period lagged explanatory variables are used as instruments to solve the endogeneity problem. The results reveal the relationship between firm value and R&D is correlated with some firm characteristics. Specifically, R&D spending has a greater impact on the firm value of large firms than small firms; a firm's growth positively affects the market valuation of its R&D spending; the impact of R&D on firm value is greater for firms with low free cash flow than for ones with HFCF; the higher the market share of a firm, the more effective the R&D spending and, therefore, the higher the market evaluation; high dependence on external financing negatively affects the firms valuation of R&D spending; labor intensity and capital intensity both have a negative effect on the relationship between firm value and R&D spending.

Lang and Stulz (1994) use data from the 1980s to investigate the relation between the market's valuation of a firm and its degree of diversification at a point in time. This paper uses the book value of assets and the estimated replacement cost of plant, equipment, and inventories to compute the denominator of Tobin's q ; it uses the market value of common stock and the book value of debt and preferred stock as the numerator of Tobin's q . It applies three measures of diversification: the first is to a Herfindahl index from the sum of the squared values of sales per segment as a fraction of total firm sales; the second is to a Herfindahl index from the firm's assets per segment; the third is simply the number of segments. This paper finds highly diversified firms (defined as those firms that report sales for five segments or more) have significantly lower mean and median Tobin's q than one segment firms and their q ratios are below one and below the sample mean and median, which supports the argument that highly diversified firms consistently have less value than specialized firms. This conclusion also holds when the analysis uses industry-adjusted Tobin's q . When the authors control for other possible explanatory variables (size, ability to access capital market and intensity of R&D) in the regression, the diversification discount reduces but is still significantly positive. Even though this paper indicates that there is negative relation between the degree of diversification and valuation, there is no definitive evidence showing the extent to which diversification hurts performance as the firms that become more diversified appear to perform poorly before becoming more diversified.

Giorgetti(2012) adopts a dynamic Bayesian panel probit model to investigate the impact of submarket concentration on a company's decision to enter at least one new submarket by diversification. She defines each submarket by the one digit ATC classification. This paper uses annual data on the sales of 208 international companies operating in 16 submarkets in 7 countries: Canada, France, Germany, Italy, Spain, UK and the U.S. from 1987 to 1998. In the probit model the dummy dependent variable is assigned to one when company i at the time t achieves sales in at least one of the submarkets in which its sales were zero at time $t-1$; otherwise it is zero. In addition to the regressor of interests, the lagged submarket concentration level faced by companies assessing entry decision, this paper controls for some other variables which may also have effect on the entry decision, including the company's size in the previous period, the number of submarkets in which it previously operated (diversification) , and the earlier entry decision. He finds a significantly negative relation between submarket concentration and the probability of entry, providing evidence of the relevant role of submarket concentration as an entry barrier rather than as an attraction to new entrants through higher markups over marginal costs. Moreover, this paper finds the company's size does not significantly influence the company's entry decision. The degree of diversification only has significantly negative impact on companies in Italy, Spain, and the United States. The earlier entry decision has a significantly positive relation to the entry decision in Italy but significantly negative relation to the entry decision in France.

Frutos, Ornaghi and Siotis(2012) present a Hotelling model of competition among prescription drugs with different quality/side effects that are still under patent protection. They assume the firms play a two-stage game. In the first stage both firms simultaneously make decisions on their persuasive advertising expenditure and in the second stage they compete in price. Promotional effort generates two market segments: brand-loyal and non-brand loyal. Brand-loyal consumers only make a choice between the drug they are loyal to and no prescription. In contrast, non-brand loyal consumers compare both drugs available. Thus, non-brand loyal doctor/patient pairs are more sensitive to price changes. This paper fully characterizes equilibria under parameters that have been chosen to reflect real world conditions, which creates three empirical predictions regarding price and advertising strategies. The paper uses quarterly data on value and sales volume of all prescription drugs sold in the USA during the period 1994q1-2003q4 from IMS Health, complemented with product level data on detailing from IMS and the corresponding data on DTCA (direct-to-consumer advertising) from TNS Media. Proxies of the quality of the drugs are collected from the Orange Book published by FDA. The paper estimates equations controlling for drugs' age and market concentration by panel data methods and a random effect estimator. The empirical results indicate promotional effort and prices are strategic complements as equilibrium prices are higher the higher advertising expenditure is. And, advertising efforts between the two competitors are strategic substitutes. Moreover, asymmetries in drug quality result in asymmetries in promotional effort.

The better quality drugs are also the ones most advertised. Furthermore, larger co-payments results in lower aggregate advertising expenditures and in lower prices.

Frank and Salkever (1997) examine price responses to generic entry in the market for both brand-name and generic drugs. They use the data of non-antibiotic prescription drugs with relatively large sales which faced generic competition for the first time over the period 1984-1987. The data indicates an upward drift in real brand-name prices but a downward drift in generic prices and in the ratio of generic to brand-name price after the generic entry. This paper uses three models to estimate the correlation between the number of generic competitors in the market and the price of brand-name or generic drugs. The first model is a single-equation fixed-effects model where the number of nonoriginator drug sellers in the market (NMFT) is treated as exogenous and time and compound specific fixed effects are considered. Another two models are two-stage models where NMFT is considered as endogenous. One model uses a two-stage least-square fixed-effects estimator, the other model uses a random-effects estimator in the first stage as the instruments, the market size and the age of the market, included in the model are time-invariant, and a fixed-effects estimator in the second stage. The results from all three models consistently support what the data itself presents. So, this paper provides evidence that only generic drug producers face severe price competition and the elasticity of demand in brand-name drugs decreases after generic entry as this segment is quality-cautious.

Wiggins and Maness (2004) uses retail-level pharmacy transaction data over 1984-1990 to study the relationship between price and the number of sellers focusing

on anti-infective segment. They assume the number of generic entrants is exogenous and conduct the Cournot-like model as well as the nested model which allows for potential nonlinear vintage effects. Following previous articles, this paper introduces instruments to control for other factors that might affect prices. The instruments include the number of other sellers in the appropriate broader category of anti-infectives to control for possible competition from related products, a dummy for versions of the same molecule sold by other innovative companies to control for brand recognition, fixed effects of product age, product group and year to control for cost and demand differences. In contrast to conclusion of previous articles about the effect of generic entry on the pharmaceutical prices, this paper finds a significant negative relationship between price and the number of competitors, whether those competitors are brand name or generic producers. The estimates indicate that an increase in the number of sellers leads to price decreases over a large range for both branded and generic drugs. But the prices of generic drugs decrease more while the prices of brand-name drugs stabilize when there are large numbers of sellers. Their results undermine the segment hypothesis discussed in previous articles. They provide some explanations for the different results. The sample they use is much larger than in prior studies. In addition, they are not only interested in drugs facing generic competition for a short period but also in those off-patent for a number of years. Most important, they do not study the general pharmaceutical industry, instead they focus on one segment of the industry---anti-infectives which allows them to control for cost and demand effects more easily.

Rizzo and Zeckhauser (2009) perform a two-equation structural model to examine how generic script share affects the average price of the brand-name drugs. They are the first time to test how the mix of consumer choices between generic drugs and brand-name drugs might affect average prices of brand-name drugs that are still purchased. In the first stage of the model, they estimate the individual's generic script share as a function of a vector of sociodemographic and health factors and of several instruments. The predicted value of the dependent variable in the first stage is used as an explanatory variable in the second stage. They use nationally representative panel data on drug utilization and cost, including adults aged 25-64 for the period 1996-2001, from the Medical Expenditure Panel Survey (MEPS). By controlling for age, education level, race, ethnicity, gender, income, marital status, health insurance status and health status, this paper finds a large and significantly negative relation between generic script share and consumers' out-of-pocket prices of brand-name drugs. In particular, a 10% increase in generic script share produces a 15.6% decline in the average consumers' out-of-pocket cost per script for the remaining brand-name drugs. In contrast, it does not find a significant effect of generic script share on the average net price paid by insurers, but overall prices of brand-name drugs decline significantly. The conclusion indicates that brand-name prices to consumers matter greatly. Even though previous articles suggest a positive relationship between generic entry and the corresponding brand-name manufacture prices, this paper shows consumer choice could actually decrease the average prices of the branded drugs continuing to be bought.

Ammann, Berchtold and Seiz (2011) analyze the relationship between demographic changes in age group and the demand for different pharmaceutical drugs as well as its influence on stock returns and profits over 20 years. They obtain demographic data from the US Census Bureau, drug age patterns from Medical Expenditure Panel Survey, sales of 20 main drugs of each of the 61 pharmaceutical companies from 1986 to 2008 from Evaluatepharma Database and profits and returns of each company from 1986 to 2008 from Datastream. First, they construct the demand growth rates of the 61 pharmaceutical companies due to demographic shifts for 1986-2008 by combining annual weights in each company with annual demand growth rates of each age profile. Second, they use panel regression to investigate the relationship between changes in the demand growth rates and pharmaceutical companies' profits and stock returns in the short term and in the long term. Third, they form the zero-investment portfolio by the results from the second step to test various trading strategies. The results of panel regressions shows that long-term forecastable demand growth predicts 3 to 5 percentage points in abnormal stock returns while short-term forecastable demand growth has a significantly negative influence on abnormal stock returns. This suggests that investors are inclined to overreact to short-term information and be inattentive to the distant future information. They also find a trading strategy taking advantage of the limited attention by investors related to demographic information could earn an annual abnormal return between 6 to 8 percent.

Chaney, Devinney and Winer (1991) use the traditional event-study approach to analyze the impact of new product introductions on the market value of 231 firms with 1101 announcements for the years 1975-84. First, they find the smallest window (-1, +1) has the biggest significant excess return, 0.25%, comparing with windows (-3, +3), (-5, +1) and (-5, +5). Second, their results indicate firms that make original-product announcements or multiple-product announcement have significantly higher excess returns than those making update-product announcements or single-product announcement. Afterwards, they regress CAR (-1, +1) on several specific variables and find firm size has no relation to the significance and magnitude of the excess return from a new product announcement, while the number of product announcements made by the firm over 10 years and the firm's system risk are negatively related to the excess return. This paper studies all industries and my paper focuses on the pharmaceutical industry. And this paper doesn't specify how to define product introduction in the pharmaceutical industry.

Sharma and Lacey (2004) investigate empirically the effects of public announcements of the FDA decisions to approve or to reject the New Drug Applications on the stock market valuation of the sponsoring firms. They conduct the analysis on a total of 344 approvals and 41 outright rejections by the FDA using the traditional event-study method. The analysis shows significant positive abnormal returns 3 days around the public announcements of the approvals and significant negative abnormal returns 3 days around the public announcements of the outright rejections, and there is no effect outside the event window. The pattern of abnormal

returns indicate the market absorb the information about new drugs efficiently into the stock valuation of the sponsoring firms and reward the firms who develop a new drug successfully while punish the firms who fail to deliver an anticipated new drug. In addition, the result that the CAR over 3 days for the sample of success is significantly smaller in magnitude than the CAR over 3 days for the sample of failure confirms the asymmetry in response of the market to success and disappointment: the market tend to respond more severely to disappointment than to success. Even though this paper mentions that managers in the firms should consider ways to hedge the risk that the market will adversely respond to negative information more severely, it does not shed any light on this point. Moreover, this paper just studies the effects of approval and outright rejection. However, other announcements during the whole approval process may affect stock valuation of the sponsoring firms. These announcements are analyzed in the present study.

Perez-Rodriguez and Valcarcel (2012) match large price changes, which are detected by an Autoregressive Moving Average-Generalized Autoregressive Conditional Heteroscedasticity (ARMA-GARCH) dynamic econometric model from the 17 worldwide biggest pharmaceutical firms from 1989 to 2008, with news produced during the drug R&D process (approval of new drugs, clinical trial results, FDA recalls, market withdrawals and safety alert information) to analyze whether extreme price changes of pharmaceutical stocks reflect unexpected information produced during the product R&D process and whether overreaction exists. Their results indicate the approval of new drugs by FDA has a significant impact on the

stock return in the ± 2 days around the approval date while extreme abnormal price spikes happen when results of clinical trials are better than expected in some cases. Negative large abnormal returns could be connected with bad news, such as negative results of clinical trials, the withdrawal of drugs from the market, FDA recalls or restrictions or warnings or rejections, and company announcements concerning the failure of clinical trials. The insignificant CAR for 1, 2, 5 and 10 days following a large price increase or decrease implies no overreaction occurs in the market.

Bartoloni (2013) applies the Granger-Causality approach and the static and dynamic econometric models of a firm's leverage to particularly investigate the role played by a firm's innovation and profitability in choice of the firm's capital structure using 2,591 industrial firms operating in Italy from 1996 to 2003. The results reveal a negative relationship between a firm's debt ratio and return on sales, indicating more profitable firms tend to use internal finance more. In addition, a positive relationship is found between alternative proxies for innovation intensity and a firm's debt ratio in both static and dynamic models, regardless of firm size, implying the need for external finance increases with the innovative effort.

Korteweg (2010) uses a panel data set of firms over the period 1994 to 2004 to estimate the present value of net benefits to debt financing, which are identified from the market values and betas of corporate debt and equity, as a function of firm-specific variables. The results reveal that low market-to-book firms with many tangible assets, low depreciation, high profitability and low volatility of earnings have higher net benefits at all leverage ratios and net benefits invariably increase and then decrease as

leverage increases, implying the existence of an optimal capital structure. On average, the maximum attainable net benefits are about 5.5% of firm value. The results also shed light on the effect of firm characteristics on optimal capital structure. Contrary to results in previous literature, a strong positive relation between profitability and optimal capital structure and a negative relation between size and optimal leverage are observed in this study. The difference occurs because, unlike cross-sectional regression used in prior empirical studies, the identification employed in the paper doesn't assume firms are optimally levered. In addition, the results indicate firms are generally slightly underlevered.

Aggarwal and Zhao (2007) estimate the relationship between leverage and firm value controlling for industry effects and other firm characteristics using a set of panel data on publicly traded non-financial US firms for the period from 1980 to 2003. Contrary to prior studies which indicate that leverage is negatively associated with firm value for high growth firms and positively associated with firm value for low growth firms, the results in this paper suggest leverage is always value reducing, regardless of the growth opportunity of firms.

Ozdagli (2012) extends the investment irreversibility model with corporate taxes, debt, and a stochastic discount factor which captures investor risk preference in order to analyze the effects of financial leverage on investment and to explain the positive relation between book-to-market values and stock returns. The analysis shows that financial leverage increases effective investment irreversibility through the

interest tax-shield and that investment irreversibility weakens the relation between stock returns and book-to-market values.

Chan, Lakonishok and Sougiannis (2001) address the importance of firms' R&D spending and examine whether stock price fully incorporates R&D expenditures. First, the paper points out that R&D activity represents a significant and growing portion of firm resources, but current accounting practices distort its effect on earnings. Failing to adjust standard valuation measures for long-term benefit of R&D would result in substantial mispricing. Second, the results reveal a comparable yearly average return between stocks in companies doing R&D and stocks in companies doing no R&D, implying no direct link between R&D spending and future stock returns. The average excess return of stocks with high R&D relative to the market value of equity over the three postformation years is 6.12 percent per year, providing evidence that an association between R&D intensity and future returns is not strong. However, they do find R&D intensity is associated with return volatility controlling for firm size, age and industry effects.

Eberhart, Maxwell and Siddique (2004) construct a sample of 8313 cases where firms unexpectedly increase their research and development expenditures by a substantial amount over the period from 1951 to 2001 to investigate the long-term (5-year period) stock returns and operating performance of firms following the unexpected R&D increases. They find significantly positive long-term abnormal stock returns and operating performance following the increases, implying R&D increases

are beneficial investments, but that markets underreact to the benefit of R&D increases.

Hirschey, Skiba and Wintoki (2012) use a sample of all publicly traded firms over the period from 1976 to 2010 to examine the distribution of R&D spending across industries and firm size classes and how aggregate R&D spending changes over time. Their results reveal R&D spending transfers from the government to the business sector over time and that corporate R&D spending grows twice as fast as advertising and capital expenditure. However, R&D spending varies across firm sizes and industries. Medium-size firms have contributed more to the growth in R&D spending than the largest firms and a few high-tech sectors account for a substantial share of R&D activity. In cross-sectional analysis, they find time-invariant firm and industry fixed effects explain 70% of the cross-sectional variation in R&D spending while time-varying factors like size, market-to-book, leverage or profitability account for less than 3%. In addition, this paper provides little evidence to support the managerial myopia hypothesis. In contrast, the results indicate the willingness of managers to invest a large share of current profit in long-term R&D projects with uncertain payoffs and no intent to reduce it even during the 2008-2010 financial crises.

Chapter 7

DATA AND METHODOLOGY

7.1 Data

The data used to study the stock performance surrounding the event dates is subject to the following criteria:

1. An unambiguous announcement date from January 2004 to December 2011 could be found in 'drugs.com', Orange Book published by FDA or Pharmaceutical companies' website.
2. The unambiguous announcement dates are at least 20 days apart from their previous event dates.
3. The firms are listed on the NYSE, the AMEX, or the NASDAQ and their daily returns from July 1, 2003 to June 30, 2012 are available in CRSP.
4. The daily returns for [-100,-11] pre-event estimated period and for 21 days surrounding each event date should be complete.

According to the criteria mentioned above, I have 118 samples from 65 listed pharmaceutical companies for submission; 104 samples from 62 public pharmaceutical companies for acceptance; 39 samples from 30 listed pharmaceutical companies for extension of FDA review deadline; 51 samples from 36 public pharmaceutical companies for Public Disclosure of Advisory Committee Recommendation; 62 samples from 47 public pharmaceutical companies for Issuance

of Complete Response Letter from FDA; 38 samples from 32 public pharmaceutical companies for resubmission; 188 samples from 91 public pharmaceutical companies for approval of an application; 42 samples from 25 public pharmaceutical companies for approval of new indications; and 163 samples from 32 public pharmaceutical companies for approval of the first-time generics.

7.2 Methodology

There are three primary methods to calculate abnormal return. First, the stock daily abnormal return is the daily individual return in excess of the daily market return, which is called the single-index market model (SIMM). Second, the stock daily abnormal return is the difference between the actual daily return and the expected daily return based on the market model estimated over a pre-event period. Third, the stock daily abnormal return is the daily individual return in excess of the predicted return from the Fama-French three-factor plus momentum model. However, Brown and Warner (1985) find that there is insufficient evidence to suggest that any one method used to calculate abnormal return produces appreciable differences in results. In this paper, I use the second method to calculate abnormal return to check how pharmaceutical companies' stocks response to each milestone during the process of their drugs' applications and approvals mentioned above and what implications of these responses are for investors.

First, I set the news announcement date of each critical event of each sample as the event date. I construct my event windows for 21 days surrounding the event date $([-10, 10])$ to observe any pattern of stocks abnormal returns and cumulative abnormal

returns (since all the event dates are from news published on websites, the date may not be the exact date when the event happens⁸). I define the event date as event date zero (Edate=0), the prior N days to the event date zero as date -N (Edate=-10,...,-1), and the post N days after the event date as date N (Edate=1,...,10).

Second, the daily abnormal return (AR) of each company j for each day t over the [-10, 10] period is calculated as:

$$AR_{j,t} = R_{j,t} - (\hat{\alpha}_j + \hat{\beta}_j R_{m,t})$$

where,

$AR_{j,t}$ is the daily abnormal return of event firm j on day t ;

$R_{j,t}$ is the actual daily return of event firm j on day t obtained from CRSP;

$R_{m,t}$ is the daily equal-weighted market return excluding dividends on day t obtained from CRSP;

$\hat{\alpha}_j, \hat{\beta}_j$ are the estimated parameters from firm j 's market model based on the pre-event period [-100, -11].

The cumulative abnormal return is the sum of abnormal returns over certain period, which is calculated by $CAR_j = \sum_{-11}^t AR_{j,t}$. Mean AR_t is the arithmetic average

of N samples' ARs on each day t ($\overline{AR}_t = \frac{\sum_{j=1}^N AR_{jt}}{N}$) and mean CAR_t is the arithmetic

average of N samples' CAR on each day (t) ($\overline{CAR}_t = \frac{\sum_{j=1}^N CAR_{jt}}{N}$). The cumulative

⁸ Brown and Warner (1985) finds if the event date is not accurate study over longer period may provide better results.

abnormal return is not only calculated over the whole window but calculated over period including different days in the window. Abnormal returns and cumulative abnormal returns would be observed and analyzed jointly to detect possible stock abnormal performance surrounding the events.

Chapter 8

EMPIRICAL RESULTS

8.1 Results For All Sample

8.1.1 Submission

Once a company develops a drug, it undergoes around three and a half years of laboratory testing before an application is made to the U.S. FDA to begin testing the drug in human. Only one in 1000 of the chemical compounds that enter laboratory testing could ever forward to human testing. There will be three phases of clinical trials on human which last about 6 years in total. If the drug demonstrates to be safe and effective the company would file a New Drug Application (NDA) to the FDA. So, submission of an NDA is a signal for positive results of clinical tests and shows the company's confidence on this new drug. Thus, I assume stocks' abnormal returns surrounding submission would be positive and cumulative abnormal return would drift upwards.

Table 2, table 3, figure 1 and figure 2 summarize the most important results for submission. Table 3 shows that none of cumulative abnormal returns are significant over different intervals, which can be explained by the results in table 2. Marginal and statistically insignificant abnormal returns happen in the whole window except for day 3 and day 10 when abnormal returns are marginal but one is significantly negative and the other is significantly positive, which can be treated as random behavior. Figure 1

confirms the random behavior, in which I can observe abnormal returns slightly move around 0. Though cumulative abnormal returns are insignificant, figure 2 demonstrates an overall downward trend in CARs even though there is an upward turn on day 0 and day 1. The trend in figure 2 is consistent with the results in table 1, where the fact that less than 50 percent of stocks have positive abnormal return occurs in most of days over the window. The results are against the hypothesis that submission is a good signal to the market and the market should respond positively to this news so that abnormal returns and cumulative abnormal returns would be positive. One of possible explanations of this behavior is that submission may not be new information when it comes to public. Before companies submit their applications they already went through three phases, about 6 years of clinical trials and published the results. The market may already anticipate a submission based on the disclosed information and adjust the stock prices long before it becomes public information. The downward cumulative abnormal returns we observe surrounding submission might be the adjustment of previous overreaction to the good clinical results.

Table⁹ 2 ARs and percentage of positive stocks for submission

Day	N	AR	Positive (%)
-10	118	-0.0016	0.40**
-9	118	0.0017	0.53
-8	118	-0.0019	0.42*

⁹ In all of the tables from here on, *** indicates statistical significance at the 0.01 level; ** indicates statistical significance at the 0.05 level; * indicates statistical significance at the 0.10 level.

Table 2 continued

-7	118	-0.0012	0.47
-6	118	0.0015	0.55
-5	118	0.0011	0.49
-4	118	-0.0085	0.42*
-3	118	-0.0031	0.45
-2	118	0.0041	0.49
-1	118	-0.0017	0.45
0	118	0.0038	0.53
1	118	0.0019	0.51
2	118	-0.0016	0.42*
3	118	-0.0055**	0.42*
4	118	-0.0030	0.41**
5	118	0.0006	0.44
6	118	-0.0019	0.39**
7	118	-0.0019	0.46
8	118	0.0017	0.56
9	118	0.0014	0.50
10	118	0.0070**	0.52

Table 3 CARs for different intervals surrounding submission

Interval	CAR
[-10, -1]	-0.012
[0, 1]	0.006
[0, 5]	-0.004
[0, 10]	-0.003
[-10, 10]	-0.013

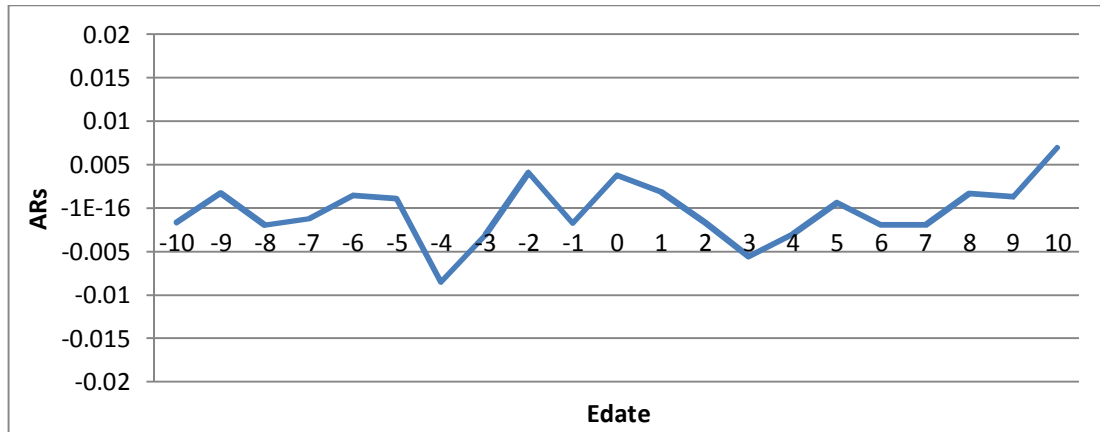


Figure 1 ARs for 21 days surrounding submission

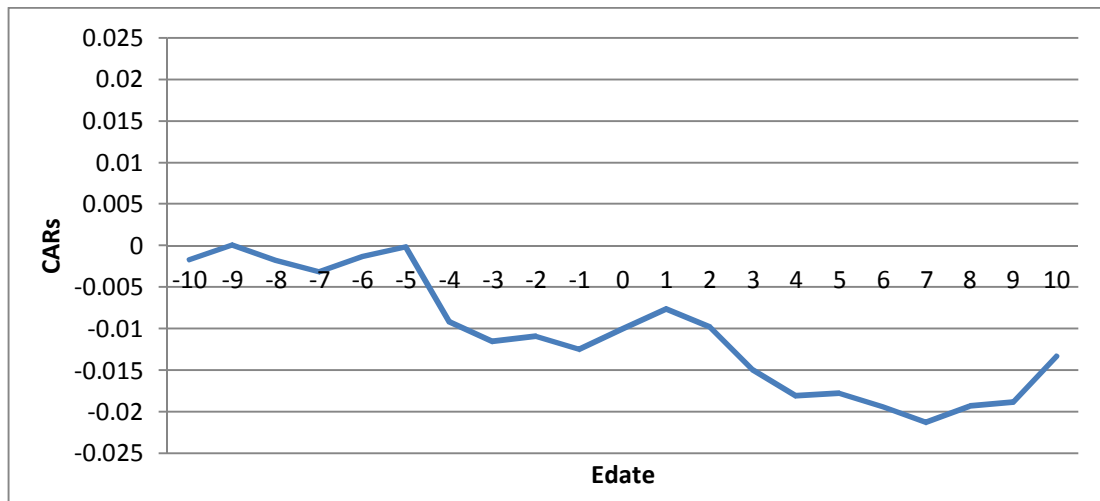


Figure 2 CARs for 21 days surrounding submission

8.1.2 Acceptance

The primary empirical results for acceptance are summarized in table 4, table 5, figure 3 and figure 4. Figure 3 indicates abnormal returns surrounding acceptance randomly distribute around 0. Table 4 shows abnormal returns over the 21 days are pretty close to 0 and all of them except for two days are statistically insignificant. The fact that more than 50 percent of stocks have positive abnormal returns happens in half

of days over the period. Table 5 shows none cumulative abnormal return in any interval under study is statistically significant. Figure 4 demonstrates no trend in cumulative abnormal returns which distribute closely around 0. The results imply that the announcement of acceptance of application by FDA does not generate any influence to the market. There are at least two reasons could explain it. First, usually FDA announces acceptance of an application in three months after a firm submits it. FDA makes the acceptance decision only based on whether the required documents are complete or not. Therefore, the announcement of acceptance is easily expected by market. Acceptance is not news but not accepted might be a shock to the market. Second, accepted by FDA doesn't suggest anything valuable about final decision of approval and after an acceptance the process would take up to two and a half years so that it couldn't attract enough interest from investors to adjust the prices.

