Insider Trading Around New Drug Approvals

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This study examines the market reaction to new drug approval announcements by the Food and Drug Administration (FDA). According to the Tufts Center for the Study of Drug Development (2001a), the average cost to develop a new drug is $802 million and the typical time frame before it reaches the market is 10-15 years. A new drug that obtains FDA approval to be marketed to the public can contribute billions of dollars to the manufacturing pharmaceutical. For example, in 1998, the anti-ulcer drug Prilosec generated over $4.0 billion in sales for Astra Pharmaceutical. Zocor, a cholesterol reducer, contributed over $2.8 billion to Merck, and Claritin, an anti-allergy drug manufactured by Warner-Lambert, produced sales of more than $1.3 billion. Sales for the entire industry exceeded $102 billion, and profits grew by almost 18%–four times that of the average Fortune 500 firm (Tanouye, 1998).

New Drug Approval Process

Prior to marketing, these drugs, which emanate from the pharmaceutical and biotechnology industries, must go through a rigorous approval process with the FDA that includes pre-clinical testing and several stages of clinical trials. In order to assess safety, new drugs must undergo preclinical testing in animals. The findings of these

data are used to open an Investigational New Drug application (IND). The IND is eventually submitted to the FDA to start human clinical studies. Human clinical tests proceed in three phases. In Phase I, the drug may be tested in patients, but is typically tested in a small number of healthy human volunteers, mostly to measure its safety, pharmacological effects, and how it is metabolized. Phase II's purpose is to determine the scientific validity (e.g., efficacy and side effects) of the drug using a larger group of patients actually suffering from the targeted disease. Phase III studies are expanded controlled and uncontrolled trials. They are done to gain additional data about effectiveness and safety needed to evaluate the benefits and risks of the drug. This phase typically tests hundreds to several thousands of people (Tufts Center for the Study of Drug Development, 2001b).

After the trials, if the drug performs as expected, the sponsor files a New Drug Application (NDA) with the FDA's Center for Drug Evaluation and Research (CDER). These applications include all the data developed during the clinical trials. FDA approval of an NDA gives the sponsor clearance to sell the drug for the indications approved (Glass, 1991). The Tufts Center for the Study of Drug Development (2001b) reports that a new product can take up to 15 years of testing before it reaches the marketplace.

Insider Trading

Since FDA decisions concerning new drugs can materially affect profitability and the corresponding value of the applying pharmaceutical, imminent approval (denial) would be good (bad) news to shareholders. Investors that anticipate the direction of the FDA decision could, therefore, profit (or avoid losses). It is well known that anticipating certain announcements can provide significant returns. For example, it is widely published that the purchase of shares in a merger target prior to the initial announcement produces a premium. For example, in 1999 Sprint jumped almost 19% around the announcement of a bid from MCIWorldCom (Lipin, Harris and Blumenstein, 1999).

In an environment where great rewards can be obtained by anticipating favorable announcements, the threat of insider trading flourishes. Substantive information about a firm that is unavailable to the general public is considered inside information. Since the information is not reflected in the current market price, the true value of the firm may be different. Asymmetric information is, thus, present whereby insiders know more than others and may be trading on the basis of this information. Trading on such information is, of course, illegal and the Securities and Exchange Commission (SEC) aggressively prosecutes violators. Michael Milken was fined $600 million and sentenced to ten years in prison in 1990 for trading on inside information.

Still, insider trading is observed around many corporate announcements including those involving earnings (Upda, 1996; Park and Jang, 1995; Bushman, Dutta, Hughes and Indejejikian, 1997; Sivakumer and Waymire, 1994), management changes (Warner, Watts and Wruck, 1988), dividends (Kaestner and Liu, 1998; John and Lang, 1991), LBOs (Harlow and Howe, 1993), tender offers (Schwert, 1996; Jarrell and Poulsen, 1989), bankruptcy (Bettis, Duncan and Harmon, 1998; Seyhun and Bradley, 1997), and stock repurchases (Raad and Wu, 1995).

Since the timing and direction of FDA decisions are uncertain, such announcements should have a significant impact on stock returns. Consequently, investors owning the stock prior to a favorable announcement should experience substantial positive returns. If the market is efficient, whereby prices quickly and accurately integrate new information, then new investors in the stock after the announcement will likely obtain little or no gain. Therefore, those investors that anticipate imminent approval and own the stock in advance of the FDA announcement experience the greatest rewards. The existence of substantial and consistent trading shortly before FDA announcements concerns the SEC as it indicates that insiders may be obtaining leaked information about the status of their new drug candidates.

