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The Cost of Paying Attention:

Cognitive Resource Scarcity and Formative Event Processing

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Abstract

Investigating limited attention in financial markets has threefold merit: in real markets, investors may learn from experience; market prices may erase individual violations of rationality; investors may act there differently than at the laboratory.

We questioned whether limited attention affects processing of *formative events*. Specifically, we studied market conduct around NDA/BLA announcements by the FDA for R&D pharmaceutical companies depend on FDA endorsement.

The attention hypothesis, combined with prospect theory led us to the following conjectures, which were corroborated by the data: the attention-grabbing property of NDA/BLA submission, along with the investors' overweighting of small chances of huge gains, results in market overpricing of the firms' stocks; the overpriced stocks revert towards the prices before attention was grabbed, and, importantly, the reversion process takes place not just for non-approved, but even for *approved* submissions; lastly, we suggested that the stock prices' reversion-to-the-mean in the latter case would take considerable time.

Keywords: Attention, Behavioral Finance; Corporate News; Event Study; FDA Announcements; Financial Markets; Pharmaceutical Companies; Probability Weighting Functions.

JEL Classification: D8 (information, Knowledge, and Uncertainty) G11 (Portfolio Choice; Investment Decisions), G14 (Information and Market Efficiency; Event Studies), G17 (financial forecasting and simulation).

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"…in an information-rich world, the wealth of information means a dearth of something else: a scarcity of whatever it is that information consumes."

Herbert Simon (1971)

The Cost of Paying Attention:

Cognitive Resource Scarcity and Formative Event Processing

Extended Abstract

Recently, psychological aspects of decision making begun playing a role in economic modeling, adding positive aspects to the traditional, normative, approach based on rationality. We were interested in asking to what extent attention deficits play a role in real market situations.

Investigating the phenomenon of limited attention in financial markets has threefold merit: in real markets, investors may learn from experience; market prices may wash out individual violations of rationality; investors may act differently in real markets than at the laboratory.

Empirical studies considered various 'attention grabbers' commonly taking place at the market. We questioned whether limited attention affects processing of *formative events*. Specifically, we studied the market behavior around NDA/BLA announcements by the FDA for innovative R&D pharmaceutical companies, whose major activity, depended on the FDA's endorsement of their applications.

The attention hypothesis, combined with prospect theory led us to the following conjectures, which were corroborated by the data: the attention-grabbing property of NDA/BLA submission, along with the investors' overweighting of small chances of huge gains, results in market overpricing of the firms' stocks; the overpriced stocks revert towards the prices before attention was grabbed, and, importantly, the reversion process takes place not just for non-approved NDAs/BLAs, but even for *approved* cases. Lastly, we suggested that the stock prices' reversion-to-the-mean in the latter case would take considerable time, rather than being immediate.

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1. Introduction

The pharmaceutical industry develops, produces, and markets drugs to be used as medication. The Pharma industry is one of the world's top five industries by revenue and capitalization, with total annual revenue of US$720 billion, the vast majority of the revenue being produced by multinational pharmaceutical giants that have been dominating the industry for decades. Over the last 20 years the industry has been changing with the rapid development of biotechnology, creating space for smaller pharmaceutical firms, generally pursuing the development of one drug.

The modern pharmaceutical industry came of age with the introduction of regulations demanding that new pharmaceutical products be proven both safe and effective before they are marketed and sold. In the US, such legislation was introduced in 1962 with an amendment to the Food, Drug and Cosmetics Act (DiMasi, 2001). Since the introduction of the requirement from pharmaceutical products to demonstrate efficacy as a condition for approval, the industry became a major driver of advances in health technology and, spending on research and development have increased significantly.

In the US, new pharmaceutical products must be approved by the Food and Drug Administration (FDA) as being both safe and effective. This process generally involves submission of an Investigational New Drug (IND) filing with sufficient pre-clinical data to support proceeding with human trials. Following IND approval, three phases of progressively larger human clinical trials are often conducted. Phase I generally studies toxicity, using healthy volunteers; Phase II examines safety and efficacy in patients; and Phase III studies efficacy in a much larger scale, using the intended patient population. Following the successful completion of Phase III testing, either a New Drug Application (NDA), or Biologic License Applications (BLA) for bio products, is submitted to the FDA. The FDA reviews the submission and if the product is perceived as having a positive benefit-risk assessment, approval to market the product in the US is granted (Liberti et al., 2011).