Table 4 ARs and percentage of positive stocks for acceptance

Day	N	AR	Positive (%)
-10	104	0.0000	0.47
-9	104	0.0011	0.53
-8	104	-0.0010	0.42
-7	104	0.0010	0.52
-6	104	-0.0008	0.49
-5	104	-0.0028	0.50
-4	104	0.0035	0.49
-3	104	0.0000	0.54
-2	104	-0.0050**	0.39**
-1	104	0.0015	0.43
0	104	0.0030	0.60**
1	104	-0.0040	0.50
2	104	0.0023	0.52
3	104	-0.0015	0.37***

Table 4 continued

4	104	0.0000	0.42
5	104	-0.0070	0.47
6	104	-0.0012	0.45
7	104	-0.0015	0.47
8	104	0.0024	0.49
9	104	0.0036	0.56
10	104	0.0040*	0.57

Table 5 CARs for different intervals surrounding acceptance

Interval	CAR
[-10, -1]	-0.004
[0, 1]	-0.002
[0, 5]	-0.001
[0, 10]	0.006
[-10, 10]	0.002

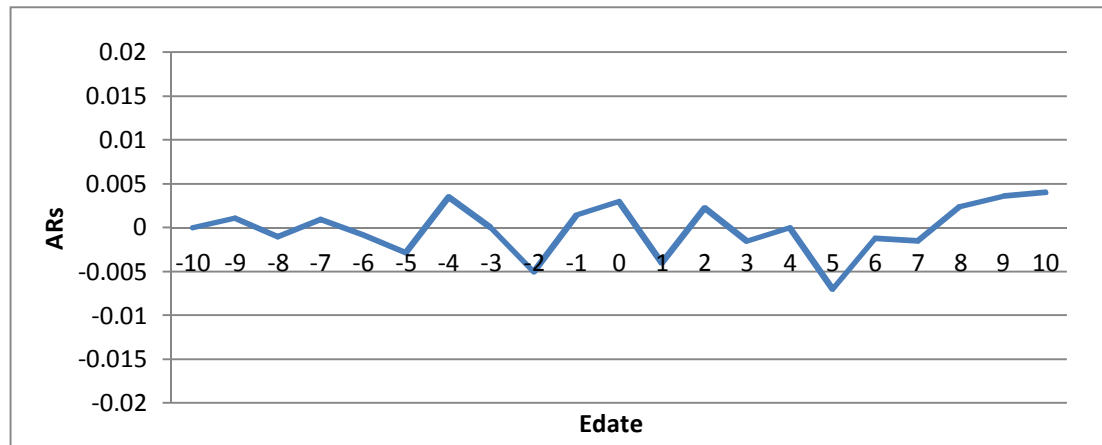


Figure 3 ARs for 21 days surrounding acceptance

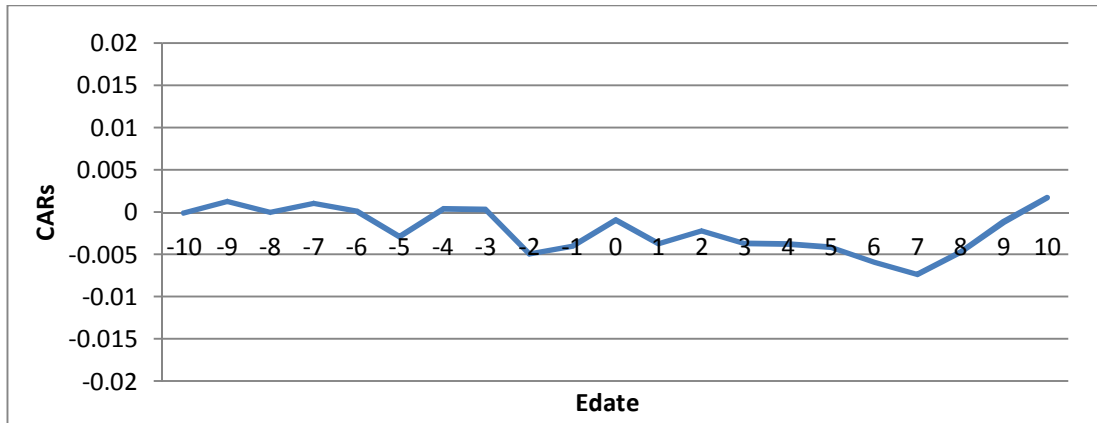


Figure 4 CARs for 21 days surrounding acceptance

8.1.3 Extension of FDA Review Deadline

The important empirical results are summarized in table 6, table 7, figure 5 and figure 6. Table 7 shows that cumulative abnormal returns are statistically significant and negative since the event date. Figure 6 confirms the results in table 7 but more straightforwardly. Figure 6 indicates cumulative abnormal return curve substantially goes down below 0 since day -1 and continues downward trend for the rest of days in the window until day 9 when it gets stable and reaches -0.06. The results in table 6 that big negative abnormal return -0.02 with statistical significance at the 0.10 level happens on day 0 and negative abnormal return -0.0075 with statistical significance at the 0.05 level occurs on day 3 could explain why cumulative abnormal returns are significantly negative in any interval after day 0 in table 7. Even though after day 3 abnormal returns are insignificant, there are negative abnormal returns in most of days which results in the persistent significance of cumulative abnormal return over interval [0,5] and [0,10]. Table 6 also shows from day 1 to day 3, only 31 percent, 36 percent

and 28 percent firms have positive abnormal returns, respectively, and the results are statistically significant, which correspondence to the significantly negative average abnormal returns in these days . The results suggest that the announcement of extension of FDA review deadline is not able to be expected by the market and it is a negative signal to market. Since FDA could not finish reviewing the application in a designated time it may indicate that there might be some ambiguous points in the application or FDA could not be positive to the effects or safety of the new drug, which warns investors that the future of the new drug application is not bright. Because the influence of extension of FDA review deadline even lasts 10 days after it is announced, the market may not be able to respond to this particular public information very quickly.

Table 6 ARs and percentage of positive stocks for extension of FDA review deadline

Day	N	AR	Positive (%)
-10	39	-0.0009	0.46
-9	39	-0.0073	0.38
-8	39	0.0072	0.51
-7	39	-0.0094*	0.33**
-6	39	-0.0013	0.54
-5	39	-0.0021	0.49
-4	39	-0.0034	0.41
-3	39	0.0036	0.64*
-2	39	0.0040	0.46
-1	39	-0.0047	0.56
0	39	-0.0200*	0.39
1	39	0.0010	0.31**
2	39	-0.0078	0.36*
3	39	-0.0075**	0.28***
4	39	0.0035	0.56

Table 6 continued

5	39	-0.0019	0.44
6	39	0.0000	0.41
7	39	-0.0016	0.41
8	39	-0.0029	0.41
9	39	-0.0043	0.46
10	39	0.0032	0.54

Table 7 CARs for different intervals surrounding extension of FDA review deadline

Interval	CAR
[-10, -1]	-0.014
[0, 1]	-0.022**
[0, 5]	-0.035***
[0, 10]	-0.040**
[-10, 10]	-0.056***

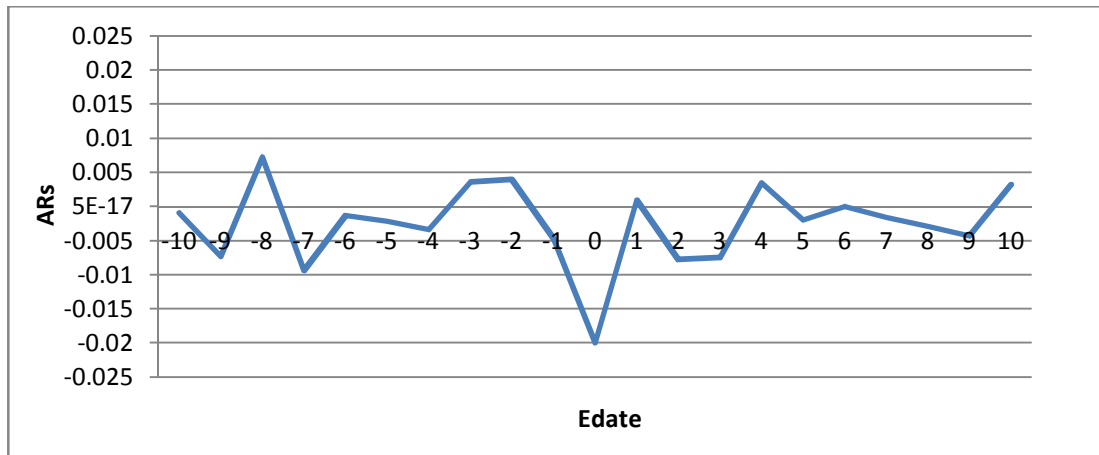


Figure 5 ARs for 21 days surrounding extension of FDA review deadline

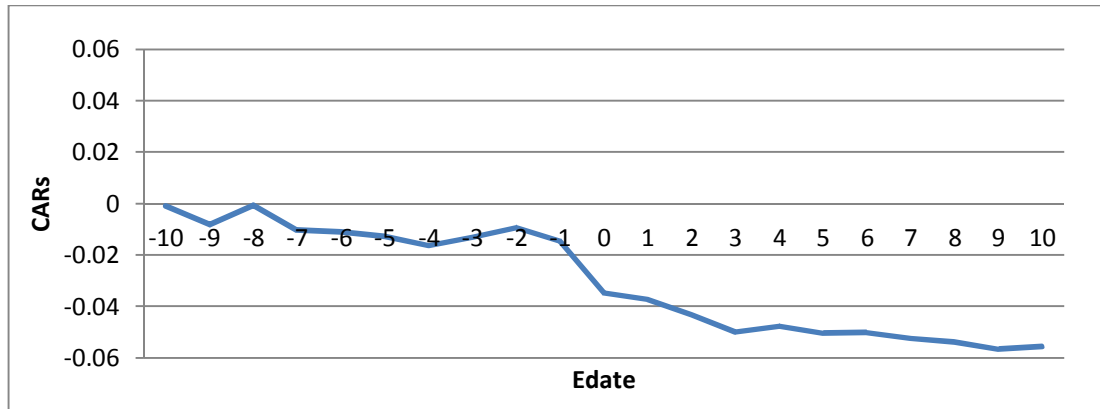


Figure 6 CARs for 21 days surrounding extension of FDA review deadline

8.1.4 Public Disclosure of Advisory Committee Recommendation

Advisory committees consist of outside experts with minimum conflict of interests. They provide FDA with independent opinions and recommendations on approval or disapproval of applications, based on summary information about the applications, including data to show the safety and effectiveness of new drugs, and copies of FDA’s review of the applications. FDA generally follows an advisory committee’s recommendation, but not necessary. Theoretically, I could expect negative abnormal return to disapproval recommendation and positive abnormal return to approval recommendation. The results of the whole sample depend on the proportion of the approval recommendations and the disapproval recommendations and the degree of the influence of them. However, the samples of public disclosure of advisory committee recommendation in this paper which are found in ‘drugs.com’, orange book and companies’ websites are those which are eventually approved, so most of them are positive recommendations, which give market an expectation that the

applications are probably approved by FDA in the future. Therefore, I assume positive abnormal returns surrounding the disclosure. I do two analyses: one is with all samples and the other is with samples excluding the disapproval recommendations.

The primary results are summarized in table 8, table 9, figure 7 and figure 8. Table 9 indicates that only cumulative abnormal return in the sample where disapproval recommendations are excluded over $[-10, 0]$ is statistically significantly positive and its magnitude is bigger than any cumulative abnormal return over any period after the event. Table 8 explains the results in table 9. Comparing the results with the disapproval recommendations to the results without the disapproval recommendations in table 8 we could see improvement in size and significance in the latter. There is no significantly positive abnormal return in the window when I include the disapproval recommendations in the sample. When I exclude the disapproval recommendations from the sample there is substantial and significant positive abnormal return happening on day -3 and day -1, which is 0.0281 and 0.0262 respectively. Figure 7 and figure 8 show the performance of the sample without the disapproval recommendations beats the performance of the sample with the disapproval recommendations, but their patterns are similar. They both have substantial positive abnormal return from day -3 to day 0 and since day 3 the abnormal returns randomly distributes about 0. The cumulative abnormal return begins to increase obviously on 3 days preceding the event and continuously goes up to day 0, but there is almost no further systematic movement thereafter. The significant positive abnormal return occurring in the 3 days preceding the public disclosure rather than on

the event day or thereafter suggests information leakage may occur before public disclosure of advisory committee recommendation and the market incorporate the information so fast that there is no significant response when the information comes to the public, which implies this market is not strong efficient. The results do satisfy my assumption that approval recommendations release a positive signal to the market.

Table 8 ARs and percentage of positive stocks
for public disclosure of advisory committee recommendation

Day	Include the disapproval recommendations			Exclude the disapproval recommendations		
	N	AR	Positive (%)	N	AR	Positive (%)
-10	51	0.0022	0.57	44	0.0030	0.59
-9	51	-0.0013	0.43	44	-0.0008	0.45
-8	51	-0.0009	0.59	44	-0.0032	0.57
-7	51	-0.0030	0.39	44	-0.0031	0.36
-6	51	-0.0026	0.41	44	-0.002	0.41
-5	51	-0.0034	0.39	44	-0.0021	0.41
-4	51	0.0000	0.43	44	0.0004	0.43
-3	51	0.0181	0.59	44	0.0281*	0.61
-2	51	0.0014	0.55	44	0.0075	0.64*
-1	51	0.0184	0.49	44	0.0262*	0.52
0	51	0.0027	0.45	44	0.0149	0.48
1	51	0.0011	0.42	44	-0.0040	0.44
2	51	-0.0085***	0.31***	44	-0.0087***	0.31***
3	51	0.0011	0.41	44	0.0028	0.41
4	51	0.0009	0.43	44	0.0005	0.43
5	51	0.0004	0.37*	44	0.0033	0.41
6	51	-0.0007	0.45	44	0.0012	0.52
7	51	-0.0042	0.39	44	-0.0045	0.39
8	51	0.0002	0.49	44	0.0016	0.52
9	51	-0.0001	0.51	44	0.0004	0.55
10	51	0.0020	0.63**	44	0.0032	0.67**

Table 9 CARs for different intervals surrounding public disclosure of advisory committee recommendation

Interval	CAR(Include approval recommendations)	CAR(Exclude disapproval recommendations)
[-10, -1]	0.030	0.054*
[0, 1]	0.006	0.012
[0, 5]	0.015	0.026
[0, 10]	-0.001	0.012
[-10, 10]	0.055	0.090

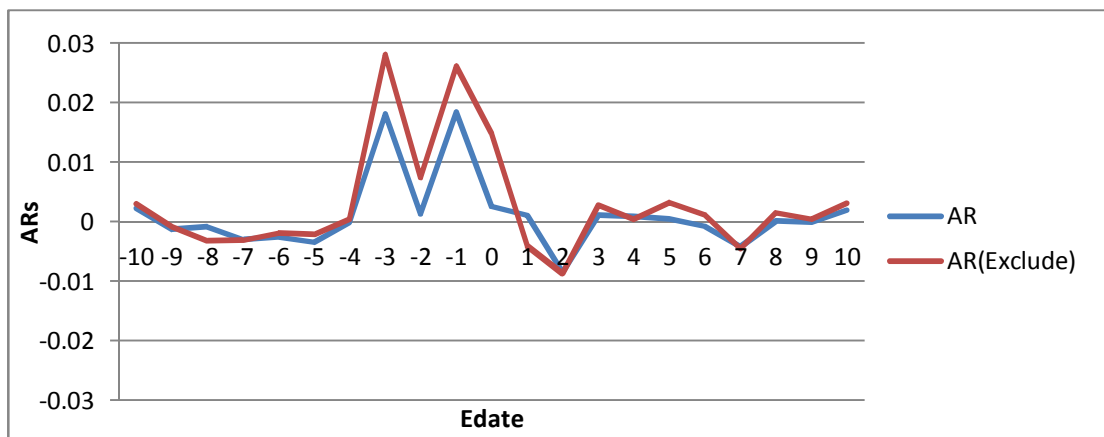


Figure 7 ARs for 21 days surrounding public disclosure of advisory committee recommendation

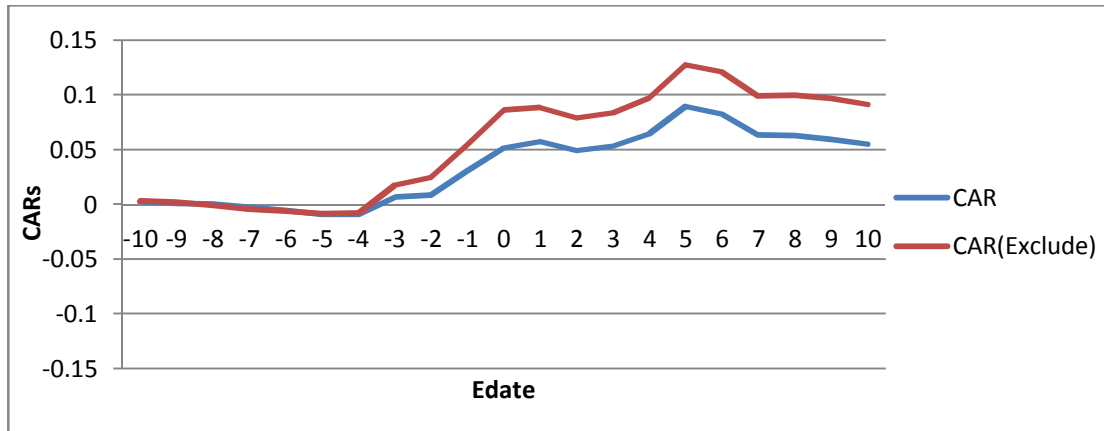


Figure 8 CARs for 21 days surrounding public disclosure of advisory committee recommendation

8.1.5 Issuance of Complete Response Letter from FDA

A complete response letter from FDA to an application informs the applicant that the agency has decided that they will not approve the application in its present form for one or more reasons, though some complete response letters may recommend actions that the applicants could take to put their applications in condition for approval. Therefore, issuance of a complete response letter should be a negative shock to the market and I expect negative abnormal return on the day when a complete response letter is issued and how long the negative abnormal return would last depends on the speed of the market response.

The most important empirical results are summarized in table 10, table 11, figure 9 and figure 10. Figure 9 shows the big dive of abnormal return, less than -0.08, happens on day 0, and abnormal return distributes about 0 as a flat and little fluctuating line thereafter. Figure 10 presents that cumulative abnormal return plummets on day 0 and continuously move down slightly afterwards till day 10, which suggests the influence of response letters from FDA is lasting and permanent. Table 11 demonstrates that cumulative abnormal returns over $[0, 1]$, $[0, 5]$ and $[0, 10]$ are negative and statistically significant at the 0.01 level. Table 10 shows that highly significant and substantial negative abnormal return happens on day 0. After day 0, even though only abnormal returns on day 3 and day 10 are significantly negative, almost all abnormal returns, except for day 9, are negative, though insignificant. This could explain the results in table 11. Table 10 also shows that less than 50 percent of firms have positive abnormal returns on the most days through the whole window.

Significant negative abnormal returns observed on day 2 and day 1 preceding the event date suggests relative information leaking into the market before the information goes to public. The empirical results indicate that the behavior of the market to issuance of the complete response letter is consistent with my expectation.

Table 10 ARs and percentage of positive stocks for issuance of complete response letter from FDA

Day	N	AR	Positive (%)
-10	62	0.0027	0.47
-9	62	0.0018	0.50
-8	62	0.0052	0.53
-7	62	-0.0006	0.53
-6	62	-0.0020	0.45
-5	62	0.0008	0.44
-4	62	0.0052	0.47
-3	62	-0.0030	0.42
-2	62	-0.0140*	0.44
-1	62	-0.0160*	0.32***
0	62	-0.0870***	0.39*
1	62	-0.0010	0.40
2	62	-0.0049	0.42
3	62	-0.0080**	0.40
4	62	-0.0013	0.50
5	62	-0.0060	0.39*
6	62	-0.0009	0.47
7	62	-0.0024	0.47
8	62	-0.0039	0.40
9	62	0.0093**	0.56
10	62	-0.0053*	0.39*

Table 11 CARs for different intervals surrounding issuance of complete response letter from FDA

Interval	CAR
[-10, -1]	-0.019
[0, 1]	-0.088***
[0, 5]	-0.105***
[0, 10]	-0.109***
[-10, 10]	-0.130***

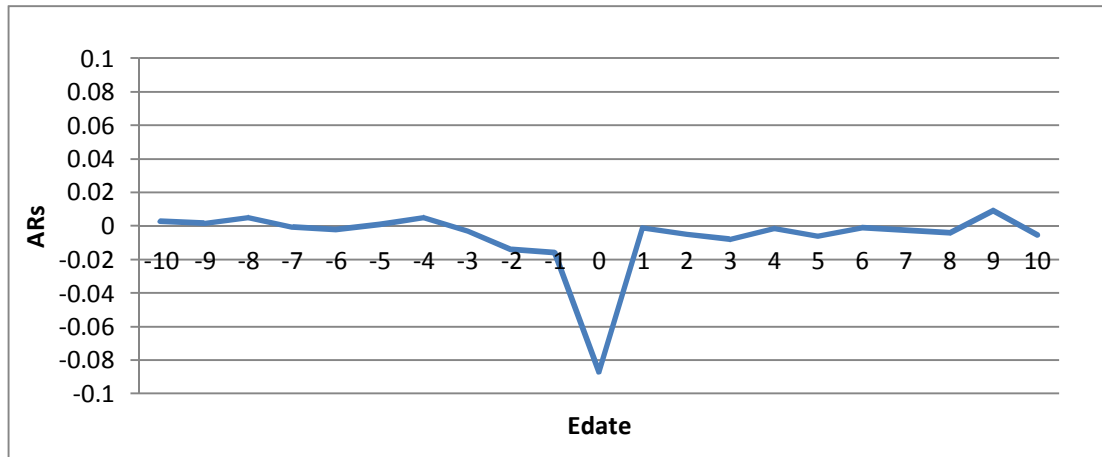


Figure 9 ARs for 21 days surrounding issuance of complete response letter

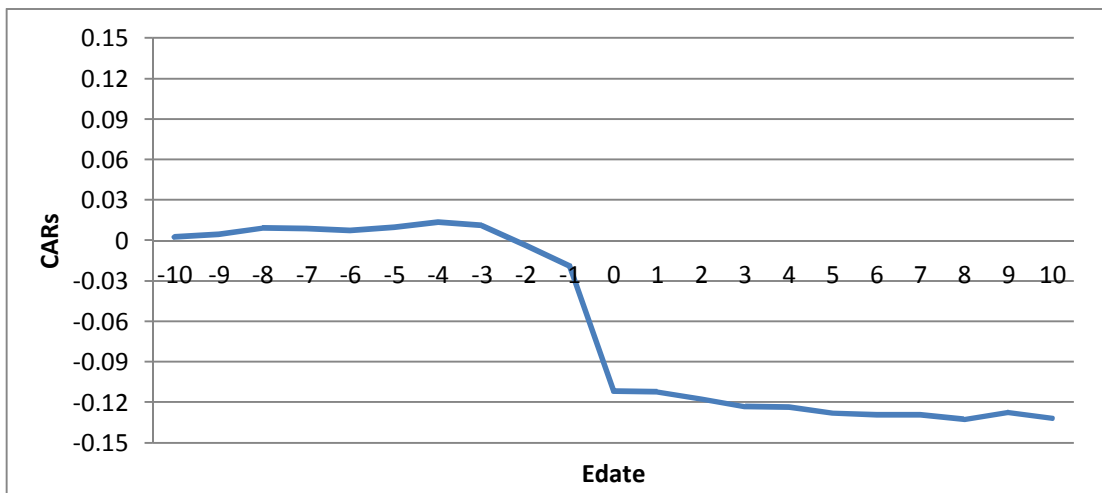


Figure 10 CARs for 21 days surrounding issuance of complete response letter

8.1.6 Resubmission

After receiving a complete response letter, the applicant must take one of the following actions: resubmission, withdrawal and request opportunity for hearing. If the applicant resubmits the application, it would start a new FDA review cycle and ignite the hope of approval of the application again. Given that I anticipate the market would have positive reaction to the announcement of resubmission.

Table 12, table 13, figure 11 and figure 12 summarize the primary results for the resubmission. Table 12 and table 13 show either abnormal returns or cumulative abnormal returns, whatever which interval they are in, are barely statistically significant. Though the results are not significant, I do find a jump of abnormal return on day 0 in figure 11, and it fluctuates slightly around 0 thereafter. The positive abnormal returns occurring 2 days preceding resubmission and lasting to day 0 cause an upward drift of cumulative abnormal return in figure 12. The upward drift of cumulative abnormal return is consistent with my hypothesis that resubmission gives the market a positive anticipation of the application from the firm. The fact shows in table 12 that abnormal return on 2 days preceding the event date is positive and statistically significant at the 0.10 level might be evidence of information leakage or inside trading. Even though the figures show the direction of the market response, the insignificant results indicate that this event cannot grab enough attention from the market.

Table 12 ARs and percentage for resubmission

Day	N	AR	Positive (%)
-10	38	0.0074	0.50
-9	38	0.0016	0.39
-8	38	-0.0049	0.50
-7	38	0.0188	0.53
-6	38	-0.0036	0.53
-5	38	0.0000	0.45
-4	38	-0.0084*	0.37
-3	38	-0.0038	0.39
-2	38	0.0148*	0.61
-1	38	0.0033	0.42
0	38	0.0356	0.66**
1	38	-0.0044	0.37
2	38	-0.0069	0.53
3	38	-0.0068	0.42
4	38	0.0014	0.55
5	38	-0.0014	0.47
6	38	0.0017	0.55
7	38	-0.0001	0.50
8	38	-0.0040	0.45
9	38	0.0040	0.61
10	38	-0.0021	0.45

Table 13 CARs for different intervals surrounding resubmission

Interval	CAR
[-10, -1]	0.029
[0, 1]	0.030
[0, 5]	0.014
[0, 10]	0.014
[-10, 10]	0.033

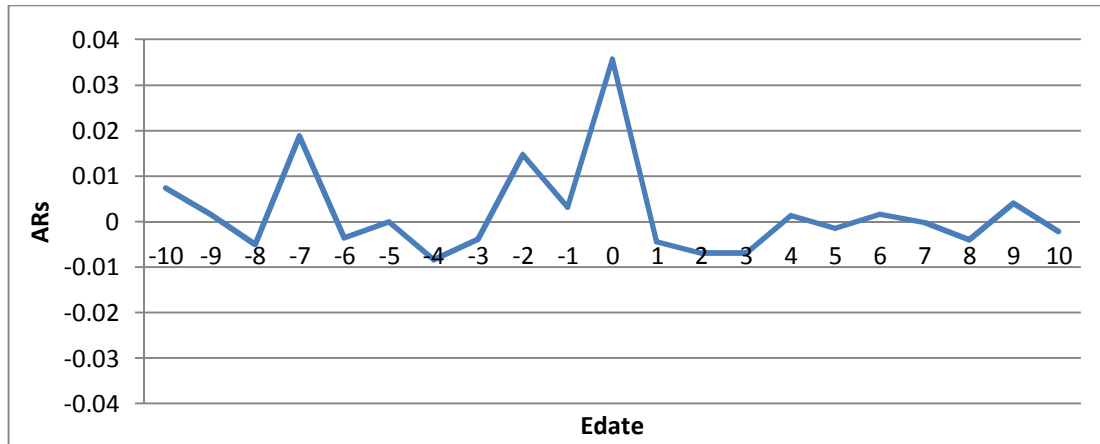


Figure 11 ARs for 21 days surrounding resubmission

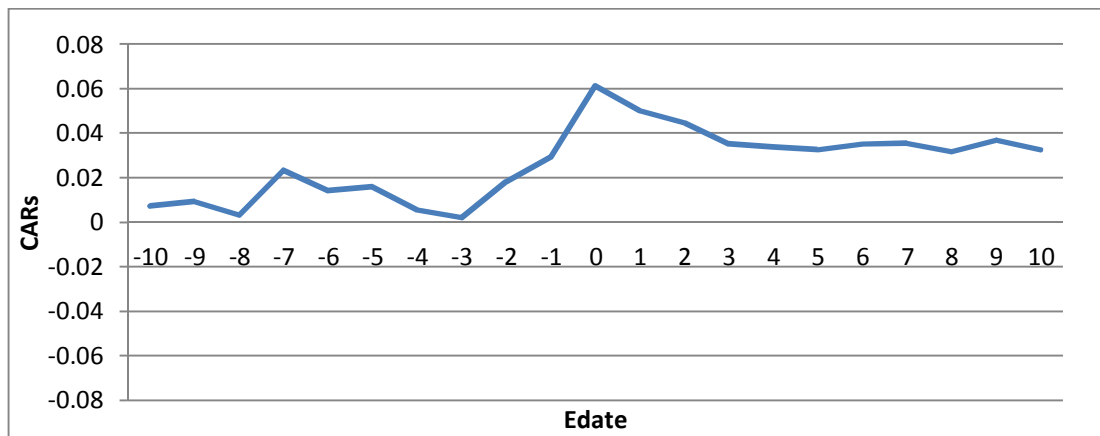


Figure 12 CARs for 21 days surrounding resubmission

8.1.7 Approval of An Application

After the FDA finally approves the application, the new drug becomes available for physicians to prescribe and the company can commercialize the drug, which means that positive abnormal return and cumulative abnormal return are expected.