Trading by several pharmaceutical insiders has captured the attention of the SEC and shareholders. A consultant for Chantal Pharmaceutical was fined and sentenced to 15 months in prison for trading on unfavorable clinical trial information (Skolnick, 1998). Other actions by the SEC deal with clinical drug researchers profiting from illegal confidential information (Cox, 1998). Shareholders of ICN Pharmaceutical filed a lawsuit in 1995 against their chairman for selling a substantial block of stock before the FDA announcement of a drug rejection (Lubman, 1995).

Given the potential returns and the previous attention in the literature concerning insider-trading performance, it is surprising that no rigorous empirical research has yet been performed to measure the impact of trading around FDA announcements. Consistent profiting by insiders from information that is not only confidential, but also the responsibility of a federal government agency, would be very disturbing. It is at this point that we investigate whether inside trading exists for the entire sample of new drug approvals from 1980-1999 by examining the return behavior around the announcements.

Identification of Insider Trading Prior to Announcement

Investors who have non-public information that is material to the value of a stock can profit from that information by buying or selling the stock prior to the public release of the information. Consider for example an unexpected positive decision regarding drug approval. Investors who are aware of a future announcement of a drug approval could buy the stock in advance of the announcement. When the announcement is made, the stock will typically increase to reflect the positive value of the drug approval.

Trading in anticipation of a public announcement is sometimes referred to as leakage; that is, the information is "leaking" out to a subset of the public domain but is not officially disclosed to the general public. Typically, trading on material non-public information is illegal if it is performed by investors who have a fiduciary duty to the

shareholders of the involved firms, or if the information is misappropriated and the investor knows (or should know) that it was misappropriated, or if the information involves a tender offer for stock. In the case of new drug decisions, a preview of the decision to selective outsiders would constitute a leak and trading on that information would be illegal.

Material events that cannot be predicted by insiders are unlikely to exhibit leakage. Such events include plane wrecks, earthquakes, fires, and other sudden unpredictable events. Events likely to exhibit leakage are those that have substantial value implications and which are known by some informed investors prior to the public release of the information. An example of such an event would be an offer by a company to buy another company. The offer has substantial value implications for both the acquiring company and the target company. Such offers require preliminary work by hundreds of employees of the involved firms as well as investment bankers and key investors. Often preparation of the offers may involve several weeks and even months. Accordingly, there are many opportunities for leakage with regard to these announcements.

An event study methodology can identify anticipatory trading. Numerous researchers have employed event studies to identify leakage in a variety of announcements. For example, in a sample of 1,814 takeover bids over the period 1975 - 1991 Schwert (1996) finds a 25% run-up in price over the 42-day period prior to the announcement. Cornell and Serri (1992) examine the impact of insider trading in the Anheuser-Bush tender offer to buy Campbell–Taggert. They find a run-up in price of the target firm that corresponds to documented insider trading (the insider trading was documented by civil and criminal litigation subsequent to the incident). Raad and Wu (1995) examine the returns associated with 204 stock repurchase announcements and find significant average excess returns associated with insider trading in the days prior to the announcement. Meulbrock (1992) examines various events in which the SEC determined insider trading occurred prior to

the public announcement. She found statistically significant excess returns prior to 145 takeover-related announcements, 12 negative earnings announcements, 10 bankruptcy announcements, and 11 other good news announcements. These are all events for which it was later determined that insider trading occurred prior to the announcement. Furthermore, excess price movement on insider trading days was 40%-50% of the subsequent price reaction to the public announcement. Meulbrock concludes that ". . . stock price run-ups before takeover announcement reflect widespread insider trading."

This study uses a similar methodology to explore anticipatory trading prior to announcements of drug approvals by the FDA. Significant positive abnormal returns prior to the announcement would be evidence of anticipatory trading, and anticipatory trading would indicate that insider trading may be occurring. Failure to find significant excess returns prior to the announcement combined with excess returns on the date of the announcement and thereafter would indicate a lack of significant anticipatory trading.

Methodology

Dates for the 167 FDA drug approvals for the period 1980 - 1999 are identified from several different sources including Kaitin, DeCerbo and Lasagna (1991), Kaitin and Manocchia (1997), Kaitin Brichard and Lasagna (1987), Kaiten Mannocchia, Seibring and Lasagna (1994) and a search of the *Federal Register: FDC Reports*. The sample includes only approvals, rather than all decisions pertaining to the status of new drugs. Since an approval is the best decision anticipated by drug makers, insider trading is most likely to occur in advance of an approval decision. A bias in the selection of the decision is, therefore, intentional and required in order to create a sample that is most conducive to insider trading.

A traditional event study methodology is employed. Stock returns are drawn from the daily returns file of the Center for Research in Security Prices (CRSP). The event day, t = 0, is the approval date.