The required documentation for an NDA consists of the drug development history during the pre-clinical and clinical phases; its ingredients; behavior in the human body; and manufacturing, processing, and packaging procedures. BLAs for biological products are approved for marketing

under the provisions of the Public Health Service (PHS) Act, which requires the manufacturing firm to possess an interstate commerce license for the product. The required documentation of a BLA contains specific information on the manufacturing processes; chemistry; pharmacology; and medical effects of the product.

Due to the long drug development process and multiple, increasingly growing, required investments, many drug development companies choose to raise funding by issuing securities and registering them at the stock exchange. As a result, by the end of 2012, more than 500 companies are being listed at the healthcare US stock markets. Frequently, the stock prices of these firms are highly volatile, manifesting the rapid information updates regarding the clinical progress and regulatory issues.

During the long journey towards FDA approval, the company usually disseminates numerous press releases; most of them arrive at the market without any prior notice. In this study, we focus on the announcement of the FDA decision whether to approve the firm's NDA/BLA (henceforth, NDA/BLA announcement. The date of this announcement (denoted by t=0 in the sequel) is usually foreknown months in advance. Several studies have investigated the effect of announcements on stock behavior in pharmaceutical companies. However, to the best of our knowledge, none of them delved into the analysis of the stock prices in the post-FDA-approval period. This study fills this gap, documenting an intriguing stock price pattern in the weeks surrounding the FDA's NDA resolution announcement. A detailed description of the alternative NDA pathways under FDA guidance appears in Appendix B.

Bosch and Lee (1994) investigated the market conduct around FDA product approvals, rejections, and disciplinary decision in the food and drug industries. Their data consisted of 194 new product approvals, 18 rejections, and 121 disciplinary decision announcements, over the years 1962 to 1989. For the 194 approvals sample, their main finding was a strongly significant positive abnormal price reaction of 1.71% for the 2 day period (-1,0). For the drug cases (130 out of the 194 approvals) they reported a significant positive abnormal price reaction on days -1 and 0 (+1.10% and +0.65%, respectively). Importantly, relevant to our research, an insignificant abnormal price reaction of -0.73% for the approvals subsample (-0.90% for the drug approvals subsample) was detected in the post announcement period (+1,..,+20).

Bosch and Lee`s research was conducted in a period which differed from the current dynamic pharmaceutical market. Furthermore, it did not make a distinction between innovative and generic companies. The last decade was vital for the pharmaceutical market, due to the emerging of newer and cheaper biological and chemical methods of drug development. These innovations enabled small and mid Cap. pharmaceutical companies develop new drugs without the hospice of "big pharma" companies.

Deeds et al. (2003) explored the effect of drug rejections on the applicant company. Covering the time period from 1992 to September 2002, they were able to identify 55 drug rejections and found a strong abnormal reaction to the rejection announcements, averaging -20% over the subsequent 50 days. Related, our study investigates abnormal returns subsequently to rejections and approvals as well.

Sharma and Lacey (2004) studied the effect of both approvals and rejections of pharmacological drugs by the FDA. Their sample of approvals and rejections included 344 and 41 drugs, respectively. They found that both the approvals and rejections were efficiently incorporated into the firms' stock prices, showing strong positive abnormal returns for approvals and strong negative abnormal returns for rejections. The reactions were significant for the days t=-1 to t=1; the average reaction to the approvals (rejections) was 1.56% (-21.03%). No substantial reaction was observed before or after this period.

Sarkar and de Jong (2006) explored FDA announcement effects at several points of the review process. Their research was conducted on an initial sample consisting of 919 firms which was screened for confounding effects, yielding a final sample of 189 firms over the years 1990 to 2001 (the approval drug subsample consisted of only 49 firms). Their sample included both large and small pharmaceutical firms, and did not make a distinction between biotechnology and traditional pharmaceuticals. Their findings indicated that the FDA approval for continued medical review and whether the drug is deemed approvable have a statistically significant impact on stock prices on the day after the Dow Jones News Retrieval Service (DJNS) release (0.787%, 2.234%, and 0.440%, for the 189 initial reviews by the FDA, 49 approvable drug subsample, and 189 final approvals, respectively). In addition, the final approvals sample had also a statistically significant abnormal return, of 0.353%, on the DJNS release day. Relevant to our study, it is worthwhile mentioning that no subsequent significant price reaction was detected till day +10 of the DJNS release day.