The most important empirical results are summarized in table 14, table 15, figure 13 and figure 14. Table 15 shows only cumulative abnormal return over $[0, 1]$ is

0.067 and statistically significant at the 0.05 level, and cumulative abnormal return over [0, 5] and [0, 10] are positive though insignificant. Table 14 could explain why cumulative abnormal return loses significance over longer periods. Table 14 shows that abnormal return on day 0 is 0.0128, statistically significant at the 0.01 level and abnormal return on day 1 is 0.0563, statistically significant at the 0.10 level. After day 1, abnormal returns are negative though insignificant except for those on day 4 and day 5, and abnormal return on day 2 is even significantly negative at the 0.01 level. Figure 13 indicates that the positive abnormal return occurs on day 0 and rise dramatically on day 1, after that the abnormal return barely deviates from 0. Cumulative abnormal return in figure 14 begins to go up steeply on day 0 and jumps above 0.06 on day 1, and then there is no systematical movement thereafter. The curve tends to be flat right above 0.06 in the last two days of the window. The behavior is in line with my expectation. The upward drift of cumulative abnormal return results from the price adjustment in anticipation of the company's profitability after the new drug application is approved. I notice that positive abnormal return begins to occur since 4 days before the event and lasts 1 day after the event, those of which on 3 days and 2 days before the event are statistically significant. This might suggest inside trading exists in the market before approval of an application.

Table 14 ARs and percentage of positive stocks for approval of an application

Day	N	AR	Positive (%)
-10	188	-0.0007	0.50
-9	188	-0.0001	0.45

Table 14 continued

-8	188	-0.0033**	0.43**
-7	188	0.0001	0.46
-6	188	-0.0020	0.40
-5	188	-0.0010	0.49
-4	188	0.0019	0.51
-3	188	0.0036**	0.57*
-2	188	0.0029*	0.59**
-1	188	0.0019	0.53
0	188	0.0128***	0.57*
1	188	0.0563*	0.49
2	188	-0.0084***	0.36***
3	188	-0.0013	0.41**
4	188	0.0002	0.25
5	188	0.0037	0.47
6	188	-0.0019	0.45
7	188	-0.0004	0.49
8	188	-0.0005	0.47
9	188	-0.0015	0.40***
10	188	-0.0004	0.50

Table 15 CARs for different intervals surrounding approval of an application

Interval	CAR
[-10, -1]	0.002
[0, 1]	0.067**
[0, 5]	0.082
[0, 10]	0.068
[-10, 10]	0.064

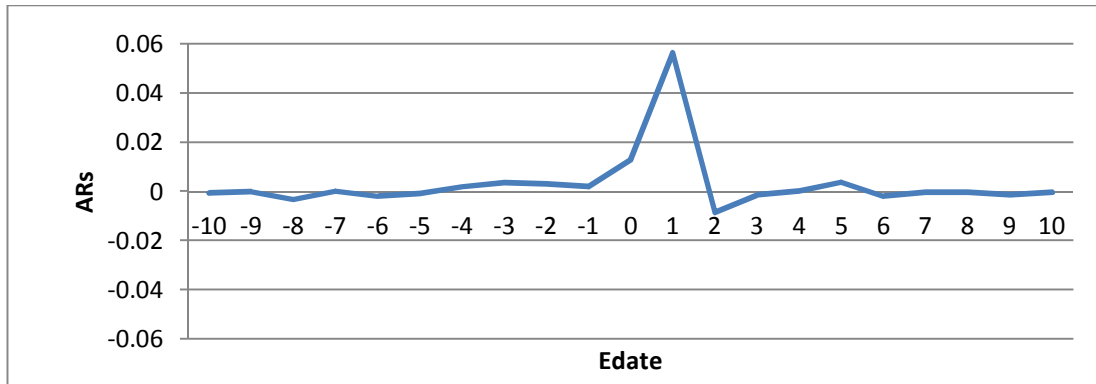


Figure 13 ARs for 21 days surrounding approval of an application

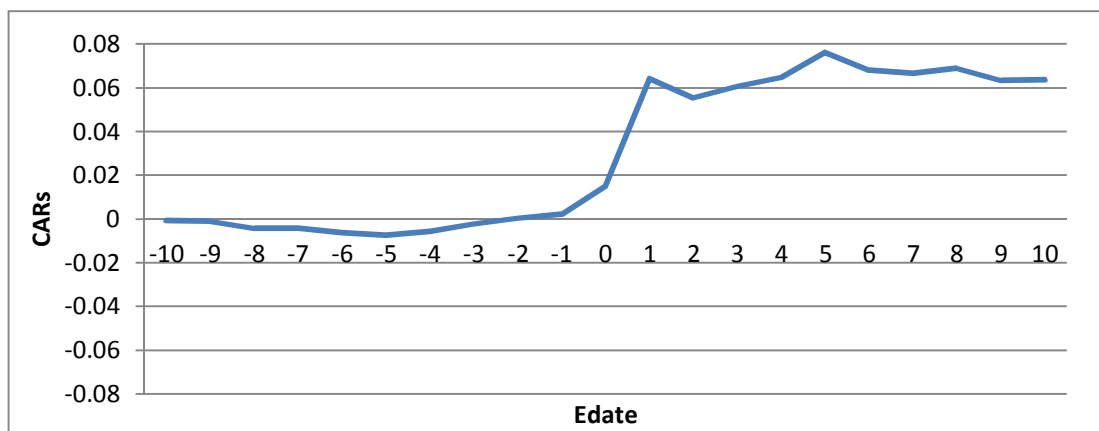


Figure 14 CARs for 21 days surrounding approval of an application

8.1.8 Approval of New Indications

On average, it takes 10 to 15 years to bring either a new molecular entity or a biologic to market, at an estimated cost of approximately \$800 million to \$1.7 billion.¹⁰ The research-based pharmaceutical industry currently invests some \$12.6 billion a year in new drug development. Historically, the drug development figure

¹⁰ Pharmaceutical Research and Manufacturers of America. *Pharmaceutical Industry Profile 2008*. Washington, DC: PhRMA; March 2008.

doubles every five years.¹¹ Of the compounds that do enter clinical testing, it is estimated that, overall, the new drug approval rate is only 19%.¹² Of the drugs that receive approval from the FDA, approximately 2 in 10 are able to recoup development costs.⁴ In addition to the risks of the time and cost required to bring new drugs to market, the pharmaceutical industry is faced with imminent patent expirations on many drugs and severe competition from generic drugs. It is estimated that 71 drugs will face first-time generic competition between 2010 and 2015.¹³ It is further projected that drugs with sales of more than \$73 billion from the 10 largest pharmaceutical companies will be exposed to generic competition between 2009 and 2012.¹⁴ For firms, developing new indication of already-approved drugs is a lower-risk strategy which can reduce the cost and accelerate the time. Furthermore, firms could get three-year market exclusivity for a new indication granted by Hatch-Waxman Act or even longer if they are able to obtain a patent on the new indication. Therefore, the approval of a new indication could indicate the extended market exclusivity and signal a potential higher demand on the drug for the additional usages

¹¹ <http://www.drugs.com/fda-approval-process.html>.

¹² DiMasi JA, Feldman L, Seckler A, Wilson A. Trends in risks associated with new drug development: success rates for investigational drugs. *Clin Pharmacol Ther.* 2010;87(3):272-277.

¹³ http://www.forbes.com/2006/06/23/drugs-patents-expiration-cz_mh_0623generics.html.

¹⁴ <http://seekingalpha.com/article/124895-big-pharma-and-patent-cliffs>.

thus signal an increase in the underlying company's shares value. I assume a positive abnormal return surrounding the event.

Table 16, table 17, figure 15 and figure 16 include the important results for approval of New Indication. Figure 15 shows abnormal return fluctuates with small magnitude around 0 and table 16 indicates that none of abnormal return in any day over the window is significant. I do see a positive and upward trend for cumulative abnormal return in figure 16, but table 17 demonstrates that not any cumulative abnormal return over any intervals under study is significant. The results suggest that approval of new indication may bring positive effect on the stocks but the effect is not phenomenal. There is one possible explanation for it. The firm could only get market exclusivity for the new indication, but if the new indication is not the only one treatment for a disease it would still face serious competition from its substitutes which may already in the market and be known by customers for a while, as well as competition from generic drugs of its original patent-expired drugs. On this condition the new indication may not be able to bring too much profit for the company and add too much value to the underlying shares.

Table 16 ARs and percentage of positive stocks for approval of new indication

Day	N	AR	Positive (%)
-10	42	-0.0006	0.57
-9	42	0.0007	0.48
-8	42	0.0031	0.67**
-7	42	0.0010	0.55
-6	42	0.0030	0.60

Table 16 continued

-5	42	-0.0025	0.45
-4	42	0.0010	0.43
-3	42	0.0030	0.48
-2	42	-0.0009	0.48
-1	42	0.0031	0.45
0	42	-0.0008	0.40
1	42	0.0036	0.51
2	42	-0.0032	0.48
3	42	0.0023	0.55
4	42	0.0010	0.40
5	42	-0.0009	0.38
6	42	-0.0025	0.60
7	42	0.0033	0.53
8	42	-0.0022	0.42
9	42	-0.0009	0.44
10	42	0.0041	0.52

Table 17 CARs for different intervals surrounding approval of new indication

Interval	CAR
[-10, -1]	0.011
[0, 1]	0.002
[0, 5]	0.002
[0, 10]	0.005
[-10, 10]	0.015

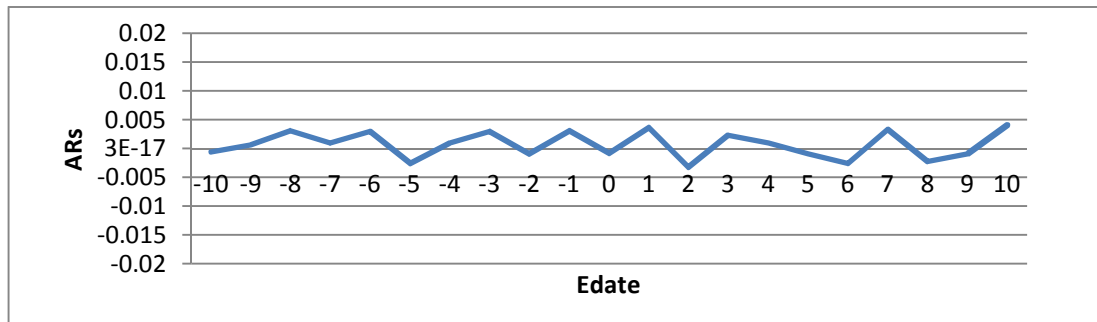


Figure 15 ARs for 21 days surrounding approval of new indications

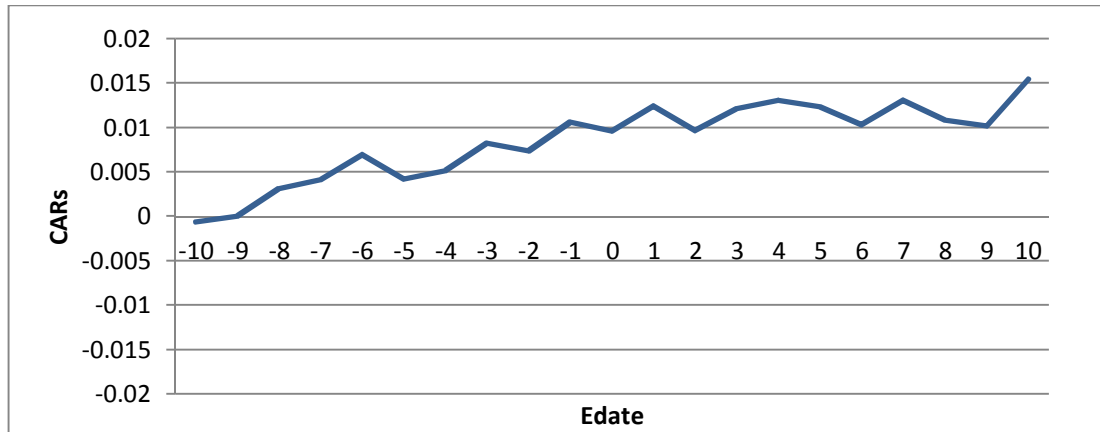


Figure 16 CARs for 21 days surrounding approval of new indications

8.1.9 Approval of First-Time Generics

Once the generic drugs enter the market, the market exclusive status of brand-name companies is jeopardized and they cannot dictate the price any more. In addition to introduce competition into the market generic drugs could be sold at significantly lower prices than their branded equivalents. As generic drug manufactures do not bear the cost in money and time to identify a new compound and prove it to be safe and effective through trials but benefit from the marketing campaign conducted by brand-name companies previously, they are able to make profit at the pretty lower prices. Therefore, approval of the first-time generic drug could be a signal that the brand-name company loses huge market share and monopoly profit of this drug, which will decrease the corresponding shares value. I expect negative abnormal return and cumulative abnormal return on this event.

The primary results are summarized in table 18, table 19, figure 17 and figure 18. Figure 17 shows abnormal return fluctuates around 0 with small magnitude, but

there are relatively big negative abnormal returns occurring on day 0, day 1, and day 3. Figure 10 demonstrates cumulative abnormal return drifts downwards since day 0 but adjusts upwards from day 5. Table 19 indicates cumulative abnormal returns are significantly negative over [0, 1] and [0, 5], but it is insignificant over [0, 10]. In table 18, I can see that abnormal returns on day 0, day 1 and day 3 are significantly negative; after day 5 abnormal returns are positive though insignificant from day 6 to day 9 and it is insignificantly slightly less than 0 on day 10, which could explain why cumulative abnormal return is insignificant over period [0, 10]. The fact that cumulative abnormal return drifts downward but slightly and reversely adjusts later in figure 18 could be explained in two ways. First, when the patent of branded expires the market would anticipate generic drugs. The Hatch-Waxman Act makes the timeline of introduce of generic drugs shorter and more predictable and the relevant price adjustment might take place surrounding the expiration of the patent. Second, only slightly additional price adjustment is necessary when generic drugs actually get approved and are ready to be produced. The phenomenon is consistent with the conclusion in Ammann, Berchtold and Seiz (2011) that investors are inclined to overreact to short-term information.

Table 18 ARs and percentage of positive stocks for approval of first-time generics

Day	N	AR	Positive (%)
-10	163	-0.0015	0.45
-9	163	0.0006	0.47
-8	163	-0.0009	0.47

Table 18 continued

-7	163	0.0002	0.45
-6	163	0.0020	0.42**
-5	163	0.0018	0.51
-4	163	-0.0002	0.48
-3	163	-0.0001	0.46
-2	163	-0.0007	0.49
-1	163	0.0009	0.55
0	163	-0.0031*	0.45
1	163	-0.0039**	0.44*
2	163	0.0007	0.52
3	163	-0.0024*	0.43*
4	163	0.0007	0.47
5	163	-0.0013	0.44
6	163	0.0004	0.52
7	163	0.0002	0.51
8	163	0.0020	0.51
9	163	0.0014	0.52
10	163	-0.0004	0.49

Table 19 CARs for different intervals surrounding approval of first-time generics

Interval	CAR
[-10, -1]	0.001
[0, 1]	-0.007***
[0, 5]	-0.009**
[0, 10]	-0.006
[-10, 10]	-0.004

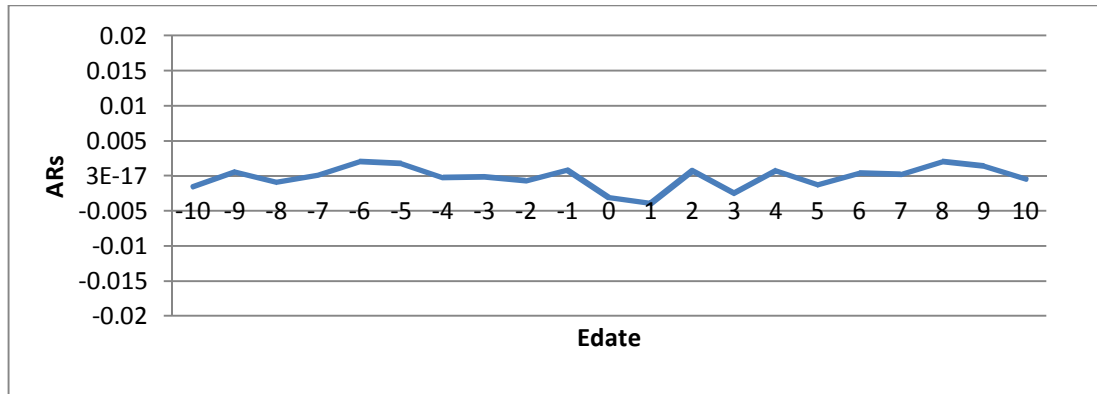


Figure 17 ARs for 21 days surrounding approval of first-time generics

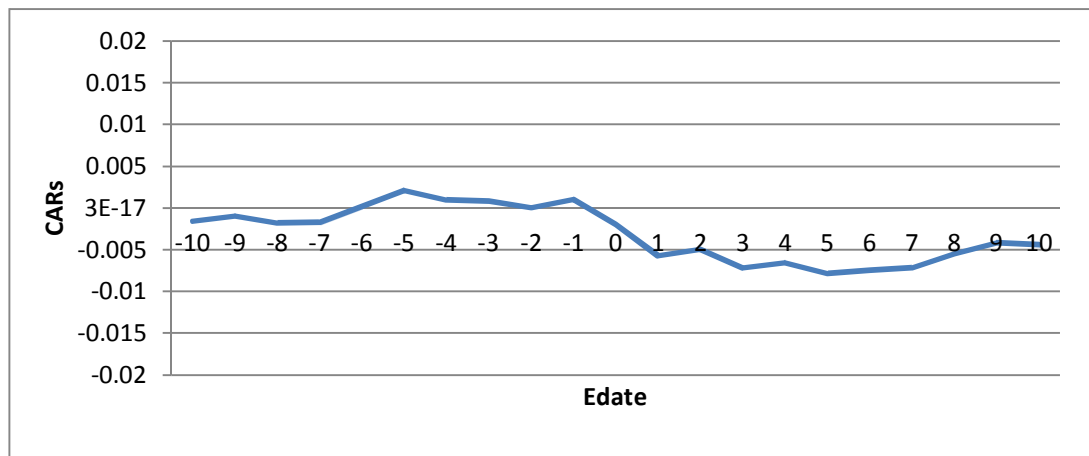


Figure 18 CARs for 21 days surrounding approval of first-time generics

In sum, the market has different reactions to different events through approval process. The results are summarized in table 20. To some event, such as submission of new drug applications, the value of the underlying stocks are inclined to move marginally and insignificantly in the opposite direction to what it is supposed to be as a result of perious overreaction. To some events, like issuance of complete response letter from FDA and approval of an new drug application, which are relatively hard to be predicted their outcomes and investors are tend to be prudential on their

anticipations, or like extension of FDA review deadline, which is not able to be predicted at all and when it happens it is beyond investors' expectation, the stock prices of the related pharmaceutical companies are adjusted substantially and significantly on the event date or/and thereafter. Investors could make money by timely capturing the abnormal fluctuation of these stocks and trade them appropriately. To some event, such as approval the first-time generics, which could be anticipated well by analyzing information already circulated in the market so that the market has already adjusted prices gradually before it really happens, the market only adjusts slightly but significantly when it really happens. To some events, like acceptance of the application by FDA and approval of new indication, which are not important enough to influence the stock value of the underlying companies, the market reactions on the event date or thereafter are slight and insignificant. Some events, like public disclosure of advisory committee recommendation and resubmission, are observed economical but insignificant market reactions on the event dates or thereafter. This behavior may result from some extreme points in the sample which will be studied in next chapter. However, I do observe significant abnormal returns existing in days right before the event date of public disclosure of advisory committee recommendation and significant cumulative abnormal return from [-10,-1], which is a strong evidence of inside trading. The same conclusion can be reached in the events of public disclosure of complete response letter from FDA and approval of an new drug application as well.

Table 20 Summary of response of stock values to 9 events of interest

Response	Substantial/Moderate & Significant	Slight but Significant	Slight & Insignificant	Mild/Economical but Insignificant
Events	<ul style="list-style-type: none"> • Extension of FDA Review Deadline • Public disclosure of advisory committee recommendation v/v • Issuance of Complete response letter from FDA v • Approval of an New Drug Application v 	<ul style="list-style-type: none"> • Approval of the first-time generic drugs 	<ul style="list-style-type: none"> • Submission of an new drug application (opposite direction) • Acceptance of an application by FDA • Approval of New Indication 	<ul style="list-style-type: none"> • Resubmission v

v indicates the evidence of inside trading exists.

I also do a robust analysis by changing the window from [-10,10] to [-4,4]. The robust analysis shows that changing the range of the window doesn't significantly change the results, which suggests my conclusions are reliable. (The results of the robust analysis are showed in appendix.)

8.2 Segmentation Results

Susana Yu and Dean Leistikow (2011) think the results should be more pronounced for the small cap stocks because they are followed by fewer analysts. They argue the reason why fewer analysts are interested in small cap stocks is because the institutional investors favor the big cap stocks due to liquidation and regulatory constraints. Since institutional investors are the primary demand for information the big cap stocks are analyzed more timely and thoroughly. In addition to the reason discussed by Susana Yu and Dean Leistikow (2011), there are two possibilities which could lead to the different performance between the small cap stocks and the big cap stocks. One is that the single new drug is much more important to the small cap stocks than the big cap stocks. Once the new drug is approved it would become the main resource of revenue for a small cap pharmaceutical firm or sometimes whether the small cap firm could turn to be profitable relies on whether the new drug is approved or not; while, to a big cap pharmaceutical firm, the to-be-approved new drug might only count for a small part of its revenue. The other possibility is that a new drug developed by a big cap firm may have more market share or more pronounced impact on the healthcare industry as the big cap firm usually invests much more money in R&D and it has more advanced lab and better research team.

As discussed above, I think it is worth to analyze the responses of stocks in different capital size. I divide my samples into 3 groups based on their capital size and use the same method in last chapter to see whether there is any substantial and significant differences in the results among the 3 groups.

8.2.1 Submission

Figure 20 shows that cumulative abnormal return of the small cap group drifts downwards further than any of other two groups. Table 22 demonstrates that cumulative abnormal return of the small cap group is significantly negative over $[0, 5]$ which may result from mild and significant negative abnormal return on day 3, -0.0105 in table 21. On the contrary, cumulative abnormal return of the big cap group in table 22 is insignificant over any period in study. Figure 20 and table 22 indicate that the reaction of the small cap group is more sizable and more significant than the reaction of the big cap group. If I see the downward drift as an adjustment of the market overreaction when it anticipates the submission before it really happens, the results are consistent with the theory that the big group stock market is more efficient than the small group stock market since the adjustment of the small cap group is more severe. Interestingly, cumulative abnormal return of the medium group drifts upwards. Table 22 shows that cumulative abnormal returns of the medium cap group over interval $[0, 1]$ and interval $[0, 10]$ are significantly positive, which satisfies the hypothesis that submission transfer a positive signal to the market. Table 23 indicates that the difference of cumulative abnormal return between the big and the small on each day over the window is insignificant.

Table 21 ARs of 3 groups for submission

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	40	-0.0048	41	0.0003	38	-0.0003
-9	40	0.0035	41	0.0004	38	0.0008
-8	40	-0.0013	41	0.0016	38	-0.0060***
-7	40	-0.0053	41	-0.0027	38	0.0046
-6	40	-0.0002	41	-0.0002	38	0.0047*
-5	40	0.0028	41	0.0006	38	-0.0015
-4	40	-0.0197	41	-0.0029	38	-0.0035
-3	40	-0.0055	41	-0.0004	38	-0.0033
-2	40	0.0152	41	-0.0003	38	-0.0018
-1	40	-0.0043	41	-0.0005	38	-0.0000
0	40	0.0059	41	0.0059	38	-0.0004
1	40	0.0009	41	0.0047*	38	0.0004
2	40	-0.0009	41	-0.0019	38	-0.0028
3	40	-0.0105*	41	-0.0023	38	-0.0033
4	40	0.0000	41	-0.0031	38	-0.0060**
5	40	-0.0013	41	0.0038	38	-0.0011
6	40	-0.0026	41	-0.0008	38	-0.0015
7	40	-0.0079*	41	0.0032	38	-0.0025
8	40	0.0056	41	-0.0009	38	0.0005
9	40	0.0022	41	0.0037	38	-0.0026
10	40	0.0131	41	0.0047	38	0.0037

Table 22 CARs for different intervals of 3 groups surrounding submission

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	-0.028	-0.003	-0.007
[0, 1]	0.007	0.011*	0.001
[0, 5]	-0.006*	0.007	-0.013
[0, 10]	0.004	0.017*	-0.015
[-10, 10]	-0.033	0.014	-0.023

Table 23 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	-0.004	-0.002	0.004	-0.007	-0.011	-0.007	-0.024
Edate	-3	-2	-1	0	1	2	3
Small-Big	-0.024	-0.0171	-0.021	-0.017	-0.020	-0.017	-0.024
Edate	4	5	6	7	8	9	10
Small-Big	-0.018	-0.019	-0.021	-0.026	-0.021	-0.020	-0.009

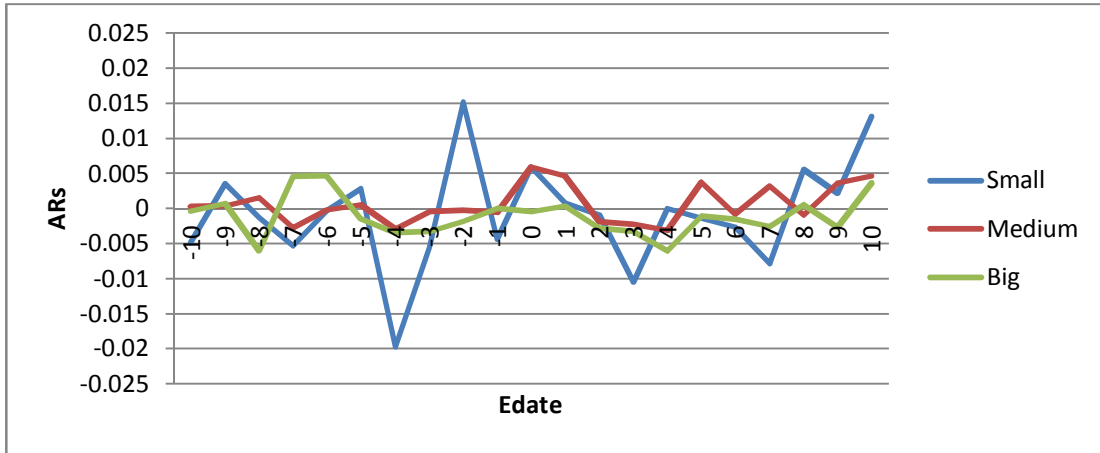


Figure 19 ARs for 21 days of 3 groups surrounding submission

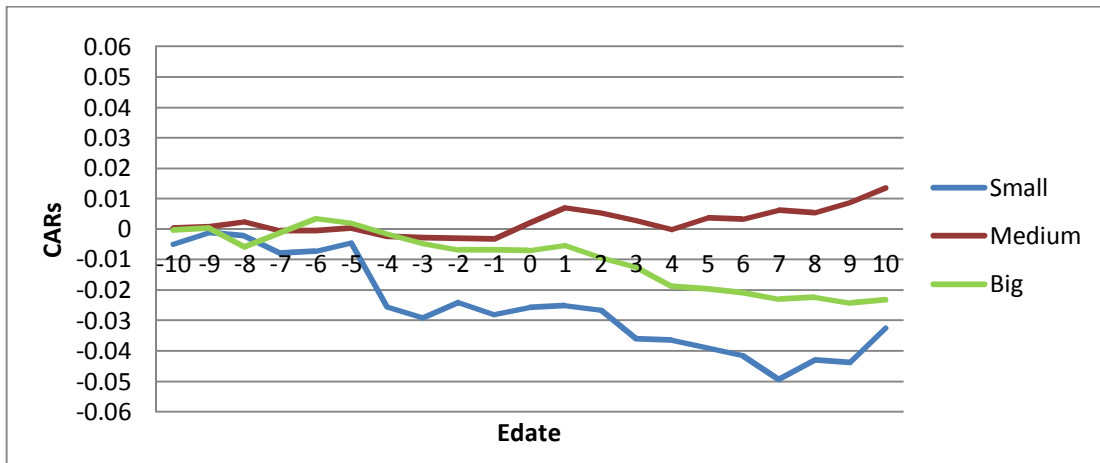


Figure 20 CARs for 21 days of 3 groups surrounding submission

8.2.2 Acceptance

Figure 22 shows that the big group's cumulative abnormal return and the small group's cumulative abnormal return move in the opposite direction through the whole window and the medium group's cumulative abnormal return has an upward trend above 0. Table 25 shows that only the big cap group has statistically significant positive cumulative abnormal return 0.01 over [0, 1] and significant negative cumulative return -0.006 over [0, 5], which is explained by results in table 24 where there is significantly positive abnormal return on day 1 and day 2, respectively and significantly negative abnormal return could be observed on day 5 and day 6, respectively. Figure 22 and Table 24 demonstrate cumulative abnormal return of the big cap group fiercely moves up and down around 0 over the windows; while cumulative abnormal return of the small cap group has a downwards trend far below 0 and sharp reverse movement in the end of the window. Even though figure 22 shows cumulative abnormal return for the small cap group moves in the opposite direction to cumulative abnormal return for the big cap group, table 26 indicates the difference between these two groups is statistically insignificant, except day 2 where the difference is marginal significant.