The estimation window is designated from day t = -230 through t = -30. The event window is designated as extending from t = -30 through t = +30. Market model parameters for each stock are estimated using equation (1),

$$R_{j,t} = a_j + b_j R_{m,t} + ej,t \qquad (1)$$

where $R_{j,t}$ is the CRSP daily return of security j on day t; $R_{m,t}$ is the return of the CRSP equally-weighted market return on day t; and a_j and b_j are the coefficients of the regression. The coefficients are then used to estimate stock performance during the event period. The excess return for security j on day t is the difference between the actual return and the predicted return as presented in Equation 2:

$$ER_{j,t} = R_{j,t} - (a_j + b_j R_{m,t}) \qquad (2)$$

The average excess return (AER) for each day t during the event period is calculated as shown using equation (3).

$$AER_t = \frac{1}{n} \sum_{j=1}^{n} ER_{jt} \qquad (3)$$

The test statistic is generated using standardized excess returns (SER) for each stock j as shown in Equation 3:

$$SER_{jt} = ER_{jt} / S_{jt}, \qquad (4)$$

where:

$$S_{jt} = \sigma_j \sqrt{1 + \frac{1}{200} + \frac{\left(R_{mt} - \overline{R}_m\right)^2}{\sum\limits_{s=-230}^{-31}(R_{ms} - \overline{R}_m)^2}}$$

The term σ_j is the estimated standard deviation of the residual from the market model regression, 200 is the number of days in the estimation period, $R_{m(bar)}$ is the average return on the CRSP market index during the estimation period, and R_{mt} is the return on the market index at time t. The test statistic for the AER at time t is given in Equation 5:

$$Z_t = \frac{1}{\sqrt{n}} \sum_{i=1}^{n} SER_{it} \tag{5}$$

The calculation of the cumulative average excess return (CAER) from t_1 through t_2 is given in Equation 6:

$$CAER[t_1, t_2] = \sum_{t=t_1}^{t_2} AER_t \tag{6}$$

Finally, the test for significance for the CAER is as follows:

$$Z = \left(\frac{1}{\sqrt{m}}\right)\sum_{t=t_1}^{t_2} Z_t$$

where $m = t_2 - t_1 + 1$.

Consistent with Meulbrock, if there is information leakage prior to the approval decision, the AER_ts and the CAERs prior to Day 0 will be positive and significant. Additionally, failure to find significant positive returns on Day 0 and/or Day 1 would indicate that the event was generally anticipated, was reflected in returns prior to the announcement, and would be evidence of leakage and insider trading. The failure to find significant positive returns prior to Day 0 combined with significant positive excess returns on and subsequent to Day 0 would indicate an absence of material information leakage and insider trading.

Test Results and Discussion

Table 1 presents the AERs during the 61-day event window. In the 30-day period preceding the new drug approval announcement, only Day -5 exhibits a significant return. This is the period most vulnerable to potential leakage and insider trading since the imminent approval of the new drugs would likely generate a positive reaction upon announcement. According to Meulbrock, evidence of insider trading, however, would be the presence of significant positive returns in this period. The return on Day -5 is negative indicating that this observation is most likely not a result of insider trading but, rather, noise. The absence of positive significant returns in this period provides evidence that there was likely no meaningful insider trading in anticipation of the favorable FDA ruling.

On the other hand, Day 0, which is the day that the announcement of approval was made to the public, is significant and

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Table 1. Average Excess Returns Around New Drug Approval Announcements

Day Relative to Event	Average Excess Return	Z statistic	Day relative to Event	Average Excess Return	Z statistic
-30	-0.001208	-0.4972	1	0.001735	1.0152
-29	-0.000800	-0.7185	2	0.001027	1.0099
-28	0.000509	0.3280	3	-0.000843	-0.8730
-27	0.000421	0.4880	4	0.001158	1.1195
-26	-0.000496	0.0002	5	0.001018	0.5883
-25	-0.002703	-2.0818	6	-0.000848	-0.8168
-24	-0.001934	-1.6480	7	0.000564	0.7930
-23	0.001222	0.9592	8	-0.000559	-0.3889
-22	-0.000687	-0.2631	9	0.000659	0.6349
-21	0.001938	1.9447	10	0.003403	3.0307**
-20	-0.001859	-1.6524	11	0.000553	0.3235
-19	-0.000276	-0.1324	12	0.001597	1.1893
-18	-0.001797	-1.4003	13	0.000735	0.6709
-17	-0.000526	-0.9253	14	-0.000145	0.3264
-16	0.000474	0.3141	15	0.001111	0.9066
-15	0.000084	0.0239	16	-0.001144	-0.7156
-14	-0.000029	-0.3559	17	-0.000607	-0.5804
-13	-0.000232	0.0009	18	0.000344	0.9217
-12	0.000716	0.3124	19	-0.000614	-0.3362
-11	0.000020	0.0998	20	-0.000141	0.3151
-10	0.000662	0.1912	21	0.001987	1.8194
-9	-0.001090	-0.6746	22	-0.000942	-1.1208
-8	-0.001534	-1.7561	23	0.002525	2.0860*

Table 1 (cont.)