Neuhierl et al. (2010) studied market reactions to corporate press releases, inter alia, FDA announcements.[2] Their FDA approvals sample consisted of 1,279 announcements of product approvals, from 2006 to 2009. They found that market prices started to move before the official press release was made. Specifically relevant to the current study, they report a positive cumulative abnormal return around FDA approval announcements, for days (-1,..,+5) surrounding the event.[3] Their figures suggested no further significant price reaction till day +21 following the press release.

The above mentioned studies did not target the small, innovative, companies which are focused on the development of new drugs or bio products, which are the subject of our research. Furthermore, we also pay attention (pun intended) to the post event period, which reveals an intriguing market behavior.

2. Testable Hypotheses and Motivating Background

Main stream asset pricing models are built under the efficient market hypothesis (Fama 1970), asserting that security prices fully reflect all available information at any point in time. Specifically, the semi-strong form of market efficiency implies that the reaction to any release of information to the public, such as, FDA decisions whether to approve firms' NDAs, should take place not later than on the announcement day.

However, in the last few decades, research by psychologists challenging the rationality paradigm has started to penetrate economic modelling. A prominent step in that direction claimed that individuals have limited attention resources (Kahneman, 1973). A vast experimental documentation of cognitive limitations has been accumulated (cf. Bell, Raiffa, and Tversky, 1988; Kahneman, 2003; Kocher and Sutter, 2006; Croson and Gächter, 2010; and reference therein), but do attention deficits play a role in real market situations? And if indeed so, then to what extent? The exploration of the effect of limited attention in financial markets has several merits. First, in real markets investors are involved in repeated situations, thus have the chance to learn from each other's experience; second, it would be reasonable to assume that market prices, being the aggregated outcome of actions of numerous individuals, would wash out individual violations of rationality. Third, investors may act differently in real market situations than at the laboratory.

[2] Note that this study took into consideration any kind of FDA announcement (e.g., innovative approvals of labeling, generic, and formulation), rather than merely announcements which are related to NDA/BLA paths.

[3] The magnitude of the cumulative abnormal return is somewhat unclear in the publicly available version of the working paper.

In this paper, we employ a unique event to test for the possibility of scarcity of cognitive resources by investors, possibly leading to mispricing due to limited attention. We focus on the announcements of the FDA decisions whether to endorse pharmaceutical R&D firms' applications for approval of the drugs and bio products they develop, known as NDAs and BLAs.

Barber and Odean (2008) tested the hypothesis asserting that individual investors are net buyers of attention-grabbing stocks, such as stocks which are being discussed in the news; stocks which are traded at abnormally high trading volume; or stocks which experience extreme returns. In a nutshell, they hypothesize that attention-limited investors consider purchasing only stocks that have caught their attention, to wit, decisions driven by the investors' preferences are activated only on a subset of securities which 'caught their eyes.' Barber and Odean's argument leans on the observation that most individual investors do not sell short, thus attention is a major factor determining the stocks they buy, but not those that they sell, leading to overpricing of stocks associated with attention-grabbing events.

Several studies, detailed henceforth, have arrived at empirical results commensurate with the attention hypothesis. These studies' attention 'generators' consist of variables such as high trading volume; advertising expenditure; unanticipated earnings announcements; stocks' upper price limit events (incorporating the three attention-grabbing events: high returns; high volume; and the event generating news); and stock recommendations in television shows. The common denominator of these attention grabbers is their relatively frequent reoccurrence, to wit, these events commonly take place in the market. Our study, in contrast, aims at questioning whether scarcity of cognitive resources, generating limited attention, has an impact on the processing of *formative events*. Specifically, we study the market conduct around NDA/BLA announcements issued by the FDA for small and mid-size, innovative, R&D pharmaceutical companies, whose major activity, and possibly entire existence, depends on the FDA's endorsement of their drug/bio product application which is submitted for approval.