Table 24 ARs of 3 groups for acceptance

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	36	-0.0018	35	0.0019	33	-0.0002
-9	36	-0.0061	35	0.0072	33	0.0026
-8	36	0.0017	35	-0.0049	33	-0.0001
-7	36	0.0049	35	-0.0007	33	-0.0012

Table 24 continued

-6	36	0.0026	35	-0.0046	33	-0.0007
-5	36	-0.0036	35	-0.0017	33	-0.0032
-4	36	0.0107	35	0.0016	33	-0.0023
-3	36	-0.0039	35	0.0071	33	-0.0032
-2	36	-0.0165***	35	-0.0004	33	0.0027
-1	36	0.0003	35	0.0020	33	0.0023
0	36	-0.0020	35	0.0121*	33	-0.0019
1	36	-0.0126	35	-0.0075**	33	0.0095**
2	36	-0.0042	35	0.0054	33	0.0063*
3	36	0.0008	35	-0.0035	33	-0.0020
4	36	-0.0007	35	0.0015	33	-0.0008
5	36	0.0039	35	-0.0006	33	-0.0060**
6	36	0.0017	35	0.0019	33	-0.0078**
7	36	-0.0092	35	0.0072*	33	-0.0023
8	36	0.0060	35	-0.0013	33	0.0023
9	36	0.0097	35	0.0012	33	-0.0005
10	36	0.0122*	35	0.0017	33	-0.0012

Table 25 CARs for different intervals of 3 groups surrounding acceptance

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	-0.016	0.007	0.002
[0, 1]	-0.015	0.004	0.010**
[0, 5]	-0.015	0.008	-0.006**
[0, 10]	0.003	0.019	-0.004
[-10, 10]	-0.010	0.026	-0.006

Table 26 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	-0.002	-0.01	-0.009	-0.003	0.000	-0.001	0.012
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.010	-0.009	-0.013	-0.013	-0.037	-0.043*	-0.040
Edate	4	5	6	7	8	9	10
Small-Big	-0.040	-0.030	-0.022	-0.029	-0.025	-0.016	0.001

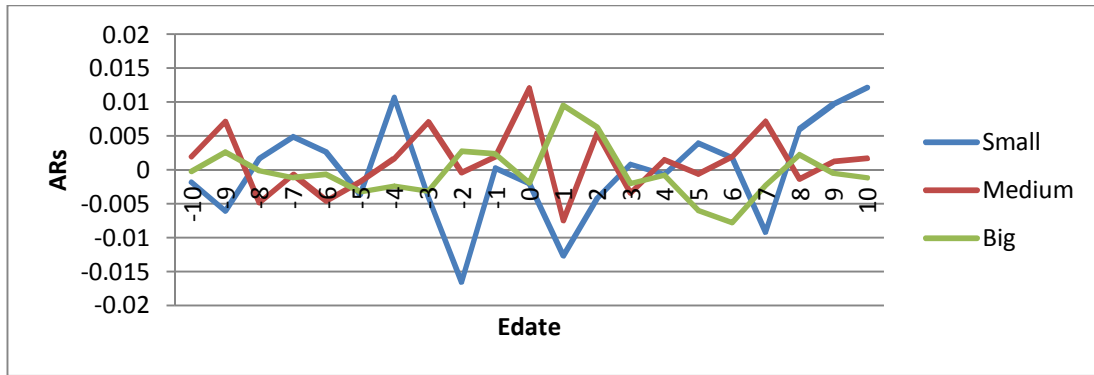


Figure 21 ARs for 21 days of 3 groups surrounding acceptance

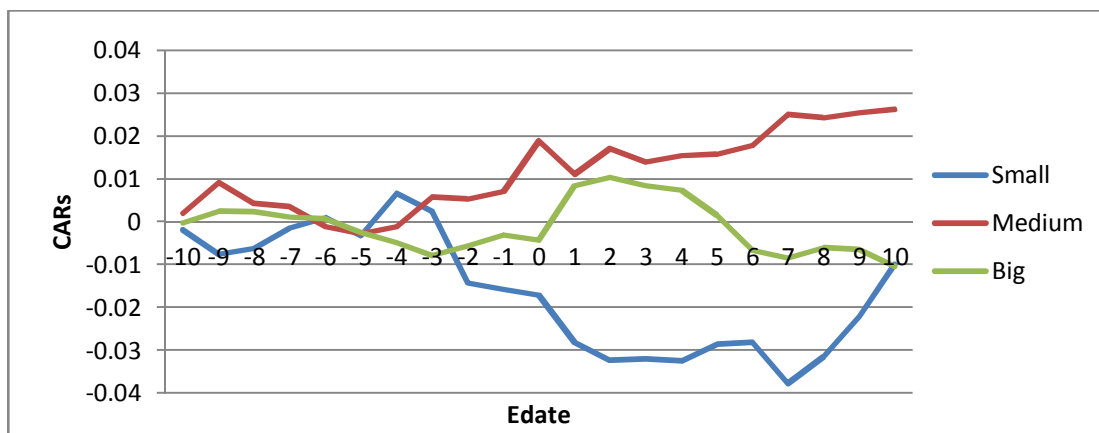


Figure 22 CARs for 21 days of 3 group surrounding acceptance

8.2.3 Extension of FDA Review Deadline

Figure 23 and figure 24 shows that both abnormal return and cumulative abnormal return of the small cap group plummet on day 0, and cumulative abnormal return of the small cap reaches about -0.12 by the end of the window of extension of FDA review deadline. Abnormal return of the big cap group decreases obviously on day 1 and day 3, which statistically confirmed by the significantly negative abnormal return on day 1 and day 3 in table 27, and abnormal return fluctuates around 0 afterwards. This event does not have much impact on the medium cap group as either

abnormal return curve or cumulative abnormal return curve moves up and down around 0. The conclusion is reinforced by table 27 and table 28 that show neither abnormal return nor cumulative abnormal return of the medium cap group on any day over the window is statistically significant different from 0. Table 28 indicates cumulative abnormal return of the small cap group is significantly negative over [0, 1], [0, 5], [0, 10] and [-10, 10] and cumulative abnormal return of the big cap group is significantly negative over [0, 1] and [0, 5]. The small cap group's response is more severe and significant and lasting longer than the big cap group's. The quicker response of the big cap group reminds me that it is studied by the market better. The fact that the small cap group responses more severely than the big cap group can be explained by the following reasons, in addition to the favor in the big of the analysts which causes the event is less surprised for the big than for the small group. First, the market is more confident in the big group than in the small group so that the market would think less negatively about what this event is to the big group when it happens, so I can observe positive abnormal return on the last 3 days over the window in the big cap group which might be an adjustment of the stock price. Second, the big cap group may have better media relationship and better marketing team so than they can response quickly or even in advance to eliminate the negative impact as much as they can. Table 28 shows the difference in cumulative abnormal return between the small group and the big group is significant at the 0.10 level on 4 days and 10 days after then event.

Table 27 ARs of 3 groups for extension of FDA review deadline

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	13	0.0072	13	-0.0011	13	-0.0088**
-9	13	-0.0080	13	-0.0026	13	-0.0113
-8	13	0.0152	13	0.0026	13	0.0037
-7	13	0.0201	13	-0.0070	13	-0.0013
-6	13	-0.0007	13	-0.0003	13	-0.0030
-5	13	0.0031	13	-0.0050	13	-0.0045
-4	13	0.0003	13	-0.0056	13	-0.0048
-3	13	-0.0054	13	0.0074	13	0.0089
-2	13	-0.0011	13	0.0167	13	-0.0034
-1	13	-0.0120	13	-0.0019	13	-0.0002
0	13	-0.0592*	13	0.0008	13	-0.0018
1	13	0.0106	13	0.0022	13	-0.0096***
2	13	-0.0266	13	-0.0012	13	0.0042
3	13	-0.0096	13	0.0009	13	-0.0137**
4	13	0.0050	13	0.0017	13	0.0040
5	13	0.0041	13	-0.0037	13	-0.0060
6	13	0.0037	13	-0.0061	13	0.0026
7	13	0.0056	13	-0.0050	13	-0.0053
8	13	-0.0101	13	-0.0003	13	0.0017
9	13	-0.0143	13	-0.0034	13	0.0049
10	13	0.0094	13	-0.0032	13	0.0035

Table 28 CARs for different intervals of 3 groups surrounding extension of FDA review deadline

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	-0.002	0.002	-0.023
[0, 1]	-0.057**	0.003	-0.011**
[0, 5]	-0.085***	0.001	-0.023**
[0, 10]	-0.088**	-0.017	-0.015
[-10, 10]	-0.116***	-0.014	-0.037

Table 29 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	0.016	0.019	0.032	0.013	0.016	0.024	0.028
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.014	0.013	0.000	0.056	-0.047	-0.072*	-0.066
Edate	4	5	6	7	8	9	10
Small-Big	-0.071*	-0.064	-0.063	-0.055	-0.064	-0.079	-0.079*

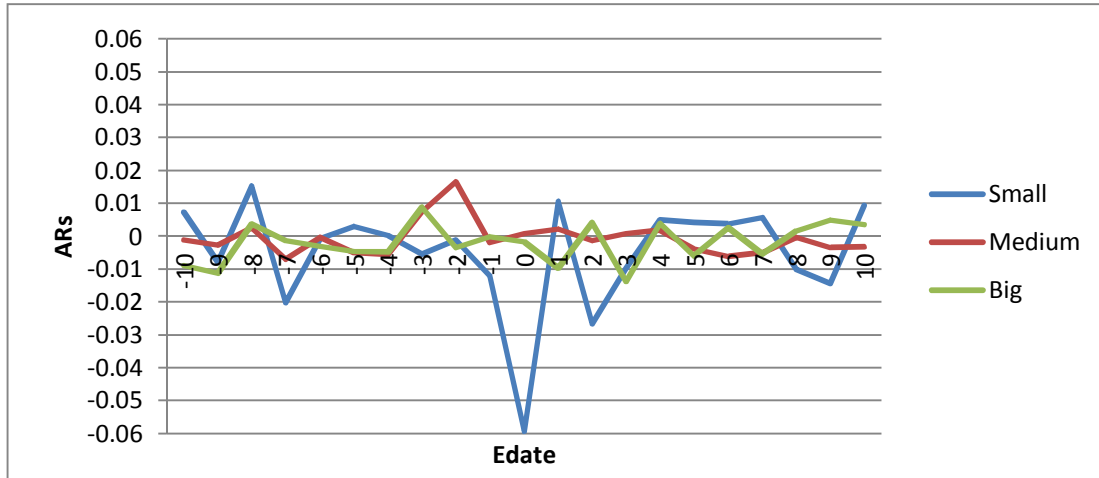


Figure 23 ARs for 21 days of 3 groups surrounding extension of FDA review deadline

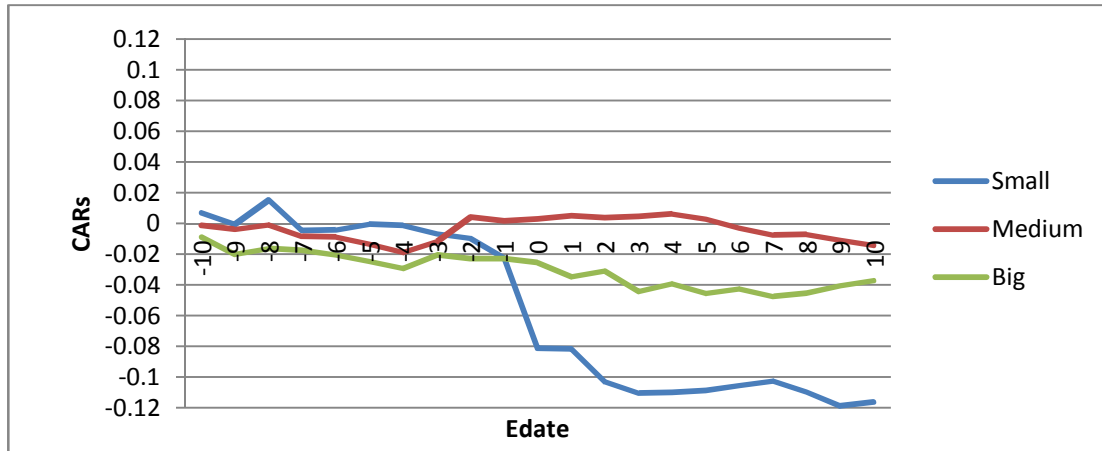


Figure 24 CARs for 21 days of 3 groups surrounding extension of FDA review deadline

8.2.4 Public Disclosure of Advisory Committee Recommendation

Figure 26 and figure 28 show that only the behavior of the big cap group is consistent with the hypothesis that public disclosure of Advisory Committee Recommendation has a positive impact on the company stock value whose new drug applications are eventually approved. Cumulative abnormal return of the big group drifts upward and stays at around 0.2 by the end of the window when bad news is included or stays at about 0.3 by the end of the window when bad news is excluded. In contrast, cumulative abnormal return of the small cap group moves with little margin around 0 and cumulative abnormal return of the medium cap group moves smoothly a little below 0; when excluding bad news from my sample the curves of cumulative abnormal return of the small cap and the medium cap become flatter and the margins around 0 turn to be less. Figure 25 and figure 26 demonstrate whether or not exclude bad news from sample abnormal return of all 3 groups begins to rise dramatically on 3 days preceding the event, but abnormal return of the small cap group and the medium cap group have a reverse adjustment thereafter and only the big cap group continues its positive abnormal return to the days after the event. The existence of positive abnormal return before the event suggests the inside trading again, which is confirmed statistically in Table 30 and table 31. Table 31 indicates that cumulative abnormal return of the small cap group is positive over $[-10, -1]$ while it is negative over $[0, 1]$, $[0, 5]$ and $[0, 10]$ which could be seen as an adjustment to the overreaction before the event. Significantly positive abnormal return of the small cap group is observed on the 3rd day before the event in table 30, either including bad news or excluding bad news.

Table 31 shows that cumulative abnormal return of the small cap group is bigger over [-10, -1] and smaller and more significant over [0, 1], [0, 5] and [0, 10] for the sample excluding bad news than for the sample including bad news, consistent with figure 32 that cumulative abnormal return of the small cap group fluctuates more fiercely when bad news is excluded. Figure 31 and figure 34 shows that taking out bad news from the sample doesn't influence the results of the big cap group much: abnormal return curves almost superpose each other and cumulative abnormal return curve almost have the same shape, only the one with bad news is a little lower than the one without bad news. Figure 30 and figure 33 indicates that excluding bad news from the sample impacts the stock value of the medium cap group a lot. After I take bad news from my sample cumulative abnormal return curve of the medium cap group is partially above 0 comparing the curve is always below 0 with the bad news and the difference between these two curve are going wider and wider since 4 days preceding the event. In addition, table 31 shows that when bad news is excluded from the sample cumulative abnormal return over [-10, -1] turns from negative to positive, and despite it is still negative after the event it is less substantial and less significant. All discussed above suggest that the big cap group is more efficient than other two groups. Table 32 and table 33 show that the gap in cumulative abnormal return between the small cap group and the big cap group is huge over the days after the event, though statistically insignificant.

Table 30 ARs of 3 groups for public disclosure of advisory committee recommendation

Day	Small						Medium						Big					
	Include Bad News		Exclude Bad News		AR		Include Bad News		Exclude Bad News		AR		Include Bad News		Exclude Bad News		AR	
	N	AR	N	AR	N	AR	N	AR	N	AR	N	AR	N	AR	N	AR	N	AR
-10	17	0.0070	14	0.0061	18	0.0008	16	0.0037	16	0.0012	14	-0.0009	16	-0.0012	16	0.0039	14	-0.0009
-9	17	0.0006	14	0.0020	18	-0.0025	16	-0.0030	16	-0.0018	14	-0.0009	16	-0.0018	16	0.0039	14	-0.0009
-8	17	-0.0003	14	-0.0029	18	0.0035	16	0.0013	16	-0.0064	14	-0.0088*	16	-0.0064	16	0.0039	14	-0.0088*
-7	17	0.0002	14	0.0010	18	-0.0016	16	-0.0038	16	-0.0079*	14	-0.0064	16	-0.0079*	16	0.0039	14	-0.0064
-6	17	-0.0034	14	-0.0027	18	-0.0053	16	-0.0064*	16	0.0014	14	0.0039	16	0.0014	16	0.0039	14	0.0039
-5	17	-0.0027	14	-0.0018	18	-0.0120**	16	-0.0114*	16	0.0056	14	0.0082	16	0.0056	16	0.0039	14	0.0082
-4	17	0.0029	14	0.0020	18	-0.0036	16	-0.0023	16	0.0008	14	0.0019	16	0.0008	16	0.0039	14	0.0019
-3	17	0.0198*	14	0.0256*	18	0.0010	16	0.0232*	16	0.0355	14	0.0361	16	0.0355	16	0.0361	14	0.0361
-2	17	-0.0057	14	-0.0023	18	-0.0032	16	0.0067	16	0.0140	14	0.183	16	0.0140	16	0.183	14	0.183

Table 30 continued

-1	17	-0.0077	14	0.0072	18	0.0092	16	0.0101	16	0.0537	14	0.0611
0	17	-0.0183	14	-0.0238*	18	-0.0230	16	0.0076	16	0.0539	14	0.0620
1	17	0.0151	14	-0.0099	18	-0.0142	16	-0.0054	16	0.0037	14	0.0040
2	17	-0.0153***	14	-0.0171***	18	-0.0094*	16	-0.0090*	16	-0.0003	14	0.0001
3	17	0.0050***	14	0.0054	18	-0.0152**	16	-0.0112**	16	0.0152**	14	0.0163**
4	17	-0.0045	14	-0.0063	18	-0.0002	16	-0.0031	16	0.0079	14	0.0113
5	17	-0.0049	14	-0.0076	18	-0.0147**	16	-0.0072	16	0.0232	14	0.0261
6	17	0.0032	14	0.0057	18	-0.0092	16	-0.0061	16	0.0047	14	0.0052
7	17	0.0033	14	0.0043	18	0.0007	16	0.0008	16	-0.0175	14	-0.0195
8	17	-0.0000	14	0.0035	18	-0.0038	16	-0.0012	16	0.0049	14	0.0029
9	17	0.0037	14	0.0054	18	0.0042	16	0.0035	16	-0.009*	14	-0.0080
10	17	0.0096	14	0.0112	18	0.0009	16	0.0036	16	-0.0045	14	-0.0049

Table 31 CARs for different intervals of 3 groups surrounding public disclosure of advisory committee recommendation

Interval	Small CAR		Medium CAR		Big CAR	
	Include Bad News	Exclude Bad News	Include Bad News	Exclude Bad News	Include Bad News	Exclude Bad News
[-10, -1]	0.012	0.034	-0.016	0.014	0.102	0.122
[0, 1]	-0.002	-0.033	-0.036	0.000	0.065	0.075
[0, 5]	-0.020	-0.060**	-0.070*	-0.029	0.148	0.171
[0, 10]	-0.003	-0.028	-0.077*	-0.031	0.081	0.093
[-10, 10]	0.008	0.010	-0.070	-0.015	0.240	0.279

Table 32 Difference in CARs between the small and the big on each day (Include the bad news)

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	0.008	0.011	0.017	0.024**	0.019	0.011	0.013
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.003	-0.019	-0.090	-0.209	-0.232	-0.234	-0.252
Edate	4	5	6	7	8	9	10
Small-Big	-0.300	-0.398	-0.382	-0.312	-0.312	-0.285	-0.233

Table 33 Difference in CARs between the small and the big on each day (Exclude the bad news)

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	0.007	0.010	0.016	0.022*	0.016	0.005	0.005
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.001	-0.022	-0.088	-0.228	-0.278	-0.277	-0.298
Edate	4	5	6	7	8	9	10
Small-Big	-0.355	-0.468	-0.448	-0.368	-0.361	-0.332	-0.269

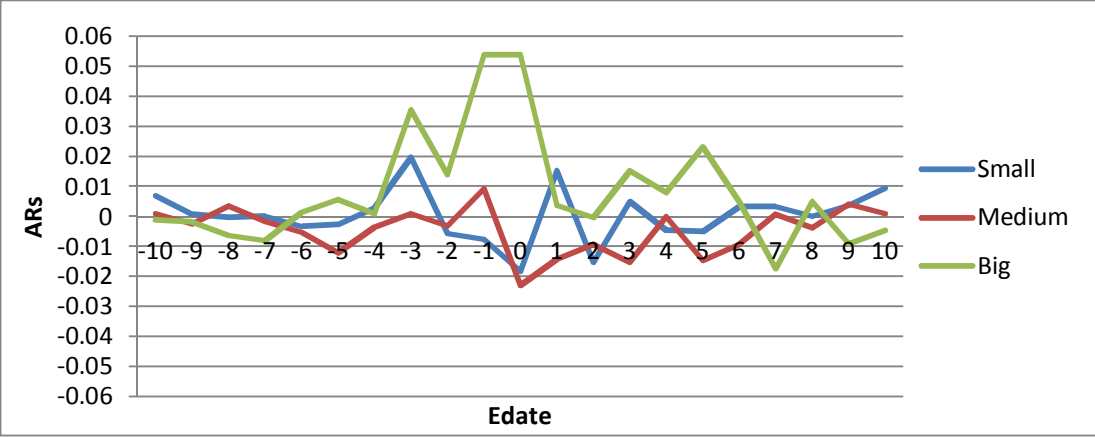


Figure 25 ARs for 21 days of 3 group surrounding public disclosure of advisory committee recommendation (Include the bad news)

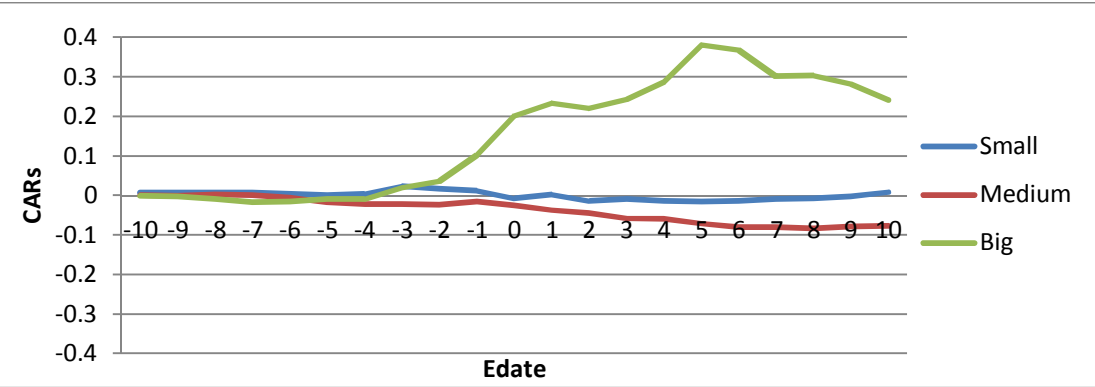


Figure 26 CARs for 21 days of 3 group surrounding public disclosure of advisory committee recommendation (Include the bad news)

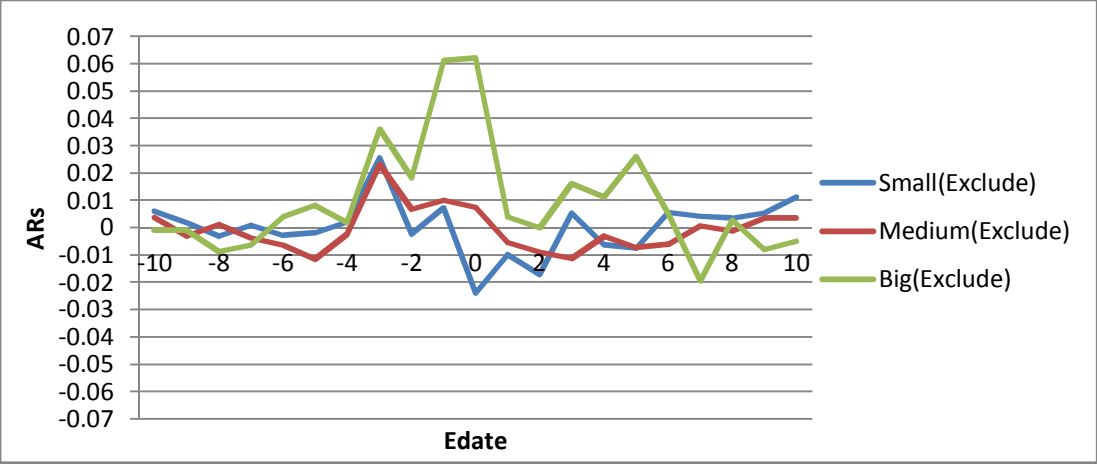


Figure 27 ARs for 21 days of 3 group surrounding public disclosure of advisory committee recommendation (Exclude the bad news)

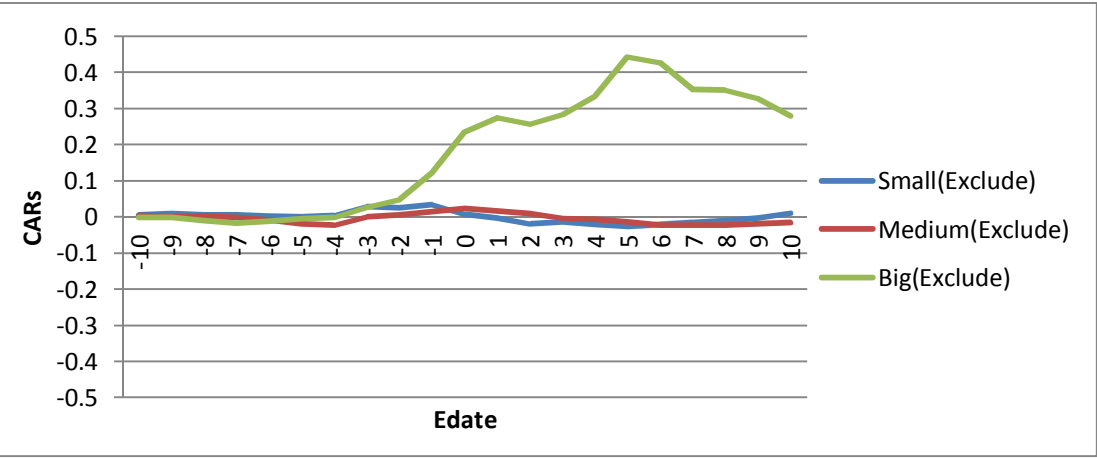


Figure 28 CARs for 21 days of 3 group surrounding public disclosure of advisory committee recommendation (Exclude the bad news)