Day Relative to Event	Average Excess Return	Z statistic	Day relative to Event	Average Excess Return	Z statistic
-30	-0.001208	-0.4972	1	0.001735	1.0152
-7	-0.001529	-1.1398	24	-0.00172	-1.2529
-6	0.001943	1.7614	25	0.000748	0.2600
-5	-0.002820	-2.1887*	25	-0.000097	-0.3895
-4	-0.001054	-0.3407	27	0.000720	1.1970
-3	-0.000742	0.0219	28	0.001093	0.9144
-2	0.000634	0.4028	29	-0.001089	-0.8607
-1	0.000731	0.5669	30	-0.000595	-0.8929
0	0.004200	3.4577**			

* Significant at the 5% level of significance (two-sided test)
**Significant at the 1% level of significance (two-sided test)

positive. In fact, the AER is significant at the 1% level. Significant returns are not present following the announcement day until Day 10 (noise.) In an efficient market, new information is quickly integrated into prices. In the case of new drug approval announcements, the significant reaction is concentrated on the day of the announcement and does not spill over into the days that follow. The market, therefore, quickly absorbed the positive information associated with the drug approval announcement by the FDA. The absence of a significant and positive drift in returns leading up to the announcement, and the quick and concentrated positive reaction on the day of announcement provides evidence that widespread insider trading (and leakage) were not present.

Table 2 shows various subperiods of CAERs preceding and following the new drug approval announcement. None of the CAERs prior to Day 0 are significant. The presence of insider trading would be exposed by significant positive returns in this period. The sign for each of the series prior to Day 0 is negative, although the value is not significantly different from zero. This CAER evidence provides further support that insider trading leading up to the announcement did not significantly impact on returns (if insider trading occurred at all). The results for Day 0 and beyond are significant and positive and indicate that there was no leakage. The announcement on Day 0 surprised the market and the positive returns are concentrated in that single day. Figure 1 shows the CAERs during the 30 days leading up to the approval announcement and the 30 days after the announcement. The pattern approaching the announcement is downward. On the announcement, a noticeable positive shift occurs and continues to drift upward throughout the period. The market interpretation of the announcement is positive. Although the reaction is not limited to Day 0, clearly the dominant contribution to the cumulative returns occurs on that single day.

Table 2. Cumulative Average Excess Returns for Selected Subperiods
Around the New Drug Approval Announcement

	CAER	Z-Stat	
CAER(-5,-1)	-0.003250	-0.8937	
CAER(-10,-1)	-0.004798	-1.0011	
CAER(-20,-1)	-0.008225	-1.5386	
CAER(0,1)	0.005935	3.1628	**
CAER(0,5)	0.008295	2.5792	**
CAER(0,10)	0.011514	2.8856	**
CAER(0,20)	0.013203	2.7477	**
CAER(0,30)	0.015830	2.5776	**

* Significant at the 5% level of significance (two sided test)
**Significant at the 10% level of significance (two sided test)

Conclusions

The existence of trading on inside information involving new drug approval announcements is difficult to conclusively measure. Evidence of possible insider trading is the presence of significant positive excess returns in advance of the announcement. In addition, the case for the existence of material insider trading and leakage would be associated with an insignificant reaction to the announcement of approval. This study finds no significant returns consistent with insider trading in the 30-day period leading up to the announcement. Furthermore, the reaction to the approval is significant, positive, and limited to the announcement day. Although some insider trading may have occurred in anticipation of the announcement, the evidence here shows that such trading (if it did occur) did not impact on prices in a

significant way. The reaction to the announcement largely surprised the market and produced a significant premium to the firms with approved new drugs.

Both the Securities and Exchange Commission and the Food and Drug Administration have expressed concern regarding insider trading associated with new drug approvals. The evidence presented in this paper shows that for drug approvals, returns and prices are unaffected by insider trading (at least on average). These results are consistent with a conclusion that FDA practices and SEC regulatory scrutiny are sufficient to limit insider trading. If there is any insider trading associated with drug approval announcements, the trading does not affect stock prices or returns.

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