Geravis at al. (2001) document that stocks which are traded at abnormally high trading volume tend to subsequently appreciate over the month; Grullon et al. (2004) find that the stocks of firms which spend a lot of money on advertising are held by more investors; Kliger and Kudryvtsev (2007) hypothesize that salient events which occur while investors hold stocks make them update the stocks' reference points, and corroborate the hypothesis using unanticipated earnings

announcements; Seasholes and Wu (2007) find that the prices of stocks traded at the Shanghai market temporarily rise following attention-grabbing events before mean-reverting to their pre-event price levels over the following five days. Moreover, they claim and substantiate that when many events happen simultaneously, search costs are not reduced, the consideration set is not narrowed, and attention-based buying is therefore absent; and Engelberg et al. (2011) find that stock recommendations broadcasted on Mad Money, Jim Cramer's popular television show, lead to large overnight returns which reverse in the subsequent months.

Barberis and Huang (2008) study the asset pricing implications of Tversky and Kahneman's (1992) cumulative prospect theory (a modified version of the celebrated 'prospect theory,' Kahneman and Tversky, 1979), particularly focusing on the role of probability weighting functions. Their main result, standing in contrast to standard expected utility predictions, is that positively skewed security returns may be overpriced, and thus earn negative average excess returns. In a nutshell, the result is due to the sub-additivity of the probability weighting functions, causing overweighting of the tails of the distribution they are applied to. As asserted by Barberis and Huang, their result that investors exhibit a preference for skewness suggests a unifying way of thinking about several seemingly unrelated facts, such as the low long-term average return on Initial Public Offerings (IPOs), probably because they are issued by young, growing, firms. The idea is that by taking a substantial position in an IPO, the investor gets a chance, albeit a small one, of a very large wealth-increase.[4]

Enthusiastic public attention to already publicly released medical R&D advances has been spotted to make stock prices soar. Huberman and Regev (2001) document a Sunday New York Times article on potential development of new cancer-curing drugs caused the stock price of the developing company, EntreMed, to rise sharply over the weekend and then partially revert, in spite of the fact that the potential breakthrough in cancer research had already been reported in the journal Nature and elsewhere. We conjecture that the attention-grabbing property of the formative event of NDA/BLA submission, along with investors' tendency to overweight the small chances of huge gains by small R&D firms filing for NDA/BLA at the FDA, may result in market overpricing of the submitting firms' stocks. Moreover, we propose that the overpriced stocks would revert, at least to some extent, towards the price level before the investors' attention was grabbed by the

[4] It is noteworthy to mention some previous studies emphasizing the potential effect of gambling on investment decisions, such as Friedman and Savage (1948); Markowitz (1952), Shiller (2000), Shefrin and Statman (2000); and Statman (2002).

NDA/BLA filing, and that the reversion process would take place for the cases of non-approved, but *even for the cases of approved* NDA/BLA submissions. Lastly, we suggest that the stock prices' reversion-to-the-mean in the latter cases would take considerable time, rather than being immediate.

Our conjecture, motivated by the above literature, yields the following testable hypotheses:

H1: Attention and Skewness Hypothesis: NDA/BLA filing ignites a period of investors' attention to the stock of the submitting firm, thereby, causes:
(i) overpricing, manifested by increasingly growing cumulative abnormal returns; and
(ii) increased trading activity, manifested by positive abnormal trading volumes.

H2: Skewness, Post-attention Hypothesis: FDA's resolution of the NDA/BLA, either in the form of approval, or non-approval, snuffs out the period of investors' attention to the stock of the submitting firm, thereby, causes:
(i) slow reversion to the former prices in case of NDA/BLA approval; and
(ii) rapid reversion to the former prices in case of NDA/BLA non-approval.

3. Data and Analysis

Our data consist of FDA's NDA/BLA announcement for small and mid-size, innovative, R&D pharmaceutical companies, as recorded at the FDA website (www.fda.gov) for the years 2006 to 2012. An announcement entered our sample provided that the announcing firm's market capitalization did not exceed $2.5bil.; it had no more than two approved drugs; and filed drugs under the FDA, either in the form of NDA, or BLA. The resulting dataset comprises of 106 events, of which 56 are of cases which were approved by the FDA (henceforth 'approvals'), and 50 not approved ('non-approvals'); the non-approvals consist of 43 Complete Response Letters (CRLs), i.e., FDA requests of some fundamental questions regarding the drug; and 7 Extensions, where the companies were asked specific clarifying questions or for some additional material.