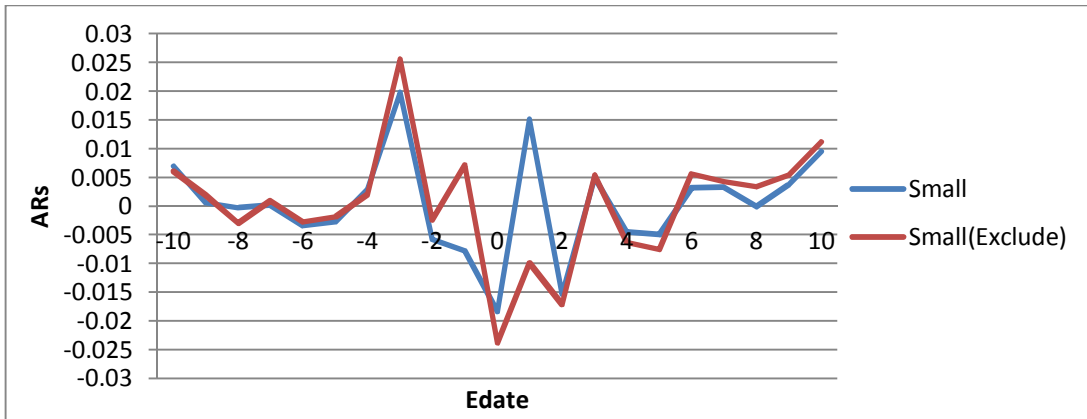


Figure 29 ARs including and excluding the bad news for the small

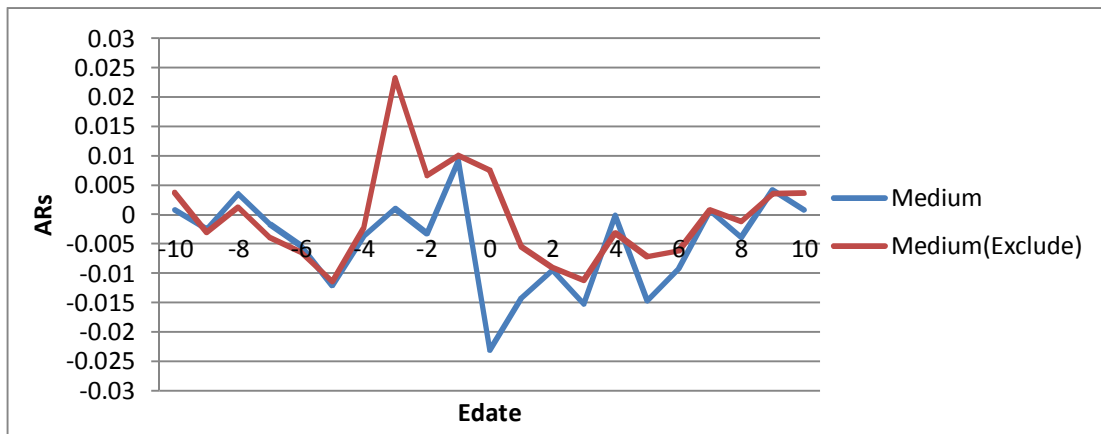


Figure 30 ARs including and excluding the bad news for the medium

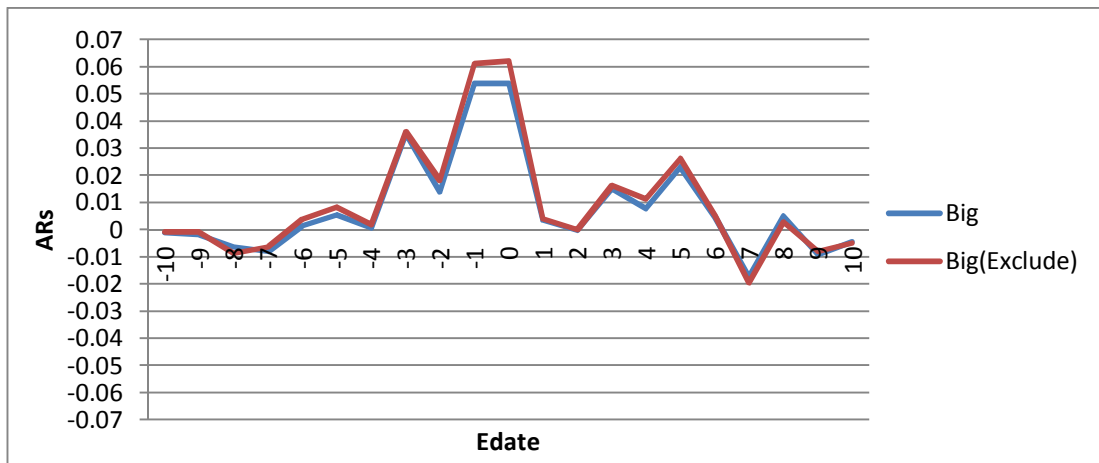


Figure 31 ARs including and excluding the bad news for the big

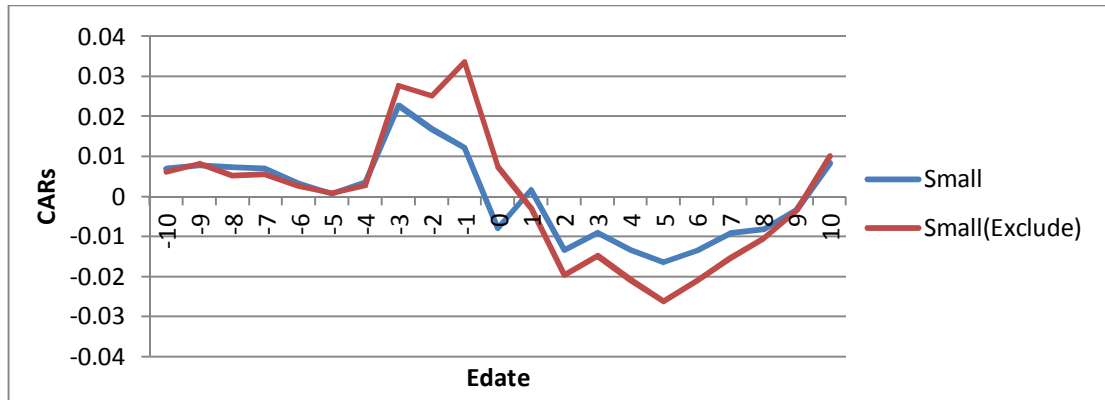


Figure 32 CARs including and excluding the bad news for the small

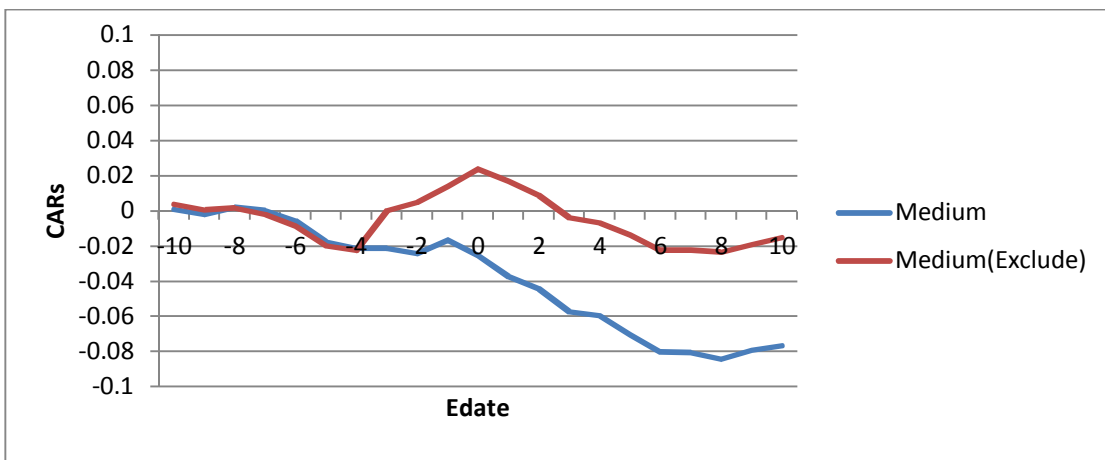


Figure 33 CARs including and excluding the bad news for the medium

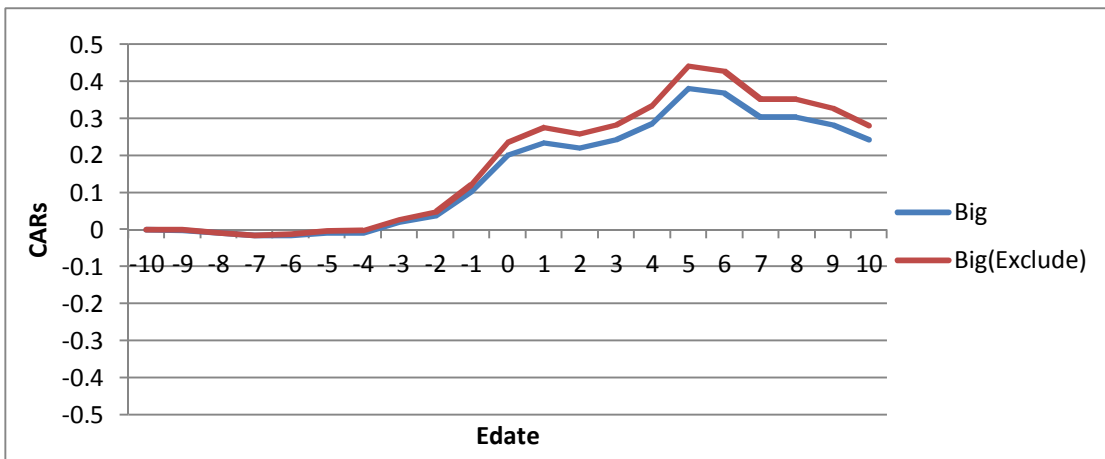


Figure 34 CARs including and excluding the bad news for the big

Interestingly, I realize that even though abnormal return and cumulative abnormal return of the big cap group are pretty substantial, they are not statistically significant. I can observe the same situation in table 32 and table 33 where the gap in cumulative abnormal return between the small cap group and the big cap group is huge since the event day, though statistically insignificant. Therefore, I wonder whether the big margin comes from one or few extreme values. Next, I try to identify and take off the extreme value(s) from the big cap group to see what would happen to abnormal return and cumulative abnormal return of this group.

The extreme value comes from the application for Provenge filed by Dendreon. The results after I delete it from the big cap sample are presented in figure 35-figure 42. Figure 35 and figure 36 show that both abnormal return and cumulative abnormal return excluding the extreme value are less fluctuated and smoother than those including the extreme, and the degree they increase is much less. Figure 36 indicates that when I delete the extreme from the sample cumulative abnormal return only increases as 25% as cumulative abnormal return with the extreme. Comparing figure 37 and figure 38 with figure 25 and figure 26, I find the gap between the small cap group and the big cap group without the extreme value is much less than the gap between the small cap group and the big cap group with the extreme value. And the pattern of the movement in small cap group and the big cap group excluding the extreme are more similar. I can observe the same performance from figure 39-figure 42 in the scenario when I get rid of disapproval recommendations from my sample.

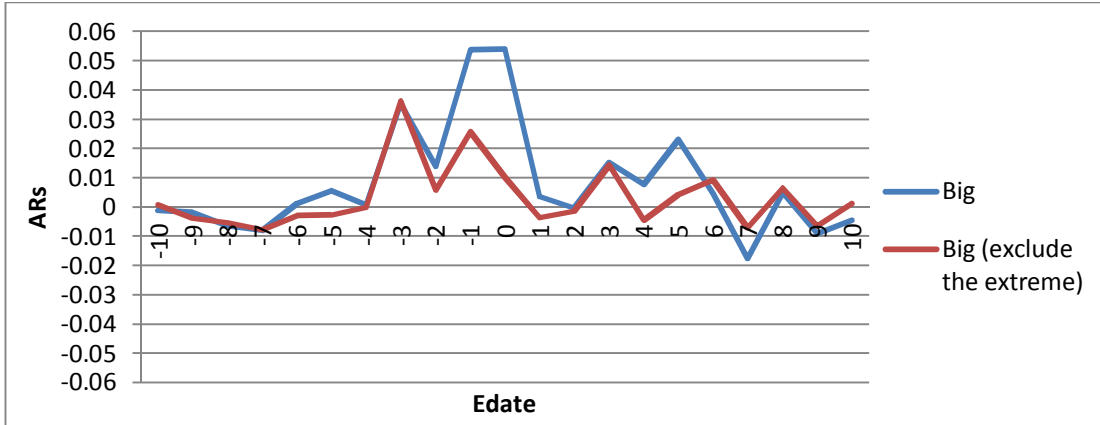


Figure 35 ARs for the big with/without the extreme value surrounding public disclosure of advisory committee recommendation

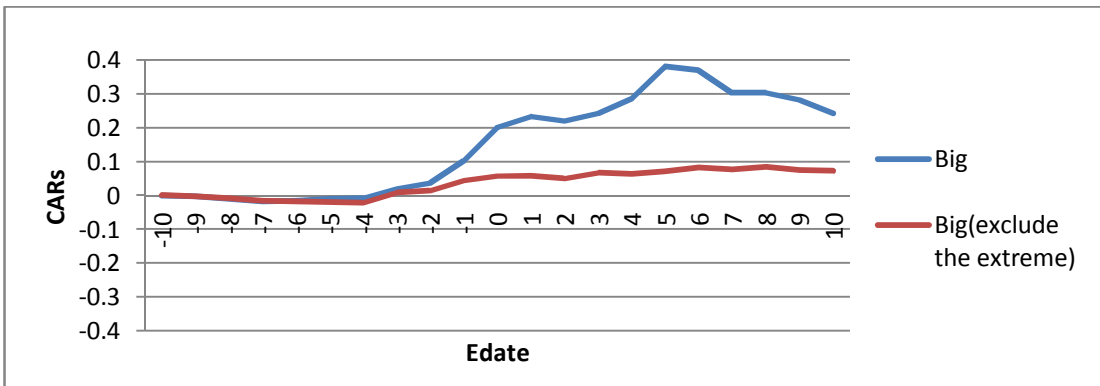


Figure 36 CARs for the big with/without the extreme value surrounding public disclosure of advisory committee recommendation

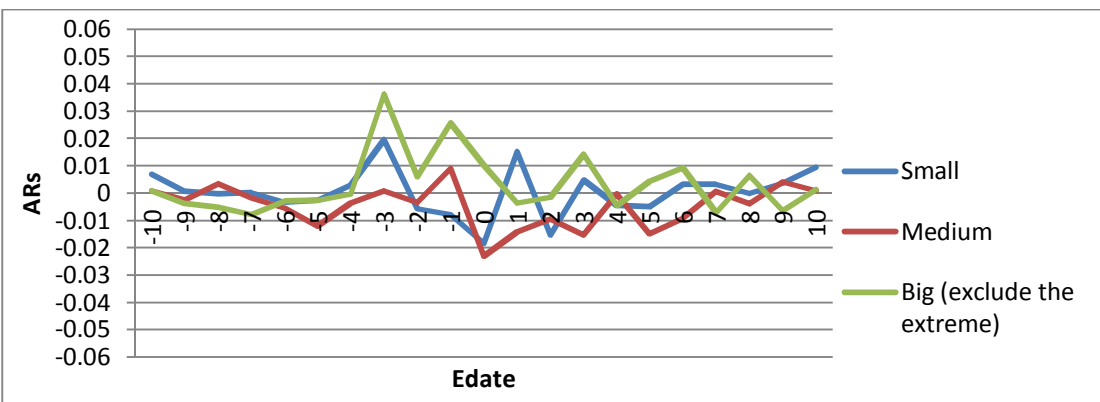


Figure 37 ARs for 3 groups but excluding the extreme from the big surrounding public disclosure of advisory committee recommendation

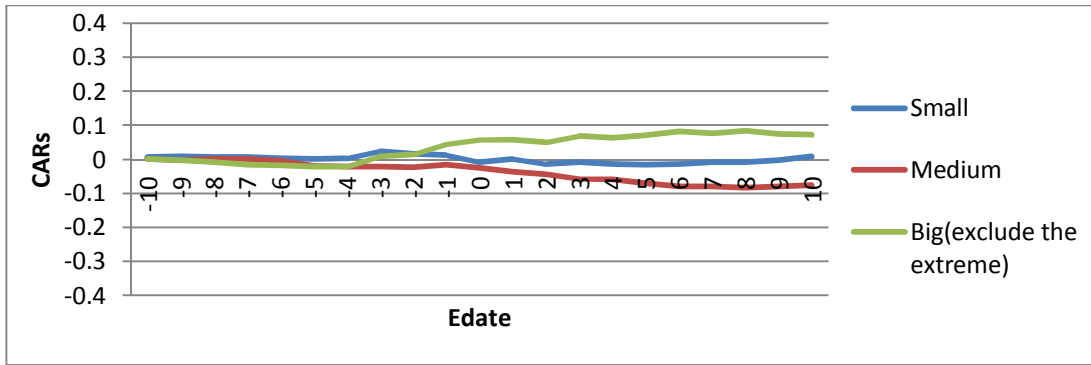


Figure 38 CARs for 3 groups but excluding the extreme from the big surrounding public disclosure of advisory committee recommendation

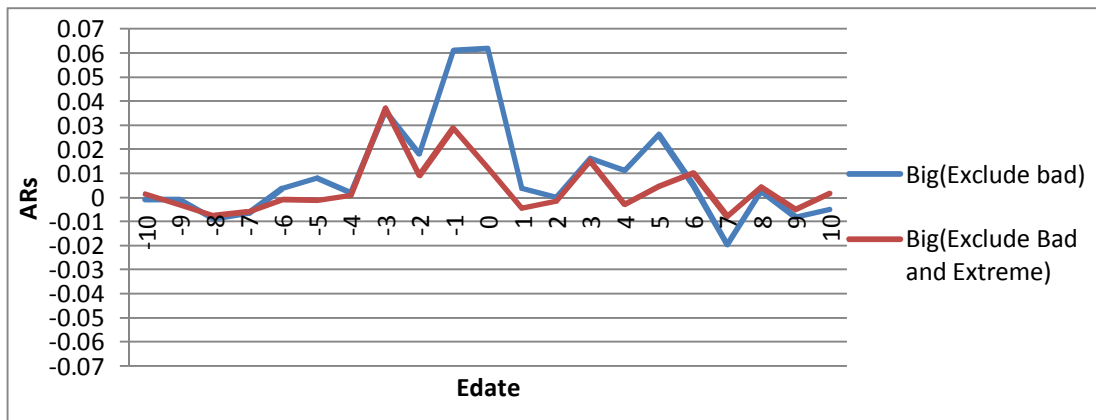


Figure 39 ARs for the big with/without the extreme value surrounding public disclosure of advisory committee recommendation (Exclude disapproval recommendations)

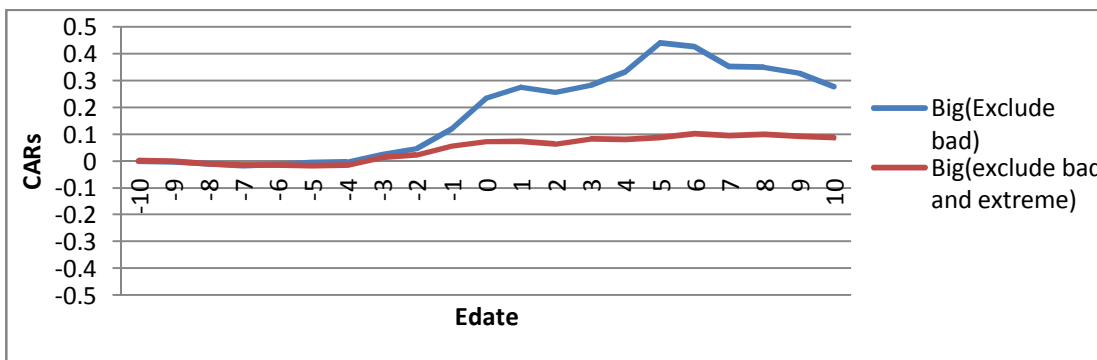


Figure 40 CARs for the big with/without the extreme value surrounding public disclosure of advisory committee recommendation (Exclude disapproval recommendations)

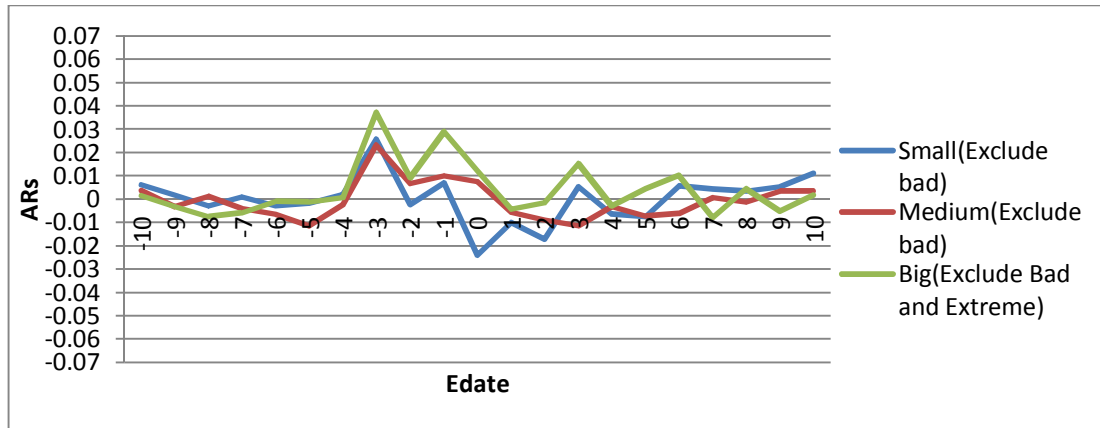


Figure 41 ARs for 3 groups but excluding the extreme from the big surrounding public disclosure of advisory committee recommendation (Exclude disapproval recommendations)

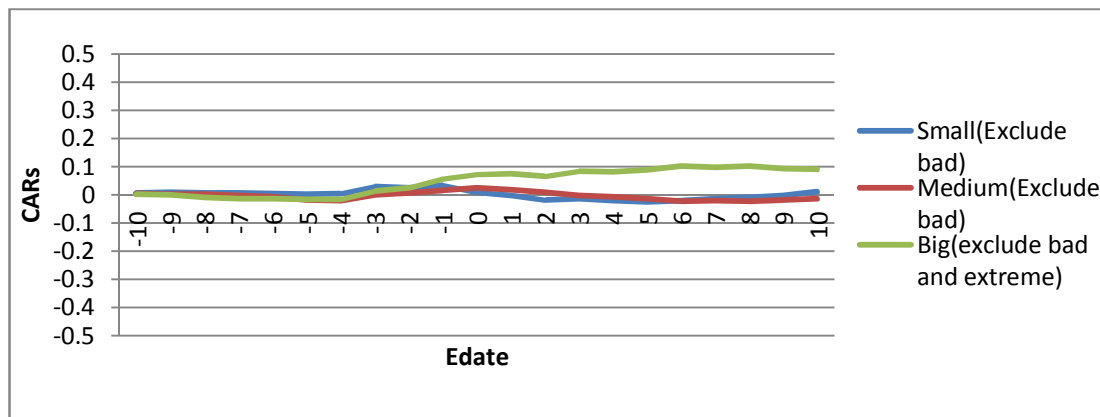


Figure 42 CARs for 3 groups but excluding the extreme from the big surrounding public disclosure of advisory committee recommendation (Exclude disapproval recommendations)

8.2.5 Issuance of Complete Response Letter from FDA

Figure 43 and figure 44 show issuance of complete response letter does have a big negative influence on the pharmaceutical firm stock value no matter what capital size they are as dramatic decline of abnormal return and apparently downward drift of cumulative abnormal return are observed in all three groups. The dramatic decline and

downward drift happen on the event day for the big cap group and the medium cap group, while they happen on 2 days preceding the event for the small cap group, which is an evidence of insider trading in the small cap group. Table 35 reinforces the suggestion since only cumulative abnormal return of the small cap group is significantly negative over [-10, -1].

Table 35 indicates that cumulative abnormal return of the small cap group and the big cap group are significantly negative over [0, 1], [0, 5], [0, 10] and [-10, 10] which could be explained by table 34 where negative abnormal return is frequently observed after the event date for the small cap group and the big cap group. Figure 44 also shows that after obvious downward drift CAR curves of the big cap group and of the small cap group slightly move down further after the event day. Even though I can see the margin of cumulative abnormal return curve are apparently different between the small cap group and the big cap group, table 36 shows that the difference between them is insignificant through the window, except day -1, which is -0.0738 and significant at the 0.10 level, suggesting that the market of the small cap group is less efficient than the big cap group.

Table 34 ARs of 3 groups for issuance of complete response letter

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	20	-0.0006	21	0.0047	21	0.0040
-9	20	0.0075	21	0.0021	21	-0.0039
-8	20	0.0034	21	0.0135	21	-0.0014
-7	20	-0.0091	21	0.0079	21	-0.0010
-6	20	-0.0045	21	-0.0012	21	-0.0004
-5	20	-0.0084	21	0.0084	21	0.0022

Table 34 continued

-4	20	0.0144	21	-0.0018	21	0.0033
-3	20	-0.0075	21	-0.0009	21	-0.0011
-2	20	-0.0351	21	-0.0065	21	-0.0028
-1	20	-0.0442	21	-0.0049	21	-0.0016
0	20	-0.0777	21	-0.0915*	21	-0.0915*
1	20	-0.0148	21	0.0088	21	0.0023
2	20	-0.0103	21	-0.0115*	21	0.0069
3	20	-0.0111	21	-0.0039	21	-0.0092
4	20	-0.0013	21	-0.0007	21	-0.0018
5	20	-0.0246**	21	0.0007	21	0.0051
6	20	0.0086	21	-0.0094	21	-0.0016
7	20	-0.0055	21	0.0022	21	-0.0041
8	20	-0.0146	21	0.0025	21	-0.0003
9	20	0.0167	21	0.0059	21	0.0057
10	20	-0.0058	21	-0.0034	21	-0.0069**

Table 35 CARs for different intervals of 3 groups surrounding issuance of complete response letter

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	-0.078*	0.023	-0.004
[0, 1]	-0.087	-0.081	-0.097*
[0, 5]	-0.125**	-0.088	-0.102**
[0, 10]	-0.130**	-0.086	-0.112**
[-10, 10]	-0.200***	-0.083	-0.115**

Table 36 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	-0.005	0.007	0.011	0.002	-0.001	-0.010	-0.001
Edate	-3	-2	-1	0	1	2	3
Small-Big	-0.008	-0.034	-0.074*	-0.060	-0.062	-0.071	-0.075
Edate	4	5	6	7	8	9	10
Small-Big	-0.078	-0.091	-0.083	-0.085	-0.088	-0.084	-0.086

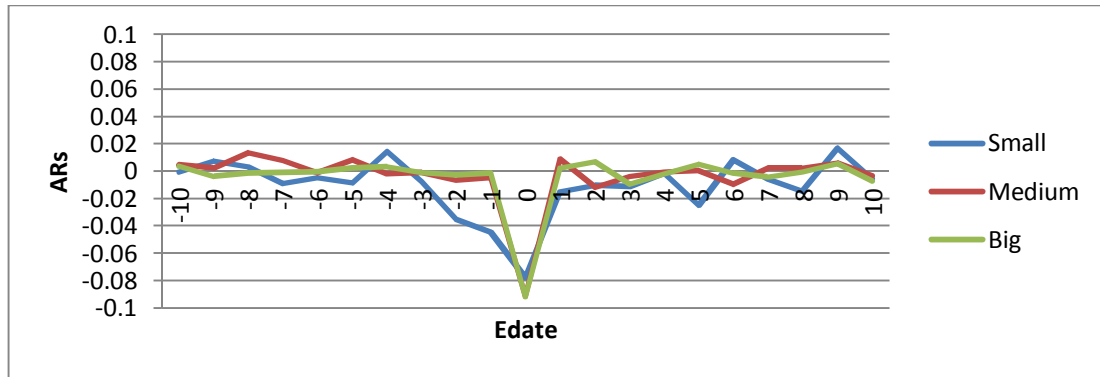


Figure 43 ARs for 21 days of 3 group surrounding issuance of complete response letter

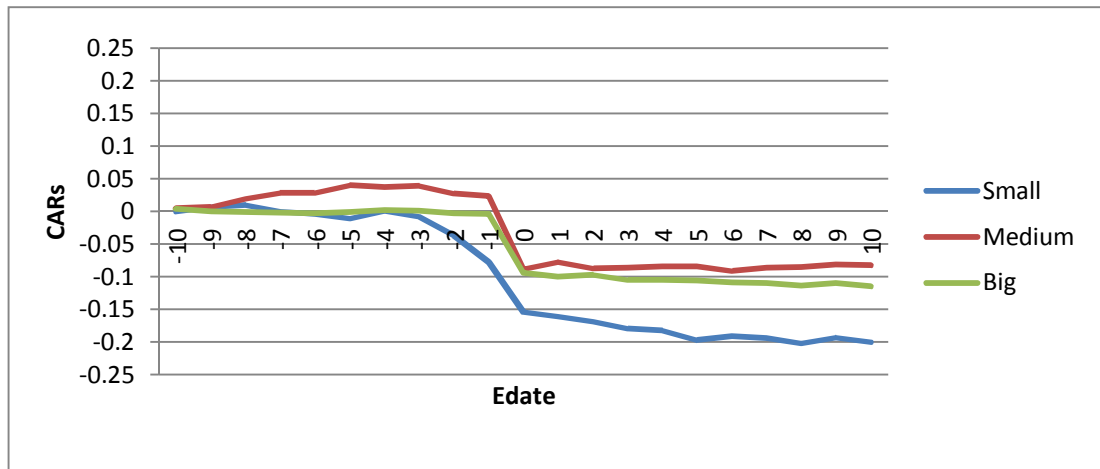


Figure 44 CARs for 21 days of 3 group surrounding issuance of complete response letter

8.2.6 Resubmission

Figure 45 and figure 46 demonstrate abnormal return and cumulative abnormal return of the medium cap group are economically and statistically insignificant. But abnormal return and cumulative abnormal return of the small cap group and the big cap group are substantial. Abnormal return of the big cap group jumps dramatically on the event day as well as cumulative return which demonstrate no systematic

movement thereafter. Abnormal return and cumulative abnormal return of the small cap group increase obviously twice over the window. One is on 7 days before the event, the other starts on 3 days preceding the event and lasts to event day. Figure 46 shows that after reaching the peak at around 0.16 cumulative abnormal return of the small cap group has a downward adjustment. Mild and Significant positive abnormal return appears on 3 days preceding the event day and lasts to the event day in table 37 suggests the existence of insider trading. Table 38 further confirms this possibility since cumulative abnormal return of the small cap group over [-10, -1] is positive and cumulative abnormal returns over [0, 5] and [0, 10] are negative, implying the adjustment of overreaction. Table 40 shows that the difference in cumulative abnormal return between the small group and the big group is statistically insignificant, though on some days the gap between them is big, such as day -1 and day 0.