We examine the market reaction to NDA/BLA announcements using the event study approach. To that end, we mark the event day as t=0 and use daily stock prices, extracted from Yahoo Finance (http://finance.yahoo.com/) for the period t=-300,..,+50, to calculate daily (logarithmic) returns. We then calculate abnormal daily stock returns using two return benchmarks and two calculation methods, i.e., a 2 x 2, design. The two benchmark returns are of the (i) Healthcare index, and (ii) S&P 500 index; and two calculation methods are by subtracting the (i) benchmark return, and (ii)

conditional return imputed by a linear regression of the stock returns on the benchmark returns, using the returns on days t=-300,..,-60 relative to the announcement date. Throughout, unless otherwise stated we present the results obtained by subtracting the Healthcare-index regression conditional returns from the stock returns (henceforth, 'Healthcare/Reg' specification). The abnormal returns obtained by the other three specifications provide qualitatively similar results. Restricting the sample to events for which data exist at least from t=-60 and till t=+50 window eliminates 5 approvals and one non-approval from the analysis, retaining 51 approvals and 49 non-approvals.

In addition, as a proxy for market attention, we compute abnormal trading volume statistics. For each event in our sample, we record the natural logarithm of the daily trading volume throughout the period t=-300,..,+50, normalize each series' by subtracting the mean and dividing by the standard deviation calculated over t=-300,..,-60, and average across all events in each subsample for each day relative the NDA/BLA announcement dates.

Pre- and at-event analysis

Figures 1 and 2 plot the cumulative average abnormal returns (CAARs) around the NDA/BLA announcement dates (blue graph, primary axis), and the average (normalized) abnormal daily volume (red bars, secondary axis), over the period t=-250,..,+50, for the approvals and non-approvals subsamples, respectively. As seen in the figures, rising attention, manifested in the shape of increased abnormal volume, starts building up as long four months (approximately 100 trading days) before the NDA/BLA approval, and three months before the NDA/BLA non-approval dates. For the approvals, as well as for the non-approvals, the abnormal volume peaks on the day after the announcement, but remains abnormally high in the subsequent couple of months.

With respect to abnormal returns, the buildup starts as early as half a year (More than 140 trading days) before the NDA/BLA approval dates, and about four months (approximately 100 trading days) before the non-approval dates.

Figures 3 and 4 zoom in at the event window of window t=-50,..,+50, and Tables 1 and 2 depict the respective CAARs around the NDA/BLA approvals and non-approvals over that event window. The tables' columns provide the abnormal returns calculated according to the 2 x 2 design employing either of the two benchmark returns (using the Healthcare, or S&P 500 indices), and two

calculation methods (i.e., subtracting the benchmark return, or the conditional return imputed by regressing the stock returns on the benchmark returns).

Inspecting the approvals (Table 1 and Figure 3), a positive CAAR of 16.47% which is significant at the 1% significance level, possesses the two month from 50 days before the approval dates till the day after them; on the day following the event, the average abnormal return is 4.5% and significant at 1% as well.[5]

In the case of the non-approvals (Table 2 and Figure 4) there is weak evidence of a positive CAAR of roughly 7% or more, depending on the specification of the abnormal return, taking place from two month till a fortnight before the event (insignificant increase of 6.93% for the 'Healthcare/Reg' specification; 5%-significance increase of 10.58% for the 'S&P500/Diff' specification). Subsequently, negative abnormal returns occupy the trading activity, generating a sharp price crash within a week after the announcement; on the day following the event, an immense negative abnormal return, of -16.18% takes place.

Post-event analysis

Inspecting Figure 3, plotting the CAARs and average abnormal daily volume around the NDA/BLA approvals, reveals that the accumulated abnormal return which took place until the FDA announcement discharges over the following two month period. Interestingly, while about half of the decline takes place in the two weeks after the announcement, subsequent negative abnormal returns are more or less evenly spread throughout the rest of the period.

Figure 4, depicting the CAARs and average abnormal daily volume for the non-approvals subset, shows that the crash surrounding the announcements lasts for about a week after the event, is followed by a few weeks of much milder, statistically insignificant when calculated over ten day batches, negative abnormal return. By about two weeks after the announcement, the average price level is about 25% below its level two months prior to the event, and by two month after it, about a third below that level.

[5] Recall that, unless otherwise stated, we refer in the discussion to the results obtained by the 'Healthcare/Reg' specification. As seen in the tables, the results obtained with the other specifications are very similar.

4. Concluding Remarks

In the last few decades, psychological aspects of decision making have begun to play a significant role in economic modeling, adding positive aspects to the traditional, normative, approach based on the axioms of rationality. Numerous laboratory results pointing at individuals' cognitive limitations have been documented. We were especially interested in asking whether attention deficits play a role outside the lab, in real market situations. And if such indeed is the case, to what extent? Investigating the phenomenon of limited attention in financial markets is worthy due to several reasons. First, in real markets, investors decide and act upon their decisions repeatedly, thus may learn from their own and others' experience; second, it would be reasonable to assume that market prices, being the aggregated outcome of the investors' actions, would wash out individual violations of rationality. Third, it may well be the case that investors act differently in real markets than at the laboratory.

Several empirical studies have arrived at results commensurate with the attention hypothesis. These studies considered attention 'generators' such as abnormal trading volume; advertising expenditure; unanticipated earnings announcements; stocks' upper price limit events (incorporating three attention-grabbing events: high returns; high volume; and the event generating news); and stock recommendations in television shows. All of these attention grabbers occur relatively frequently, to wit, these they commonly take place in the market. We, however, aimed at questioning whether limited attention has an impact on the processing of *formative events*. Specifically, we studied the market behavior around NDA/BLA announcements issued by the FDA for small and mid-size, innovative, R&D pharmaceutical companies, whose major activity, and possibly entire existence, depended on the FDA's endorsement of their drug/bio product application which was submitted for approval. To that end, we gathered data on the FDA's NDA/BLA announcements for small and mid-size, innovative, R&D pharmaceutical companies, for the years 2006 to 2012, and examined the market reaction to the approval- and non-approval-announcements, using the event study approach.

One of the tenets of cumulative prospect theory (Tversky and Kahneman, 1992) is sub-additivity of the decision weights, manifested by inverse-s shaped probability weighting functions. Focusing on the probability weighting functions, Barberis and Huang (2008) arrived at the intriguing result that

investors may exhibit a preference for skewness, as such investments may provide them with a chance, albeit a small one, of a very large wealth-increase.

The attention hypothesis and the abovementioned features of prospect theory led us to the following conjectures, which were corroborated by the data. Namely, that the attention-grabbing property of the formative event of NDA/BLA submission, along with the investors' tendency to overweight the small chances of huge gains by small R&D firms filing for NDAs/BLAs, would result in market overpricing of the firms' stocks. Moreover, we proposed that the overpriced stocks would revert, at least to some extent, towards the price level before the investors' attention was grabbed by the NDA/BLA filing, and that the reversion process would take place not just for the cases of non-approved NDAs/BLAs, but even for the *approved* cases. Lastly, we suggested that the stock prices' reversion-to-the-mean in the latter case would take considerable time, rather than being immediate.

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Appendix A: Tables and Figures