Table 37 ARs of 3 groups for resubmission

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	12	0.0123	13	-0.0001	13	0.0104
-9	12	0.0089	13	-0.0004	13	-0.0030
-8	12	-0.0177	13	-0.0045	13	0.0065*
-7	12	0.0625	13	0.0145**	13	-0.0173
-6	12	-0.0164	13	-0.0009	13	0.0055
-5	12	-0.0020	13	-0.0039	13	0.0059
-4	12	-0.0170	13	-0.0027	13	-0.0061
-3	12	0.0109*	13	-0.0032	13	-0.0178
-2	12	0.0290	13	0.0048	13	0.0116*
-1	12	0.0380	13	-0.0176	13	-0.0079
0	12	0.0315*	13	-0.0071	13	0.0822
1	12	-0.0100	13	-0.0026	13	-0.0012
2	12	-0.0238	13	0.0005	13	0.0012

Table 37 continued

3	12	-0.0101	13	-0.0113	13	0.0007
4	12	0.0084	13	-0.0018	13	-0.0017
5	12	-0.0162	13	0.0092	13	0.0016
6	12	0.0052	13	-0.0023	13	0.0023
7	12	-0.0089	13	0.0083	13	-0.0004
8	12	-0.0123**	13	-0.0071*	13	0.0068
9	12	0.0245***	13	0.0003	13	-0.0112
10	12	-0.0019	13	-0.0037	13	-0.0008

Table 38 CARs for different intervals of 3 groups surrounding resubmission

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	0.119	-0.012	-0.011
[0, 1]	0.020	-0.010	0.080
[0, 5]	-0.025	-0.013	0.077
[0, 10]	-0.019	-0.018	0.075
[-10, 10]	0.085	-0.028	0.045

Table 39 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	0.002	0.015	-0.013	0.073	0.034	0.030	0.013
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.038	0.063	0.130	0.114	0.084	0.060	0.041
Edate	4	5	6	7	8	9	10
Small-Big	0.046	0.030	0.034	0.028	0.007	0.049	0.041

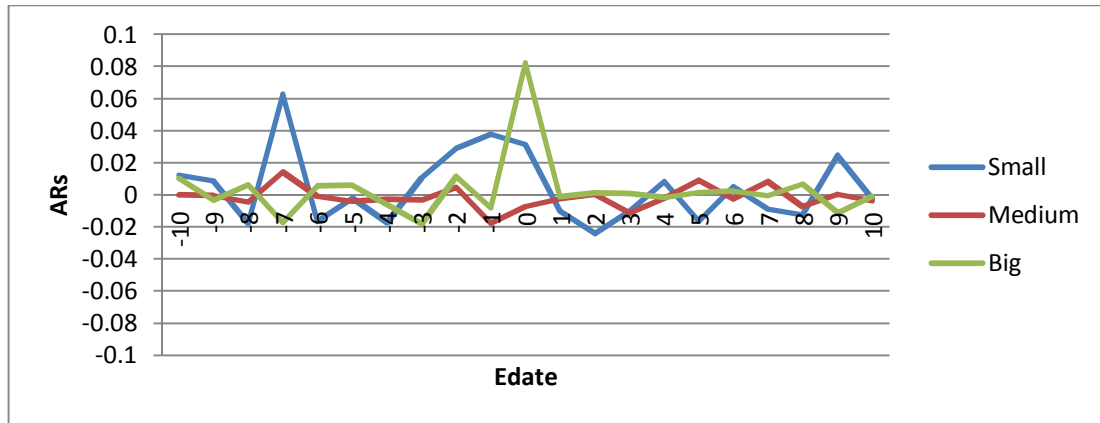


Figure 45 ARs for 21 days of 3 groups surrounding the resubmission

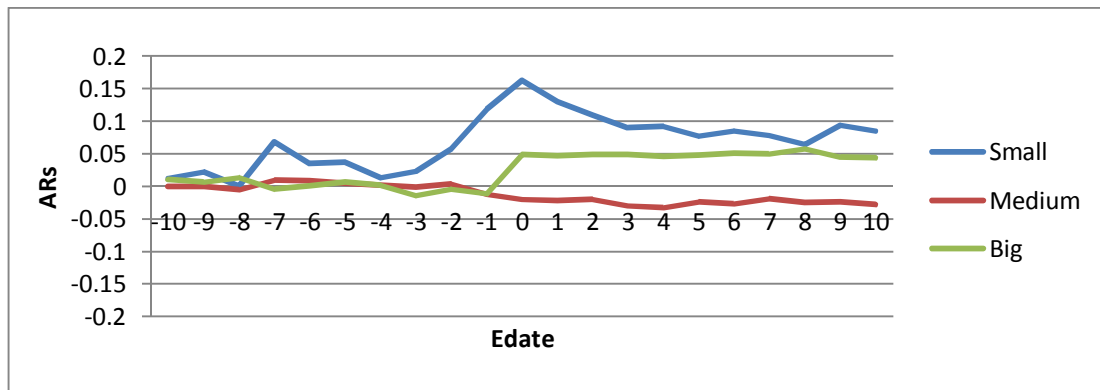


Figure 46 CARs for 21 days of 3 groups surrounding the resubmission

I want to know whether the facts that the gap of cumulative abnormal return between the small cap group and the big cap group are economically significant but statistically insignificant and abnormal return of the small cap group on day -7 and that of the big cap group on day 0 are economical and insignificant come from the extreme value(s). I identify the extreme value in the small cap group comes from the application of Silenor filed by Somaxon Pharmaceuticals and the extreme value in the big cap group comes from the application of Feraheme filed by AMAG pharmaceuticals. I take off these extreme values from my sample and do the previous

analysis again. The results are showed in figure 47 to figure 52. By putting abnormal returns and cumulative abnormal returns with or without the extreme values in the same figure I can observe that both cumulative abnormal returns and abnormal returns are flatter and less fluctuated for the sample without the extremes than the sample with the extremes. Figure 48 demonstrates that there is no drift of cumulative abnormal return in the small cap group surrounding resubmission when I take off the extreme, while obvious upward drift happens in the small cap group including the extreme. Figure 49 shows only slight increase occurs on resubmission day in big cap group without the extreme, instead of a big jump on the resubmission day in the big group with the extreme. Figure 50 indicates that even though cumulative abnormal returns in both big groups with or without the extreme have upward drift, the drift in the big group without the extreme is smoother and more gradual. Comparing figure 51 and figure 52 to figure 45 and figure 46, either abnormal return curves or the cumulative abnormal return curves for all 3 groups are much closer and more consistent in the sample excluding the extremes than those in the sample including the extremes.

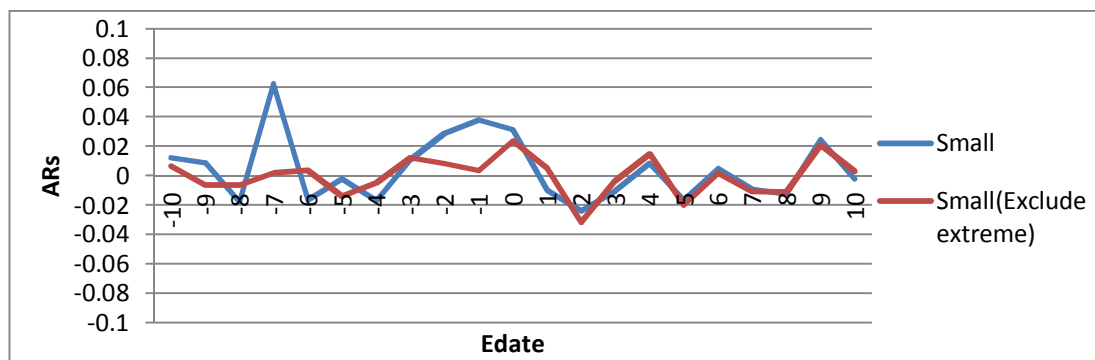


Figure 47 ARs for the small with/without the extreme value surrounding resubmission

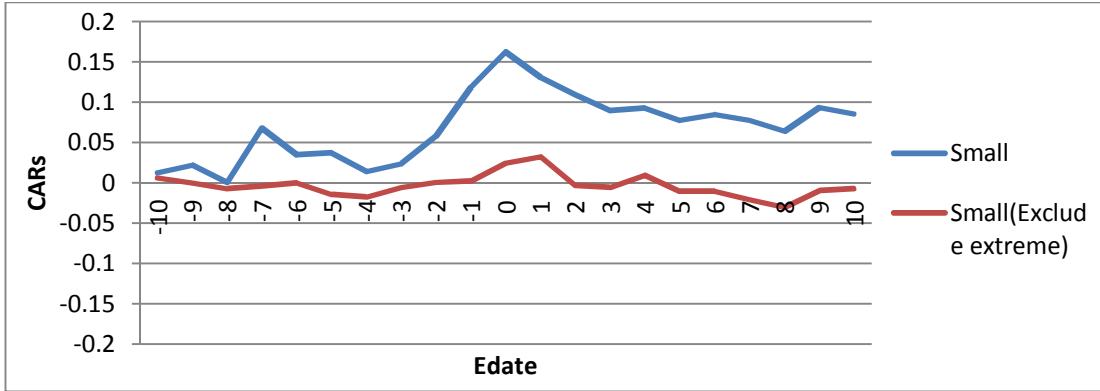


Figure 48 CARs for the small with/without the extreme value surrounding resubmission

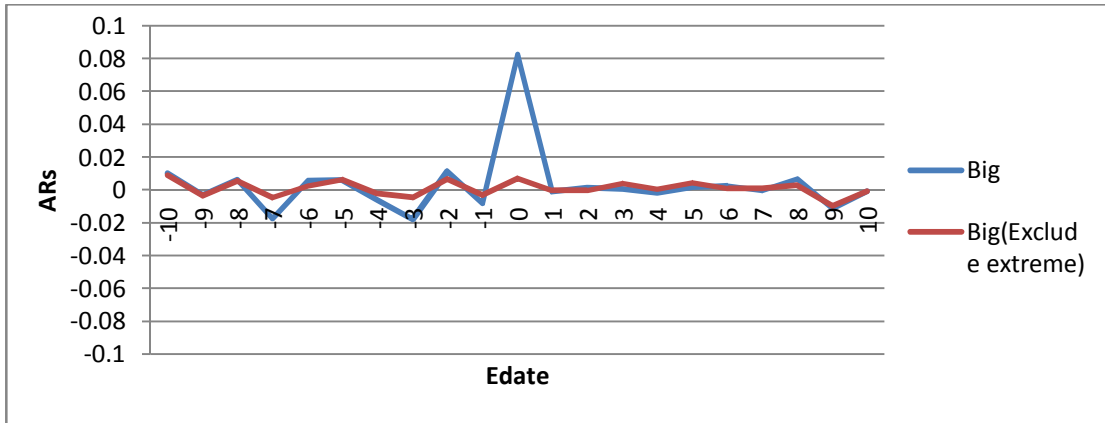


Figure 49 ARs for the big with/without the extreme value surrounding resubmission

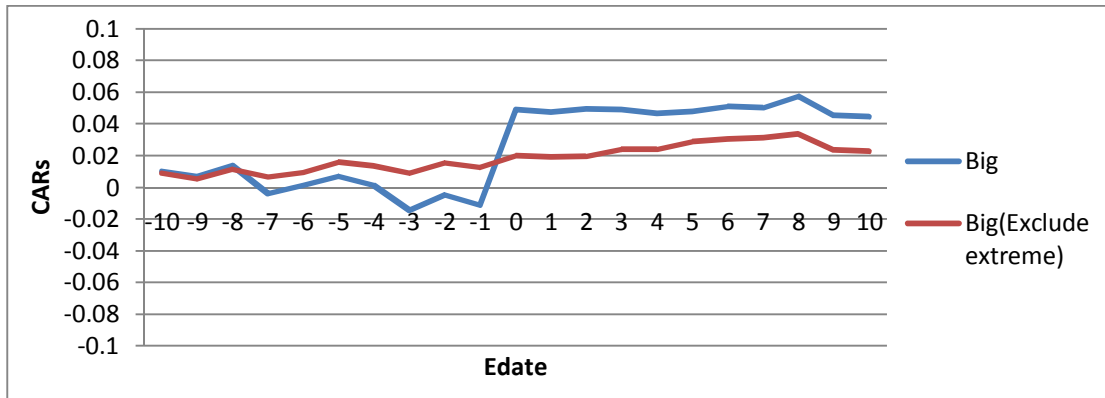


Figure 50 CARs for the big with/without the extreme value surrounding resubmission

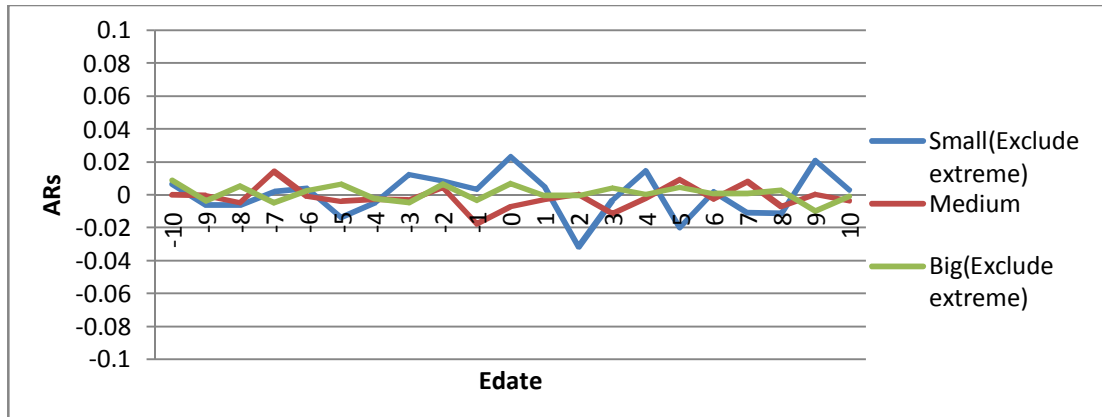


Figure 51 ARs for 3 groups but excluding the extreme from the small and the big surrounding resubmission

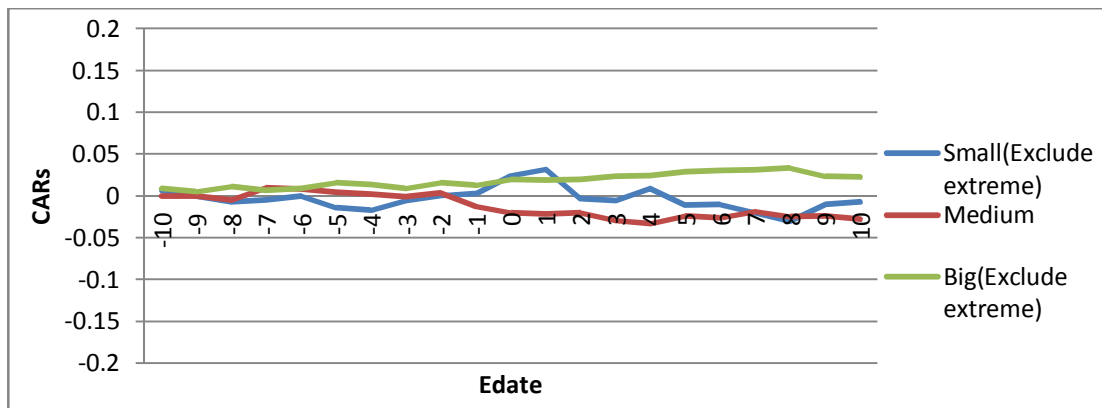


Figure 52 CARs for 3 groups but excluding the extreme from the small and the big surrounding resubmission

8.2.7 Approval of An Application

Figure 53 and figure 54 shows there is a bump on the event day for abnormal returns and cumulative abnormal returns of the medium cap group and the big cap group. Table 40 shows that both the medium cap group and the big cap group have significantly positive abnormal return on the event day. Table 41 shows that cumulative abnormal return of the medium cap group over interval $[0, 1]$, $[0, 5]$ and

[0, 10] are significantly positive which means the increasing stock value in medium cap group resulting from approval of an application is sustainable. Cumulative abnormal return of the big cap group is significantly positive only over interval [0, 1] which means the adjustment of this group is very fast. Figure 53 and figure 54 indicates abnormal return and cumulative abnormal return of the small cap group have big jump on 1 day after the event day, though it is statistically insignificant in table 40 and table 41. Significantly positive abnormal return preceding the event day for the small cap group and the medium cap group suggest the existence of inside trading in these two groups. Even though abnormal return and cumulative abnormal return of the small cap group look quite different from those of the big cap group on the event day and thereafter, table 43 indicates the difference is not statistically significant.

Table 40 ARs of 3 groups for approval of an application

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	65	-0.0028	64	-0.0015	61	0.0023
-9	65	-0.0001	64	-0.0019	61	0.0015
-8	65	-0.0085	64	0.0003	61	-0.0013
-7	65	-0.0025	64	0.0035*	61	-0.0004
-6	65	-0.0023	64	-0.0024	61	-0.0012
-5	65	-0.0032	64	-0.0013	61	0.0018
-4	65	0.0039	64	0.0046*	61	-0.0029
-3	65	0.0051**	64	0.0048	61	0.0007
-2	65	0.0062	64	0.0013	61	0.0007
-1	65	-0.0024	64	0.0067	61	0.0011
0	65	0.0074	64	0.0193***	61	0.0114**
1	65	0.1552	64	0.0024	61	0.0044
2	65	-0.0150***	64	-0.0035	61	-0.0059***
3	65	0.0032	64	-0.0042**	61	-0.0031
4	65	0.0050	64	-0.0025	61	-0.0020

Table 40 continued

5	65	0.0125	64	-0.0004	61	-0.0015
6	65	-0.0045	64	-0.0012	61	-0.0001
7	65	-0.0069	64	0.0023	61	0.0036
8	65	-0.0037	64	0.0001	61	0.0018
9	65	-0.0030	64	0.0007	61	-0.0024
10	65	-0.0001	64	-0.0014	61	0.0003

Table 41 CARs for different intervals of 3 groups surrounding approval of an application

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	-0.009	0.014	0.002
[0, 1]	0.156	0.022***	0.016*
[0, 5]	0.225	0.011*	0.003
[0, 10]	0.183	0.011*	0.007
[-10, 10]	0.153	0.025*	0.009

Table 42 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	-0.005	-0.007	-0.014*	-0.017*	-0.018*	-0.022**	-0.016
Edate	-3	-2	-1	0	1	2	3
Small-Big	-0.011	-0.007	-0.011	-0.016	0.113	0.105	0.131
Edate	4	5	6	7	8	9	10
Small-Big	0.150	0.187	0.164	0.152	0.154	0.142	0.144

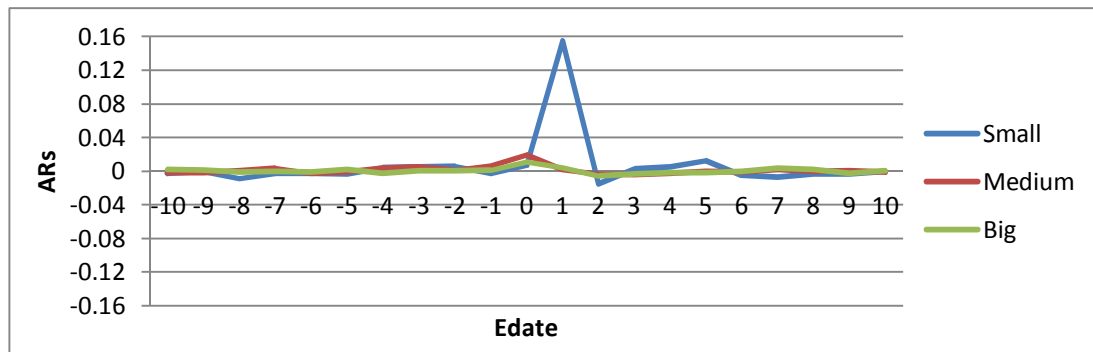


Figure 53 ARs for 21 days of 3 groups surrounding approval of an application

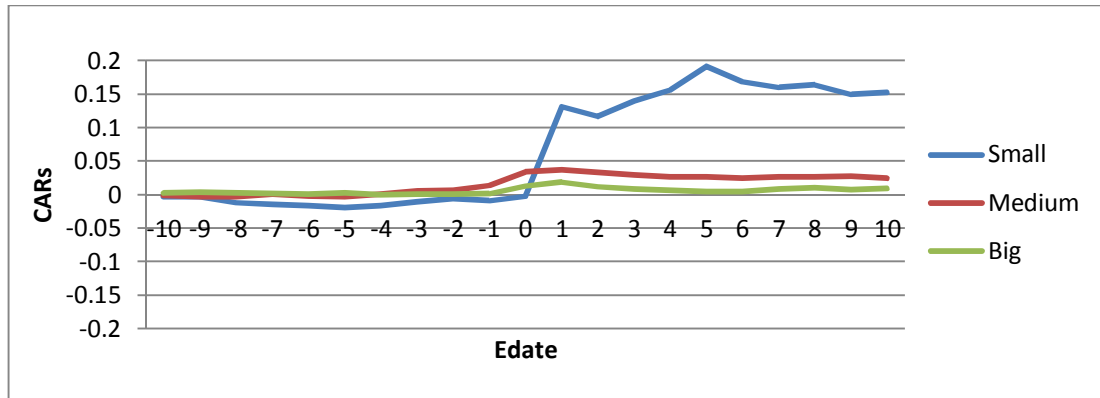


Figure 54 CARs for 21 days of 3 groups surrounding approval of an application

One possible explanation to extraordinary high but statistically insignificant abnormal return and cumulative abnormal return of the small cap group is that there are one or some extreme value(s) in the sample. I identify this extreme value is the application of Fanapt filed by Vanda Pharmaceuticals. I do the analysis mentioned above again after I delete the extreme from the small cap group. The results are summarized in figure 55 to figure 58. Figure 55 and figure 56 show that both abnormal return and cumulative abnormal return of the small cap group without the extreme value only increase about one third of those of the small group with the extreme value on the 1st day after the approval day. Taking off the extreme from the small cap group does not change the pattern of this group's response to the event and my results show that after I delete the extreme value from the small cap group the positive abnormal return on day 1 turns to be statistically significant at the 0.05 level and table 44 shows cumulative abnormal returns over interval $[0, 1]$ and $[0, 5]$ are significant at the 0.05 level. Comparing figure 57 and figure 58 to figure 53 and figure 54, I find the difference between the small cap group without the extreme and the big

or the medium cap group is much less than the difference when the extreme observation is in the sample. Figure 58 demonstrates that some parts of cumulative abnormal return of the small cap group without the extreme even superimpose the curve of the medium cap group after the event day, contrary to the results with the extreme that cumulative abnormal return of the small cap group is at least 3 times higher than that of the medium cap group after the event day.

Table 43 CARs of the small including or excluding extreme value over different intervals

Interval	CAR (Include Extreme)	CAR (Exclude Extreme)
[-10, -1]	-0.009	-0.007
[0, 1]	0.156	0.064**
[0, 5]	0.225	0.059**
[0, 10]	0.183	0.042
[-10, 10]	0.153	0.030

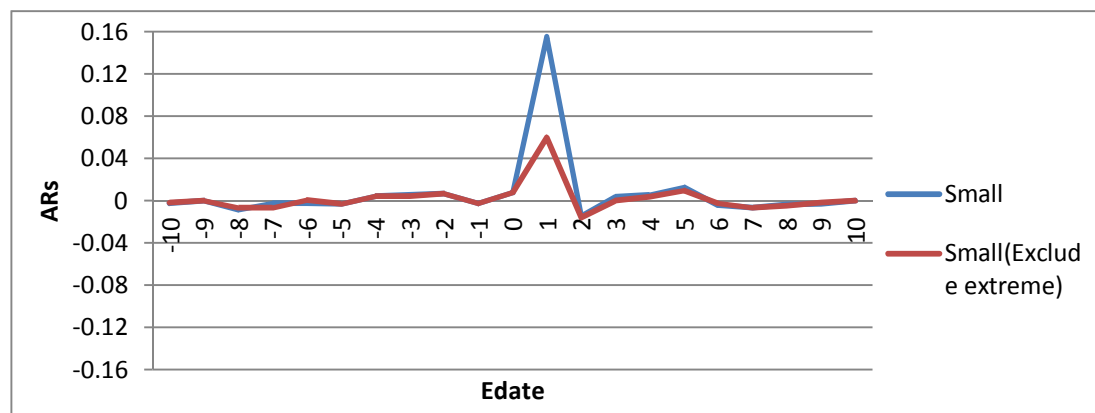


Figure 55 ARs for the small with/without the extreme value surrounding approval of an application

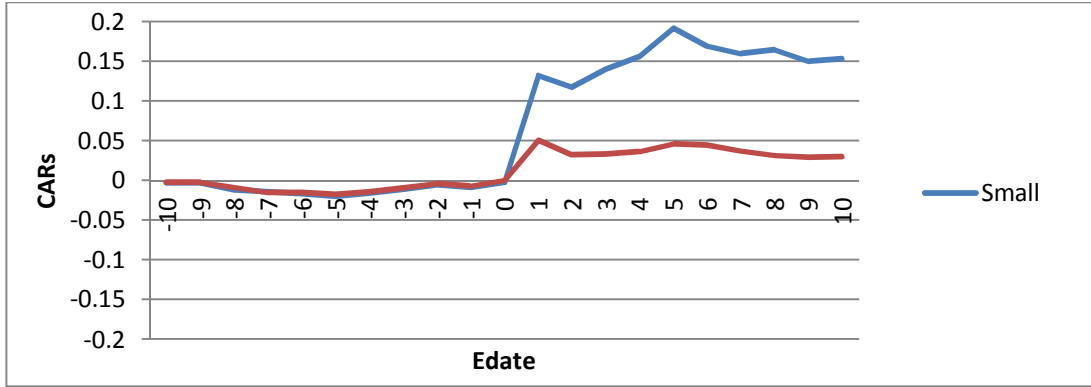


Figure 56 CARs for the small with/without the extreme value surrounding approval of an application

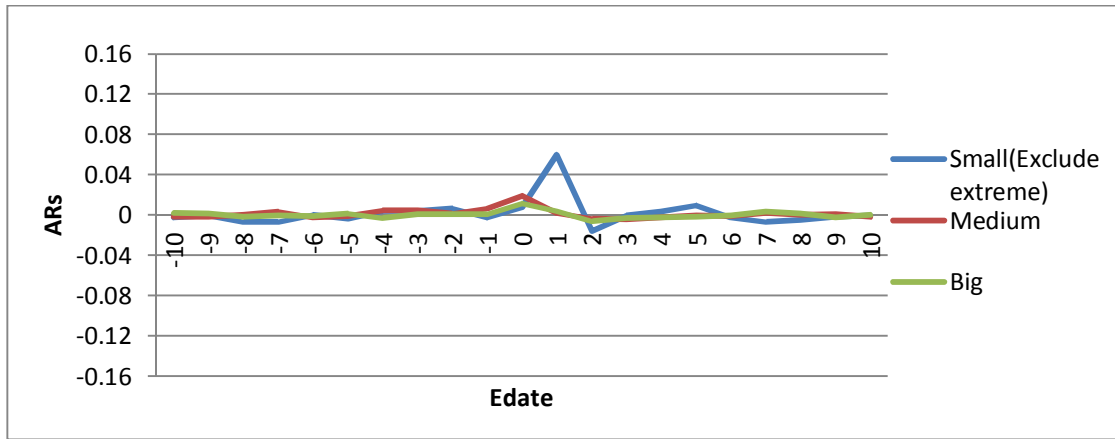


Figure 57 ARs for 3 groups but excluding the extreme from the small surrounding approval of an application

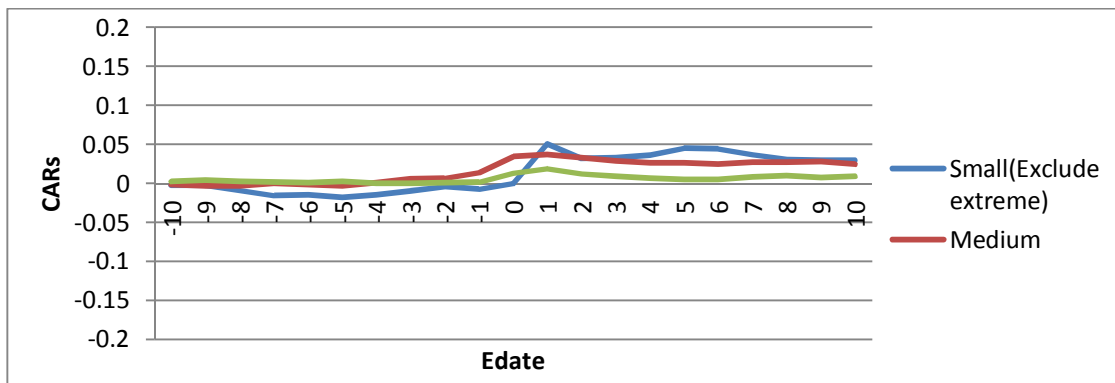


Figure 58 CARs for 3 groups but excluding the extreme from the small surrounding approval of an application

8.2.8 Approval of New Indication

Figure 59 shows abnormal returns of the three groups all fluctuate randomly around 0. Figure 60 shows that cumulative abnormal return of the big cap group mostly moves below 0 but cumulative abnormal returns of the small and the medium cap group mostly move above 0. The results in table 45 are consistent with the pattern in figure 60, where cumulative abnormal returns of the small and medium cap group over any interval under study are positive while cumulative abnormal return of the big group over any interval after the event day is negative, though none of them is statistically significant. Table 44 demonstrates that abnormal returns of the small cap and the medium cap group on some days over the window are mild or significant; in the contrast, abnormal return of the big cap group over the whole window is trivial and insignificant. The different result between the big cap group and the small/medium cap group implies approval of new indication has different impact on the 3 groups' value: the impact on the big cap group is negligible; while the impact on the small/medium group cannot be ignored. The possible explanation of the trivial impact of approval of new indication on the big cap group is that to-be -lost market share of the upcoming expired drug of a big cap pharmaceutical company is too big to be offset by approval of new indication for two reasons: first, the huge market share would attract many generic competitors entering the market once it is expired; second, the ability of new indication generating profit for the company is limited. Table 46 demonstrates that despite totally different performance of cumulative abnormal returns of the small cap group and the big cap group the difference is not significant.