Table 1: CAARs around NDA/BLA approvals

Days relative to event	Number of days	'Healthcare/Reg'		'Healthcare/Diff'		'S&P500/Reg'		'S&P500/Diff'	
		CAAR, %	t-statistic	CAAR, %	t-statistic	CAAR, %	t-statistic	CAAR, %	t-statistic
-50 to 1	52	16.47%	2.75	16.01%	2.67	17.24%	2.88	16.90%	2.82
-40 to 1	42	15.13%	2.81	14.19%	2.64	15.78%	2.93	14.91%	2.77
-30 to 1	32	10.99%	2.34	10.26%	2.18	11.82%	2.52	11.05%	2.35
-10 to 1	12	7.20%	2.50	6.85%	2.38	7.41%	2.58	7.15%	2.49
-2	1	1.45%	1.74	1.49%	1.79	1.25%	1.50	1.39%	1.67
-1	1	0.57%	0.68	0.48%	0.58	0.70%	0.84	0.72%	0.87
0	1	0.05%	0.06	-0.10%	-0.12	0.04%	0.04	-0.18%	-0.21
1	1	4.50%	5.42	4.46%	5.37	4.55%	5.47	4.46%	5.37
2	1	-3.33%	-4.01	-3.25%	-3.92	-3.37%	-4.05	-3.17%	-3.82
3	1	-1.32%	-1.59	-1.39%	-1.67	-1.35%	-1.63	-1.41%	-1.69
2 to 10	9	-8.49%	-3.41	-8.43%	-3.38	-8.90%	-3.57	-8.53%	-3.42
2 to 20	19	-10.26%	-2.84	-10.20%	-2.82	-10.77%	-2.98	-10.51%	-2.90
2 to 30	29	-13.21%	-2.95	-13.25%	-2.96	-14.02%	-3.13	-13.59%	-3.04
2 to 40	39	-14.48%	-2.79	-14.43%	-2.78	-15.75%	-3.04	-14.87%	-2.87
2 to 50	49	-16.45%	-2.83	-16.56%	-2.85	-17.69%	-3.04	-16.01%	-2.75
2 to 10	9	-8.49%	-3.41	-8.43%	-3.38	-8.90%	-3.57	-8.53%	-3.42
11 to 20	10	-1.78%	-0.68	-1.76%	-0.67	-1.88%	-0.71	-1.98%	-0.75
21 to 30	10	-2.95%	-1.12	-3.05%	-1.16	-3.25%	-1.24	-3.08%	-1.17
31 to 40	10	-1.26%	-0.48	-1.18%	-0.45	-1.73%	-0.66	-1.28%	-0.49
41 to 50	10	-1.97%	-0.75	-2.13%	-0.81	-1.95%	-0.74	-1.14%	-0.43

Table 2: CAARs around NDA/BLA non-approvals

Days relative to event	Number of days	'Healthcare/Reg'		'Healthcare/Diff'		'S&P500/Reg'		'S&P500/Diff'	
		CAAR, %	t-statistic	CAAR, %	t-statistic	CAAR, %	t-statistic	CAAR, %	t-statistic
-50 to -11	40	6.93%	1.30	10.25%	1.93	7.20%	1.35	10.58%	1.99
-40 to -11	30	4.47%	0.97	7.70%	1.67	4.37%	0.95	7.77%	1.69
-30 to -11	20	1.06%	0.28	3.30%	0.88	0.94%	0.25	3.35%	0.89
-20 to -11	10	1.46%	0.55	2.15%	0.81	1.49%	0.56	2.20%	0.83
-10 to -1	10	-12.95%	-4.87	-12.35%	-4.64	-13.08%	-4.92	-12.15%	-4.57
-10 to -0	11	-15.41%	-5.52	-14.71%	-5.27	-15.84%	-5.68	-14.60%	-5.23
-10 to 1	12	-31.58%	-10.84	-31.32%	-10.74	-32.52%	-11.16	-31.67%	-10.87
-2	1	-2.48%	-2.94	-2.28%	-2.70	-2.52%	-2.99	-2.32%	-2.76
-1	1	-6.52%	-7.74	-6.24%	-7.42	-6.56%	-7.80	-6.16%	-7.32
0	1	-2.46%	-2.92	-2.36%	-2.81	-2.75%	-3.27	-2.45%	-2.92
1	1	-16.18%	-19.22	-16.60%	-19.73	-16.68%	-19.83	-17.07%	-20.29
2	1	-2.83%	-3.36	-2.57%	-3.05	-2.74%	-3.26	-2.50%	-2.97
3	1	-0.95%	-1.12	-0.84%	-1.00	-0.96%	-1.14	-0.87%	-1.03
4	1	-0.79%	-0.94	-0.85%	-1.01	-0.90%	-1.07	-0.99%	-1.18
1 to 3	3	-19.95%	-13.69	-20.01%	-13.73	-20.38%	-13.98	-20.43%	-14.02
4 to 10	7	-2.02%	-0.91	-1.45%	-0.65	-2.00%	-0.90	-2.04%	-0.91
11 to 20	10	-2.32%	-0.87	-2.22%	-0.83	-2.91%	-1.10	-2.54%	-0.96
21 to 30	10	-3.49%	-1.31	-3.40%	-1.28	-3.69%	-1.39	-3.50%	-1.32
31 to 40	10	1.90%	0.71	1.88%	0.71	1.54%	0.58	1.79%	0.67
41 to 50	10	0.15%	0.06	0.75%	0.28	-0.12%	-0.04	0.88%	0.33

Figure 1: CAARs and abnormal daily volume statistics around NDA/BLA approvals, for t=-250,..,+50.