Table 44 ARs of 3 groups for approval of new indication

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	14	0.0030	16	-0.0029	14	-0.0008
-9	14	0.0011	16	0.0010	14	-0.0011
-8	14	0.0037	16	0.0065*	14	-0.0030
-7	14	-0.0045	16	0.0094*	14	0.0004
-6	14	0.0040	16	0.0013	14	0.0012
-5	14	-0.0086	16	-0.0003	14	0.0026
-4	14	-0.0006	16	-0.0004	14	0.0026
-3	14	0.0071	16	0.0026	14	-0.0003
-2	14	0.0030	16	-0.0060	14	0.0002
-1	14	0.0080*	16	0.0013	14	0.0002
0	14	-0.0009	16	0.0058	14	-0.0047
1	14	0.0112	16	-0.0033	14	0.0019
2	14	-0.0087	16	0.0007	14	-0.0045
3	14	0.0041	16	0.0000	14	0.0022
4	14	0.0053	16	0.0002	14	-0.0043
5	14	0.0002	16	0.0012	14	-0.0060
6	14	-0.0162	16	0.0047	14	0.0021
7	14	0.0071	16	-0.0009	14	0.0031
8	14	0.0013	16	-0.0099***	14	0.0026
9	14	0.0028	16	0.0032	14	-0.0088
10	14	0.0005	16	0.0094*	14	0.0016

Table 45 CARs for different intervals of 3 groups surrounding approval of new indication

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	0.016	0.013	0.003
[0, 1]	0.009	0.002	-0.003
[0, 5]	0.010	0.004	-0.015
[0, 10]	0.009	0.012	-0.014
[-10, 10]	0.023	0.024	-0.011

Table 46 Difference in CARs between the small and the big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	0.004	0.006	0.013*	0.008	0.010	-0.002	-0.005
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.002	0.005	0.013	0.017	0.025	0.021	0.023
Edate	4	5	6	7	8	9	10
Small-Big	0.033	0.038*	0.021	0.023	0.022	0.035	0.034

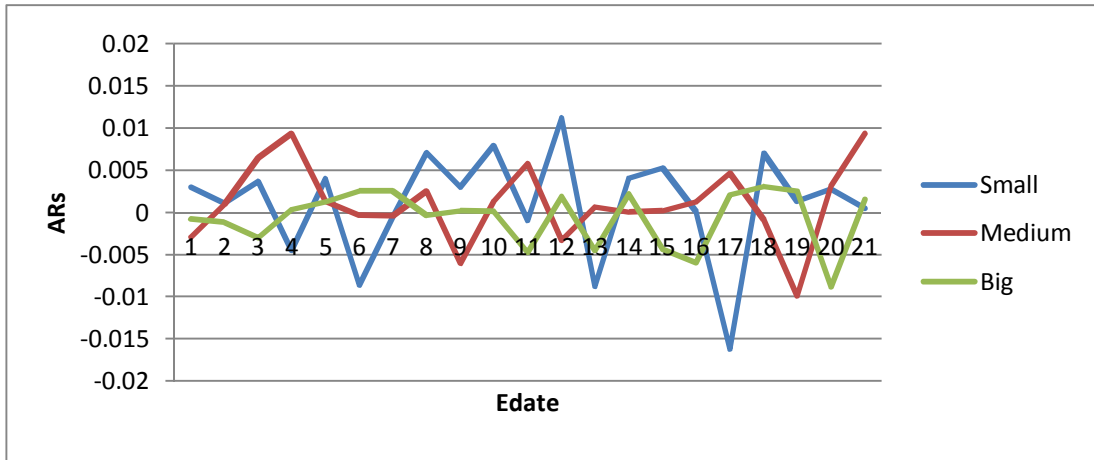


Figure 59 ARs for 21 days of 3 groups surrounding approval of new indication

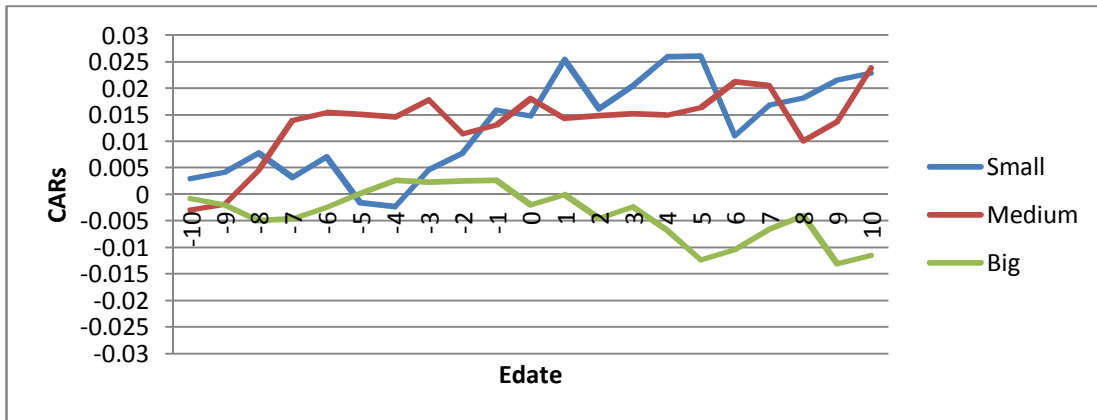


Figure 60 CARs for 21 days of 3 groups surrounding approval of new indication

8.2.9 Approval of First-Time Generics

Figure 61 and figure 62 show that approval of the first-time generics hits all three groups to different degrees. Abnormal return of the small cap group declines on the 1st day after the approval and that of the medium cap group declines on the approval day; abnormal return of the big cap group also declines from day 0 to day 3, but the decline is smooth and tiny, only 20% -30% of the magnitude of the small cap and the medium cap group. Cumulative abnormal return of the small cap group declines on the 1st day after the approval and has no more systematic movement since then; cumulative abnormal return of the medium cap has a down trend since the day before the approval and has a small reverse movement on day 7 and stays flat since day 9; cumulative abnormal return of the big cap moves smoothly and slightly around 0. Table 48 indicates that cumulative abnormal return of the small cap group is significantly negative over interval $[0, 1]$, cumulative abnormal return of the medium group is significantly negative over interval $[0, 5]$, and cumulative abnormal return of the big group is insignificant over any interval. The results imply that the big cap group is not influenced a lot when corresponding first-time generic drug is approved and the approval hits the medium cap group most and it take the medium cap group longer to adjust than the small cap group. There are some reasons could explain these behaviors. First, since the big cap group is the favorite target for the analysts, approval of their corresponding first-time generics has been anticipated long time ago and the price adjustment may have happened then. Second, it's easier for the big group to overcome negative impact of approval of specific first-time generic. The big group

usually has better publicist and better relationship with media. For example, they may announce a breakthrough in their new drugs under development to distract the attention of the market. However, table 49 shows the difference of cumulative abnormal return between the small cap group and the big cap group is insignificant after approval of the first-time generics.

Table 47 ARs of 3 groups for approval of first-time generics

Day	Small		Medium		Big	
	N	AR	N	AR	N	AR
-10	54	0.0014	56	-0.0034*	54	-0.0027
-9	54	0.0030	56	-0.0030	54	0.0019
-8	54	0.0034	56	-0.0037**	54	-0.0023
-7	54	0.0017	56	0.0001	54	-0.0011
-6	54	0.0047	56	0.0008	54	0.0007
-5	54	0.0019	56	0.0030	54	0.0002
-4	54	0.0004	56	-0.0024	54	0.0012
-3	54	-0.0017	56	-0.0027	54	0.0039**
-2	54	-0.0027	56	0.0010	54	-0.0008
-1	54	0.0004	56	0.0016	54	0.0002
0	54	-0.0002	56	-0.0070	54	-0.0015
1	54	-0.0073**	56	-0.0024	54	-0.0021
2	54	0.0026	56	0.0012	54	-0.0015
3	54	-0.0033	56	-0.0017	54	-0.0024
4	54	0.0013	56	-0.0020	54	0.0029
5	54	-0.0003	56	-0.0026	54	-0.0008
6	54	0.0011	56	-0.0018	54	0.0021
7	54	-0.0010	56	-0.0022	54	0.0040***
8	54	-0.0007	56	0.0050**	54	0.0018
9	54	-0.0005	56	0.0033**	54	0.0014
10	54	-0.0007	56	-0.0000	54	-0.0004

Table 48 CARs for different intervals of 3 groups surrounding approval of first-time generics

Interval	CAR (Small)	CAR (Medium)	CAR (big)
[-10, -1]	0.013	-0.009	0.003
[0, 1]	-0.008**	-0.009	-0.004
[0, 5]	-0.007	-0.014**	-0.005
[0, 10]	-0.009	-0.010	0.004
[-10, 10]	0.004	-0.018	0.007

Table 49 Difference in CARs between the Small and the Big on each day

Edate	-10	-9	-8	-7	-6	-5	-4
Small-Big	0.004	0.005	0.011*	0.014**	0.017**	0.019**	0.017*
Edate	-3	-2	-1	0	1	2	3
Small-Big	0.011	0.009	0.009	0.011	0.005	0.010	0.009
Edate	4	5	6	7	8	9	10
Small-Big	0.007	0.007	0.005	0.001	-0.002	-0.004	-0.004

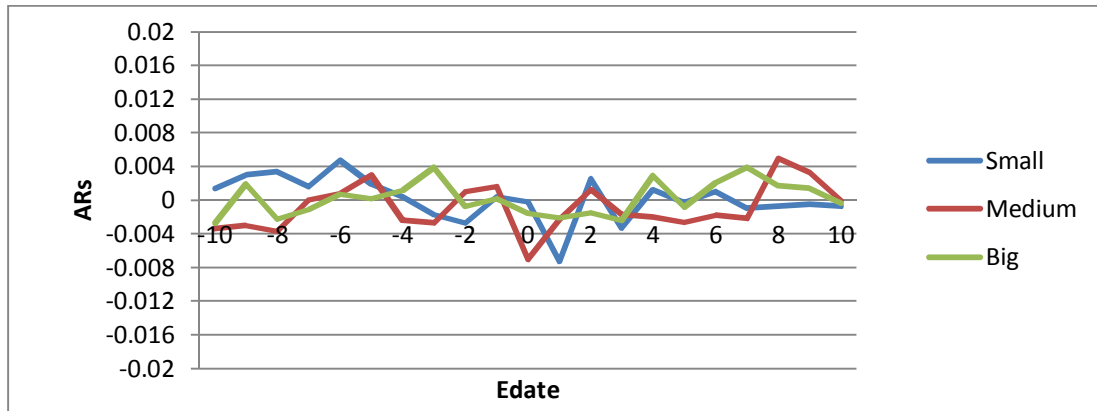


Figure 61 ARs for 21 days of 3 groups surrounding approval of first-time generics

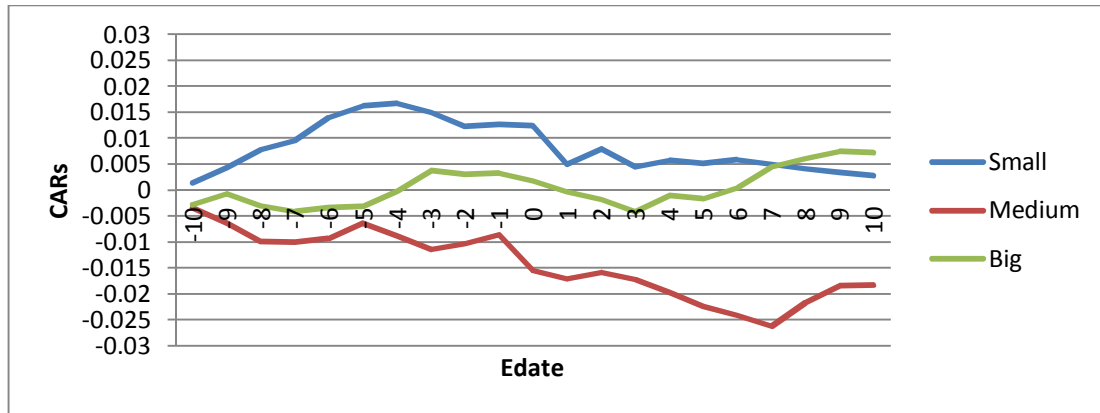


Figure 62 CARs for 21 days of 3 groups surrounding approval of first-time generics

In conclusion, despite the results discussed above show that there are some different patterns of response in direction or in degree or in time frame to each event between the small cap group and the big cap group, most of the differences are statistically insignificant, except for day 2 in acceptance and day 4 and day 10 in extension of FDA review deadlines. Cumulative abnormal returns of both the small cap group and the big cap group have downward drift over the window of submission, but the small cap group's is more noticeable and more significant than the big cap group's. Cumulative abnormal returns of the small cap group and the big cap group move in a totally opposite direction surrounding acceptance. Cumulative abnormal return of the big cap group fiercely moves up and down around 0 over the windows; while cumulative abnormal return of the small cap group has a downwards trend far below 0 and a sharp reverse movement in the end of the window. Extension of FDA review deadline impacts both the value of the small cap group and the big cap group stocks economically and significantly, though the small cap group reacts more

dramatically than the big cap group. Abnormal return and cumulative abnormal return of the small cap group move smoothly and slightly around 0 surrounding public disclosure of advisory committee recommendation. In contrast, abnormal return and cumulative abnormal return of the big cap group jump dramatically on one day preceding the event, though insignificantly. The post-event price adjustment to the event overreaction of the small cap group is more noticeable. The impact of take disapproval recommendations out of the sample is more severe on the small cap group than on the big cap group. When taking off the extreme point (Provenge filed by Dendreon) from the big cap group, the increase of the big cap group drops by 75% of that when the extreme is included and the gap between the small cap and the big cap gets much closer, accordingly. Both the small group and the big group experience significant and substantial plummet surrounding issuance of complete response letter from FDA, but the small cap group responds earlier than the big cap group, which is before the event day, an evidence of insider trading in the small cap group. The price adjustments of the small cap group and the big cap group to resubmission are economically significant but statistically insignificant. Cumulative abnormal return of the small cap group rise noticeably twice before the event day and adjusts downwards to half of its highest point after the event, suggesting an existence of insider trading. Both results for the small cap group and the big cap group seem distorted by some extreme values in their group. After deleting the extreme values (Silenor filed by Somaxon Pharmaceuticals in the small cap group and Feraheme filed by AMAG pharmaceuticals in the big cap group) from sample, I can see cumulative abnormal

return of the small group has no drift and cumulative abnormal return of the big group barely has a gentle upward drift. The big jump of abnormal return on the event day in the big cap disappears when the extreme value is taken out of the sample. The value of the big cap group stocks increases marginally but significantly on the event day when the new drug applications are approved. On the contrary, the value of the small group rises dramatically but insignificant on the first day after the approval day. Getting rid of the extreme value (Fanapt filed by Vanda Pharmaceuticals) from the small cap group, I find the results of the small cap group turn to mild but significant and the shapes of its abnormal return and cumulative abnormal return are closer to those of the big cap's and medium cap's. The value of the big cap group fluctuates around 0 with little margin and slide slightly below 0 at the end of the window surrounding approval of new indication. To the contrary, the value of the small cap group has an upward trend starting 4 days preceding the event. Nether of their responses is significant. Approval of the first-time generics does not have obvious impact on the big cap group in the study window, but it influence the stock value of the small cap group significantly and negatively.

Chapter 9

CROSS-SECTIONAL ANALYSIS

In the empirical study above I identify that extension of FDA review deadline, issuance of complete response letter from FDA and approval of the first-time generics have significant negative influence on the stock returns, which I class as ‘bad’ events; while public disclosure of advisory committee recommendation and approval of a new drug, which I class as ‘good’ events. From the managers’ perspective, it is not good that the firm’s stock is too sensitive to a single event, especially when the event might cause big loss in the stock’s value. Managers must be interested in the determinants of abnormal returns resulting from these events and are willing to take actions to mitigate the influence of these events. From investor’s perspective, they are also interested in these determinants in order to take full advantage of these events for arbitrage. Therefore, to check how firm’s attributes drive the individual announcement abnormal return, I would like to analyze the relation between the individual announcement abnormal return and specific firm’s characteristics variables, the percentage of institutional ownership, firm’s diversification measured by the number of segments in the firm, firm’s R&D intensity measured by R&D expenditure/total asset, leverage measured by total liability/total asset, profitability measured by net income/total asset and growth opportunity measured by market value/book value by regressing

individual abnormal return on these variables. The firm's characteristics variables are obtained from COMPUSTAT.

Table 50 Regression results
Dependent Variable: individual firm abnormal return

		Bad events	Good events
Intercept		-0.1306**	0.5458***
	Institutional Ownership Percentage		
Instown_perc		0.0290	-0.3612**
Diversification	# of segments	0.0070	-0.0081
R&D intensity	R&D/Total Asset	0.0794	-0.3318
	Total Liability/Total Asset		
Leverage	Net Income/Total Asset	0.1000*	-0.3275***
Profitability	Market Value/Book Value	0.2500***	-0.7052***
Growth opportunity		0.0001	-0.0022
Observations		170	147
R-Square		0.26	0.21

Note: bad events are comprised of extension of FDA review deadline, issuance of complete response letter from FDA and approval of the first-time generics. Good events are comprised of public disclosure of advisory committee recommendation and approval of a new drug.

Table 50 presents the results of cross-sectional analysis. The percentage of institutional ownership has significant negative impact on the abnormal return for good events but no significant impact on the abnormal return for bad news. The reason that firms with higher institutional ownership have smaller positive abnormal return is

that institutional investors financially and intellectually put much more effort to analyze the firms of interest than individual investors. They have more resources and less cost to obtain the information in advance, which is confirmed that I can observe positive abnormal return occurring in days before the announcement date for public disclosure of advisory committee recommendation and approval of a new drug, an evidence of inside information. When the information suggesting the success of a new drug introduction from a firm actually comes into public, the higher percentage of institutional ownership a firm has, the less surprising this information is to its investors and the lower positive abnormal return occurs. The fact that percentage of institutional ownership has no significant influence on abnormal return for 'bad' news may result from difficult access to the information of extension of FDA review deadline and issuance of complete response letter from FDA in advance except for approval of the first-time generics, even for institutional owners.

The firm's leverage has positive influence on the abnormal return for 'bad' news and negative influence on the abnormal return for 'good' news. Overall, the firm's leverage mitigates the magnitude of the abnormal return, indicating there is more 'surprise' to the market associated with new drugs introduced by firms with lower leverage. The link between leverage and the abnormal return could be explained by the following possible two reasons. First, lower leverage may reflect a firm's less need in outside financial resources. Only firms with more innovative activities finance outside more. Therefore, high leverage may suggest a firm has active innovative activities and multiple new drugs under R&D so that information about a

single new drug introduction causes less ‘surprise’ in the market than information for a firm with low leverage. Second, lower leverage may reflect a firm’s less willingness of borrowing money as it faces high cost by doing this. More productive firms or less risky firms or firms with better credit in successful new drug introductions face fewer constraints in accessing debt financing so that they are more willing to finance with debt and have higher leverage.

The firm’s profitability has the same influence on the abnormal return as the firm’s leverage. It positively influences the abnormal return for ‘bad’ news and negatively influences the abnormal return for ‘good’ news. The higher profitability of a firm suggests that the new drug might account for only a small part of its total profit. Therefore, information on failure or success in delivering a new drug would cause less fluctuation to the underlying firm’s stock with high profitability than that with low profitability.

The firm’s diversification, R&D intensity and growth opportunity have no significant influence on the abnormal return. Overall, the results indicate that using firm’s characteristics to predict the magnitude of the abnormal return from the announcements during the new drug approval process provides little predict value. Future study could focus on the new drug’s characteristics rather than the firm’s attributes, such as what kind of disease the new drug treats (drug’s classification), how many substitutes of this new drug already exist in the market (drug’s market share), what is the predicted percentage of this new drug accounting for the total profit of the sponsoring firm (drug’s profit share).

Chapter 10

SUMMARY

This paper uses the traditional event-study method to examine the abnormal return surrounding announcements during the new drug approval process over the period from 2004 to 2011 to check which announcement matters to the valuation of the related pharmaceutical companies' stocks. The results reveal that extension of FDA review deadline, issuance of complete response letter from FDA and approval of the first-time generics have negative influence on the valuation of the stocks; public disclosure of advisory committee recommendation and approval of a new drug have positive significant impact on the related firms' stock returns; submission of a new drug application (NDA), acceptance of a NDA by FDA, resubmission of a NDA and approval of new indication have no significant impact on the stock returns. The conclusion is further confirmed when I divide the sample into 3 groups by capital size. Even though there are differences in direction or in degree or in time frame for response to each event between small capital size and big capital size, none of the differences is significant. This is consistent with the conclusion in prior literatures that size doesn't have significant influence on the abnormal return. The cross-sectional analysis presents that firm's leverage and profitability could decrease the influence of a single event, no matter it is good or bad, on the stock returns; institutional ownership percentage decrease the impact of a good event on the stock value while no significant

relation to a bad event impact; firm's diversification, R&D intensity and growth opportunity have no significant influence on the abnormal return. However, the results imply firm's characteristics provide little predict value to the magnitude of the abnormal return, suggesting that future study could study drug's attributes instead of firm's characteristics. The reasons why this present paper does not study the impacts of drug's attributes on the abnormal return are as follows. First, there is no efficient resource for me to obtain the data of drug's attributes (drug's classification, historic sales data of each drug to the whole market or the company). Second, it is hard to objectively estimate future revenue and expenses attributable to a new drug. I hope future studies would have better resource to access drug's attributes and develop an objective estimation of a new drug's future sales. In addition, the present paper only investigates the impact of announcements during the drug approval process, and future research could extend it to the whole new drug development process, including trials before submission applications, marketing after approval and recall or withdrawal. The future study could also use trading value instead of abnormal return as the variable of interest.

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Appendix

A COMPARISON OF RESULTS BETWEEN [-10, 10] AND [-4, 4]

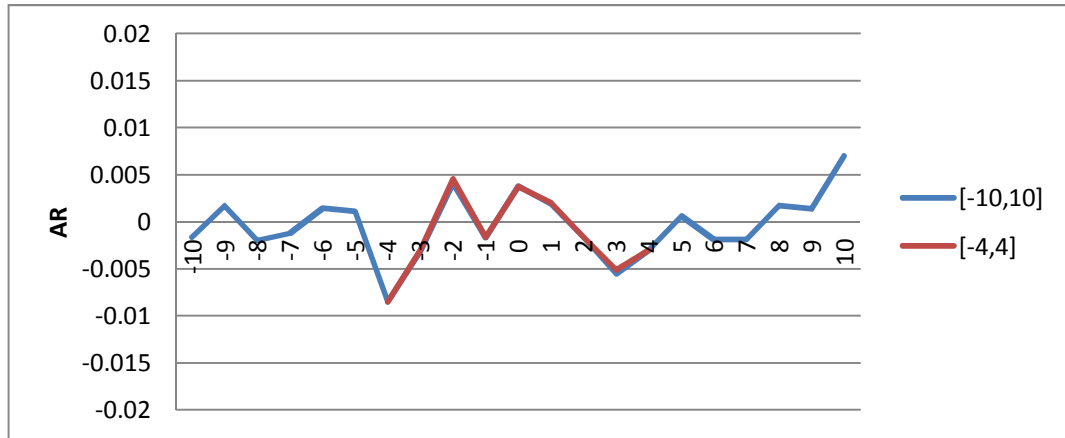


Figure 63 ARs of [-10, 10] and [-4, 4] for submission

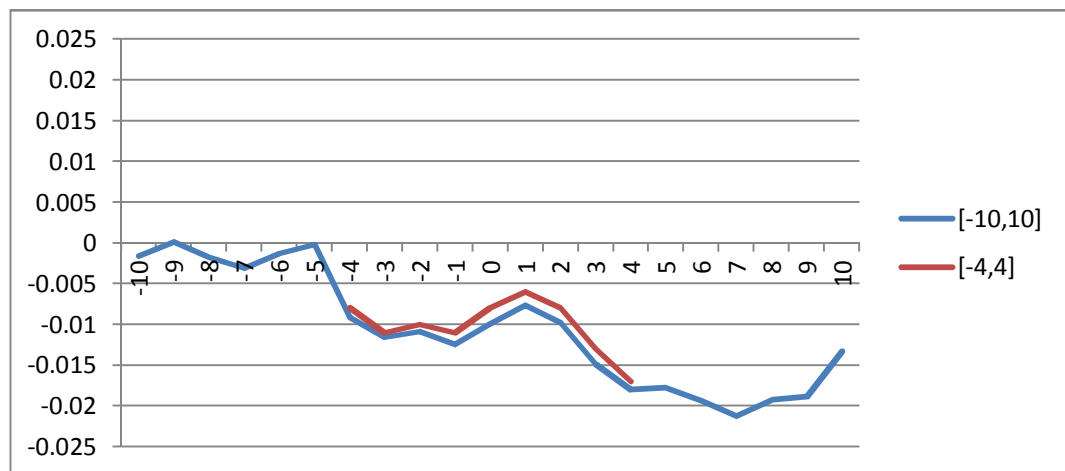


Figure 64 CARs of [-10, 10] and [-4, 4] for submission

Table 51 CARs for different intervals in [-10, 10] and [-4, 4] for submission

Interval	CAR	Interval	CAR
[-10, -1]	-0.012	[-4, -1]	-0.011*
[0, 1]	0.006	[0, 1]	0.006*
[0, 5]	-0.004		
[0, 10]	-0.003	[0, 4]	-0.005
[-10, 10]	-0.013	[-4, 4]	-0.017**

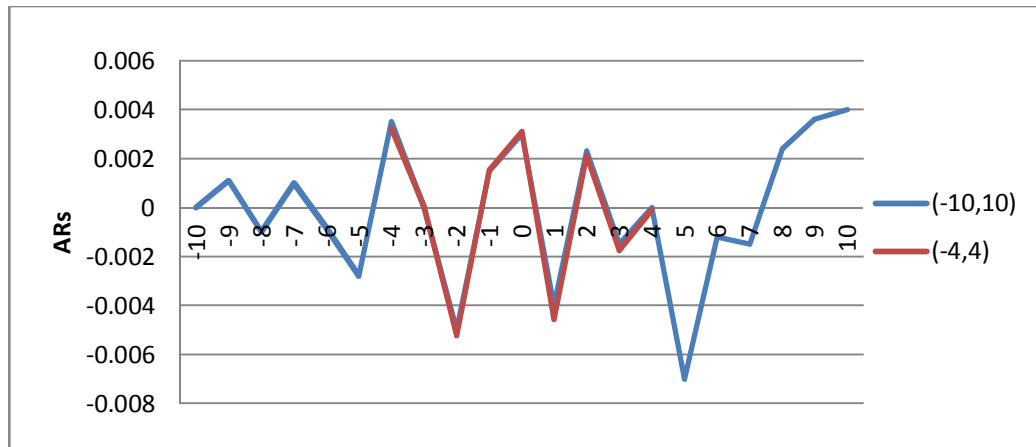


Figure 65 ARs of [-10, 10] and [-4, 4] for acceptance

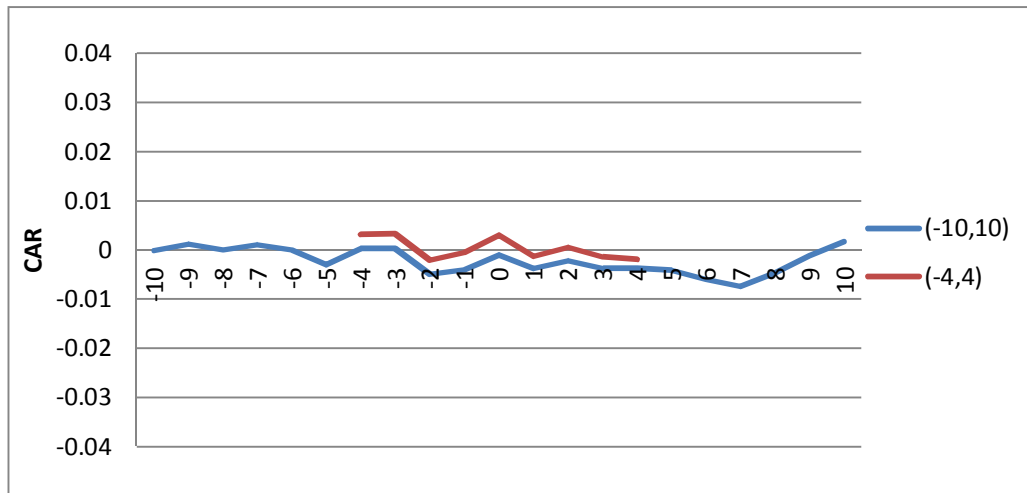


Figure 66 CARs of [-10, 10] and [-4, 4] for acceptance

Table 52 CARs for different intervals in [-10, 10] and [-4, 4] for acceptance

Interval	CAR	Interval	CAR
[-10, -1]	-0.004	[-4, -1]	0.002
[0, 1]	-0.002	[0, 1]	-0.005
[0, 5]	-0.001		
[0, 10]	0.006	[0, 4]	0.000
[-10, 10]	0.002	[-4, 4]	0.000

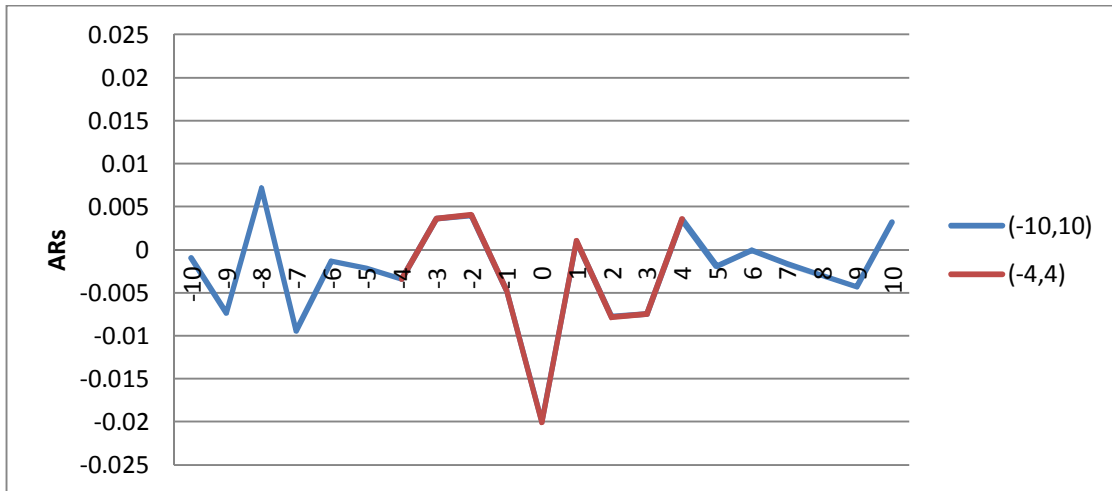


Figure 67 ARs of [-10, 10] and [-4, 4] for extension of FDA review deadline

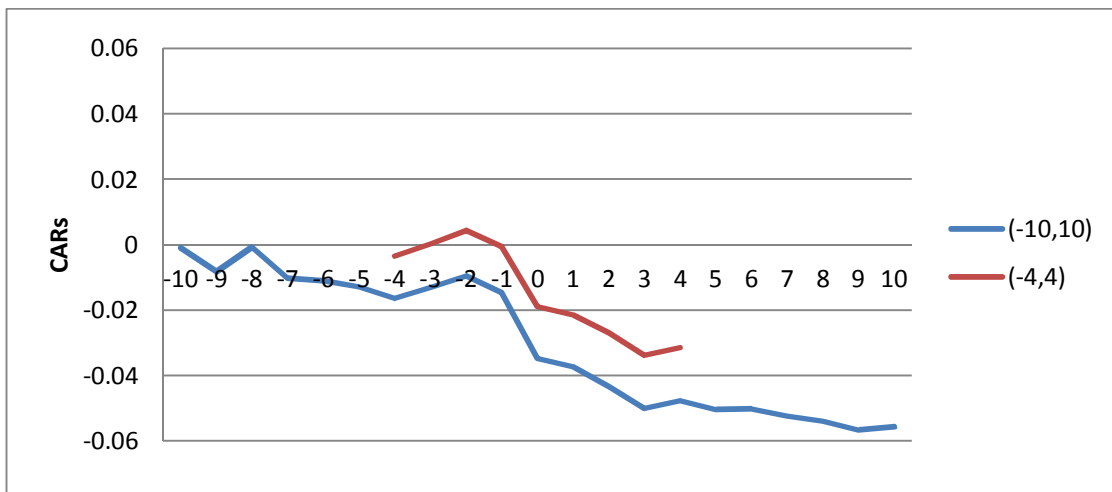


Figure 68 CARs of [-10, 10] and [-4, 4] for extension of FDA review deadline

Table 53 CARs for different intervals in [-10, 10] and [-4, 4] for extension of FDA review deadline

Interval	CAR	Interval	CAR
[-10, -1]	-0.014	[-4, -1]	0.000
[0, 1]	-0.022**	[0, 1]	-0.022**
[0, 5]	-0.035***		
[0, 10]	-0.040**	[0, 4]	-0.035***
[-10, 10]	-0.056***	[-4, 4]	-0.031*

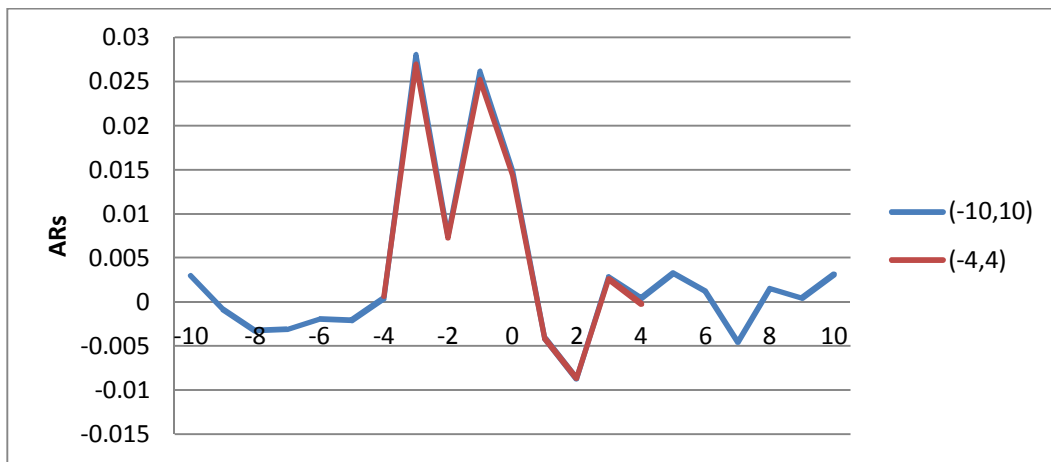


Figure 69 ARs of [-10, 10] and [-4, 4] for public disclosure of advisory committee

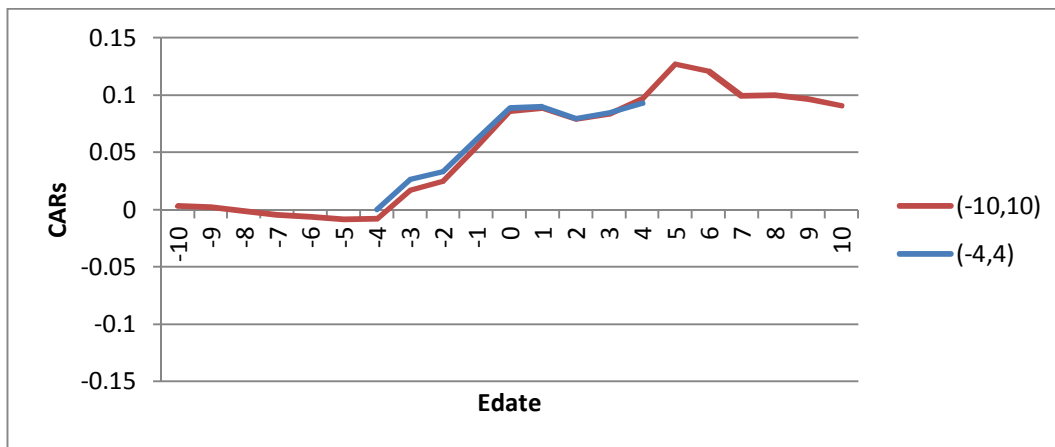


Figure 70 CARs of [-10, 10] and [-4, 4] for public disclosure of advisory committee

Table 54 CARs for different intervals in [-10, 10] and [-4, 4] for public disclosure of advisory committee

Interval	CAR	Interval	CAR
[-10, -1]	0.054*	[-4, -1]	0.061**
[0, 1]	0.012	[0, 1]	0.012
[0, 5]	0.026		
[0, 10]	0.012	[0, 4]	0.011
[-10, 10]	0.090	[-4, 4]	0.093

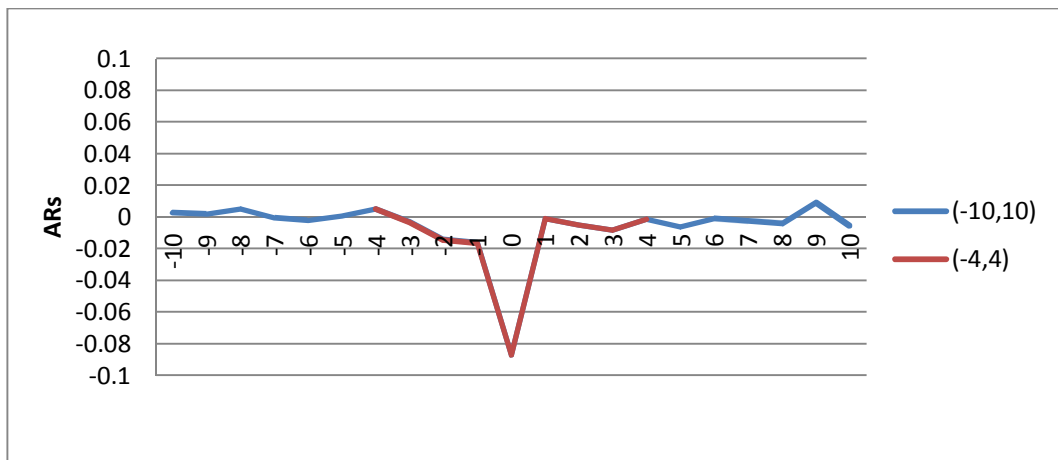


Figure 71 ARs of [-10, 10] and [-4, 4] for issuance of complete response letter from FDA

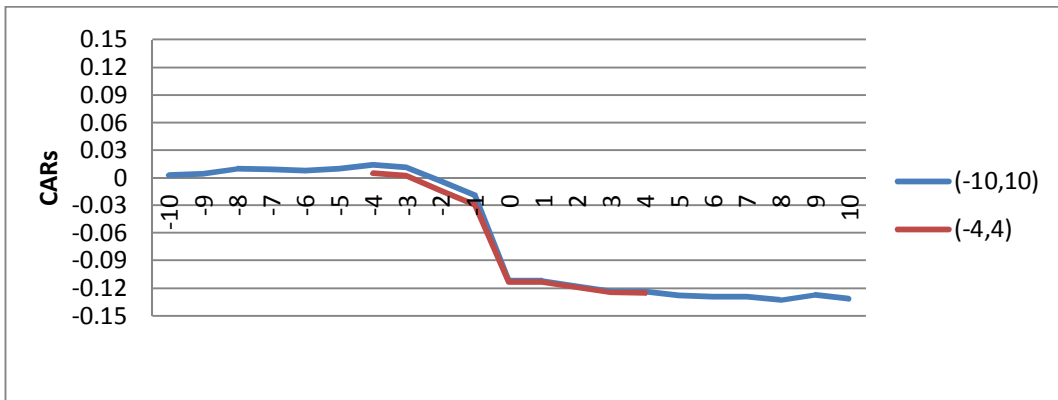


Figure 72 CARs of [-10, 10] and [-4, 4] for issuance of complete response letter from FDA

Table 55 CARs for different intervals in [-10, 10] and [-4, 4] for public disclosure of advisory committee

Interval	CAR	Interval	CAR
[-10, -1]	-0.019	[-4, -1]	-0.029**
[0, 1]	-0.088***	[0, 1]	-0.088***
[0, 5]	-0.105***		
[0, 10]	-0.109***	[0, 4]	-0.100***
[-10, 10]	-0.130***	[-4, 4]	-0.125***

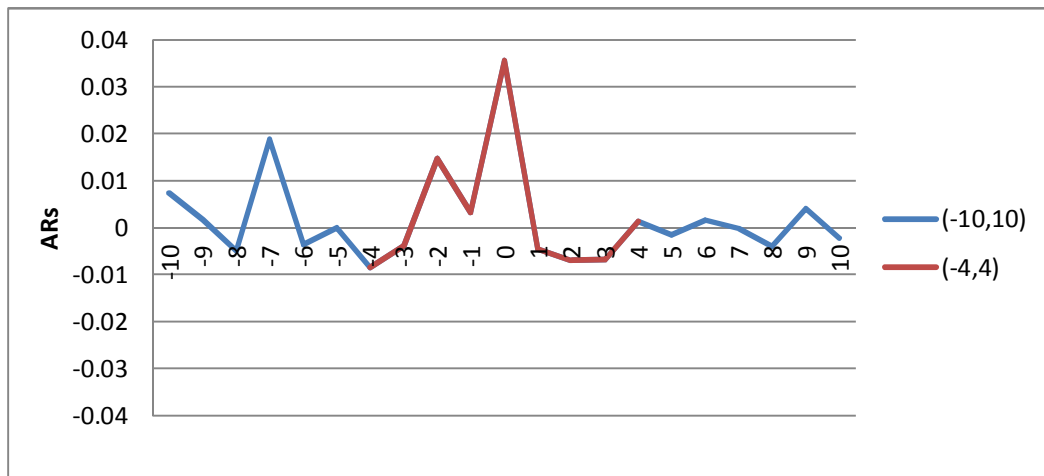


Figure 73 ARs of [-10, 10] and [-4, 4] for resubmission

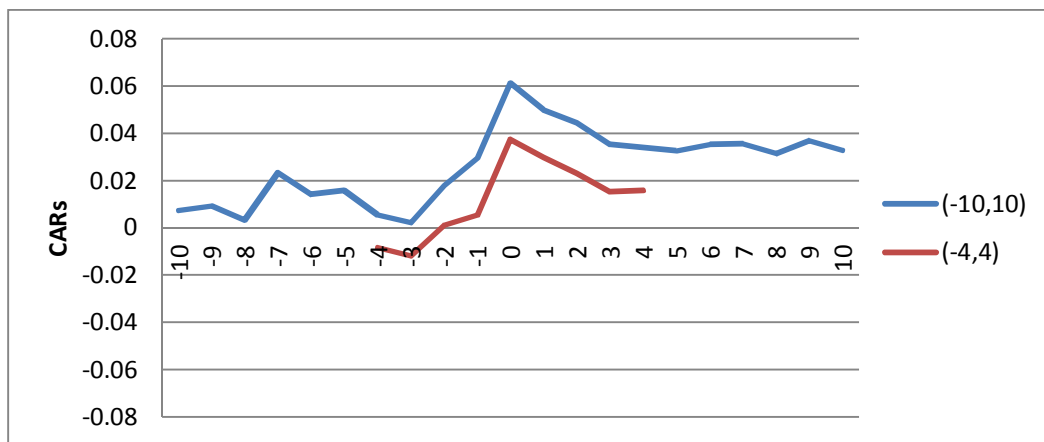


Figure 74 CARs of [-10, 10] and [-4, 4] for resubmission

Table 56 CARs for different intervals in [-10, 10] and [-4, 4] for resubmission

Interval	CAR	Interval	CAR
[-10, -1]	0.029	[-4, -1]	0.006
[0, 1]	0.030	[0, 1]	0.030
[0, 5]	0.014		
[0, 10]	0.014	[0, 4]	0.016
[-10, 10]	0.033	[-4, 4]	0.016

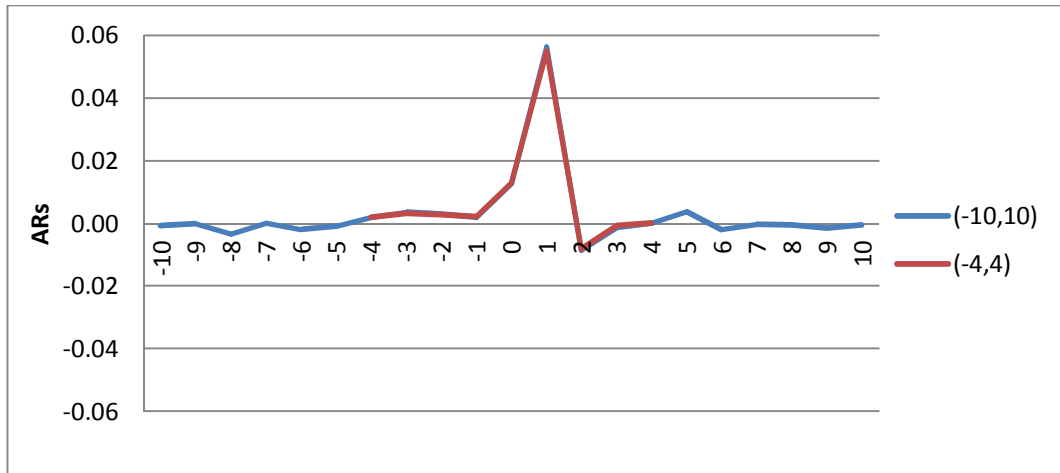


Figure 75 ARs of [-10, 10] and [-4, 4] for approval of an application

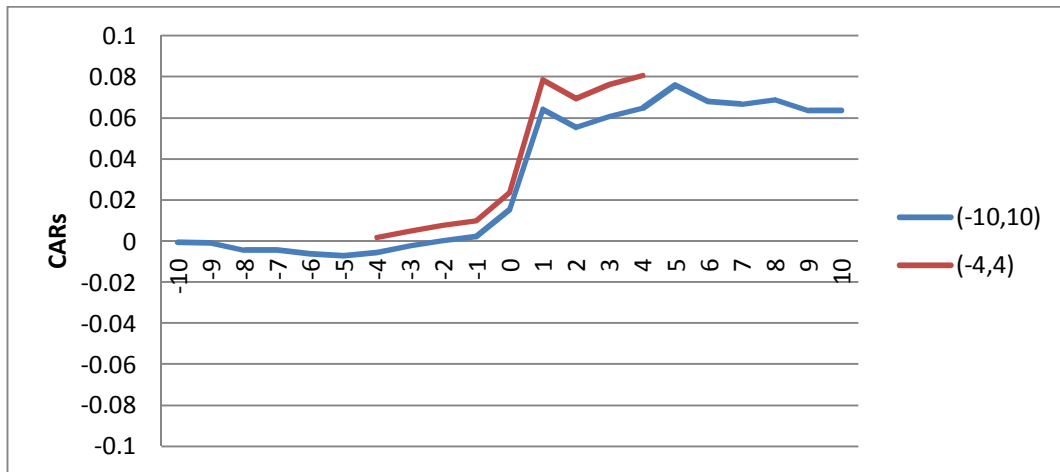


Figure 76 CARs of [-10, 10] and [-4, 4] for approval of an application

Table 57 CARs for different intervals in [-10, 10] and [-4, 4] for approval of an application

Interval	CAR	Interval	CAR
[-10, -1]	0.002	[-4, -1]	0.010**
[0, 1]	0.067**	[0, 1]	0.066**
[0, 5]	0.082		
[0, 10]	0.068	[0,4]	0.068
[-10, 10]	0.064	[-4, 4]	0.081*

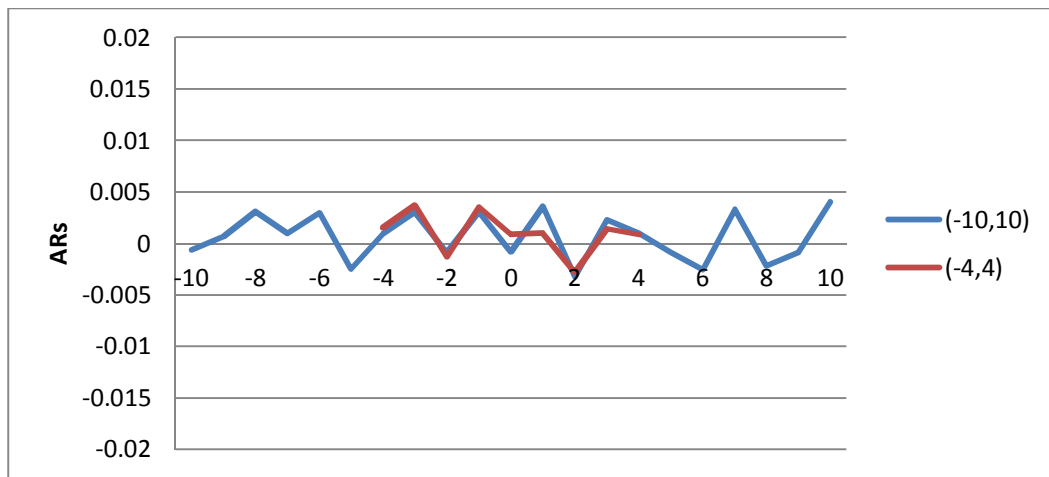


Figure 77 ARs of [-10, 10] and [-4, 4] for approval of new indication

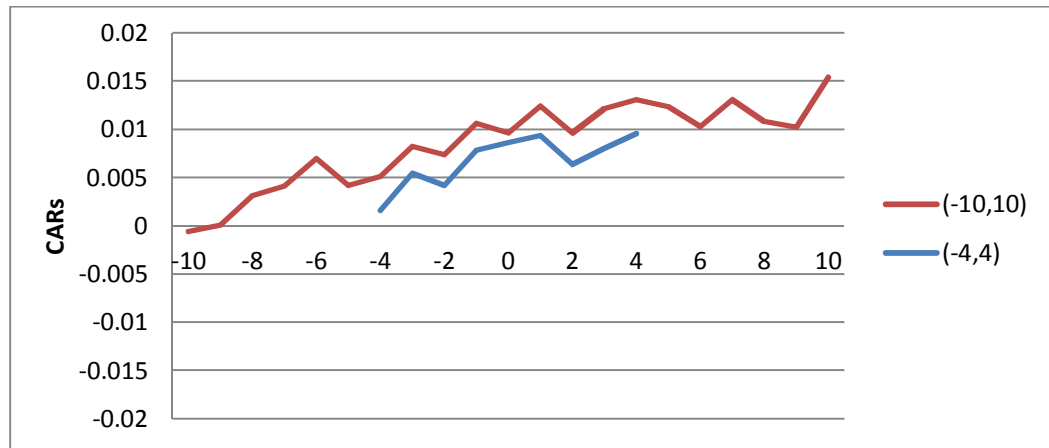


Figure 78 CARs of [-10, 10] and [-4, 4] for approval of new indication

Table 58 CARs for different intervals in [-10, 10] and [-4, 4] for approval of new indication

Interval	CAR	Interval	CAR
[-10, -1]	0.011	[-4, -1]	0.008
[0, 1]	0.002	[0, 1]	0.001
[0, 5]	0.002		
[0, 10]	0.005	[0, 4]	0.002
[-10, 10]	0.015	[-4, 4]	0.010

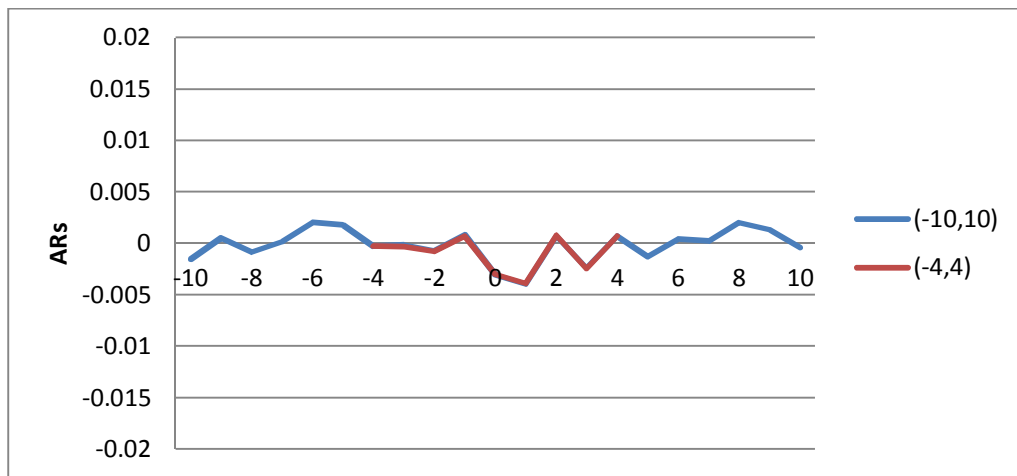


Figure 79 ARs of [-10, 10] and [-4, 4] for approval of first-time generics



Figure 80 CARs of [-10, 10] and [-4, 4] for approval of first-time generics

Table 59 CARs for different intervals in [-10, 10] and [-4, 4]
for approval of first-time generics

Interval	CAR	Interval	CAR
[-10, -1]	0.001	[-4, -1]	-0.001
[0, 1]	-0.007***	[0, 1]	-0.007***
[0, 5]	-0.009**		
[0, 10]	-0.006	[0, 4]	-0.008**
[-10, 10]	-0.004	[-4, 4]	-0.008*