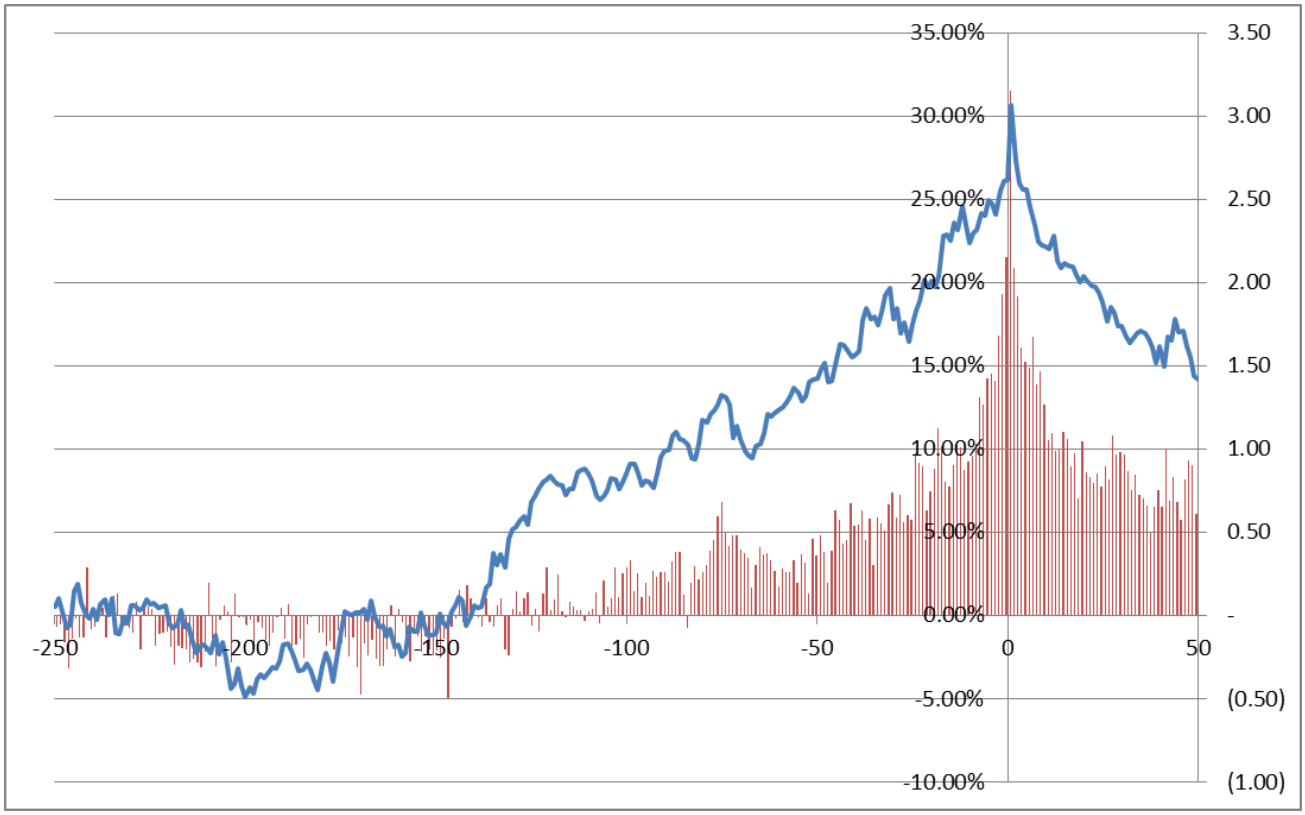


Figure 2: CAARs and abnormal daily volume statistics around NDA/BLA non-approvals, for t=-250,..,+50.

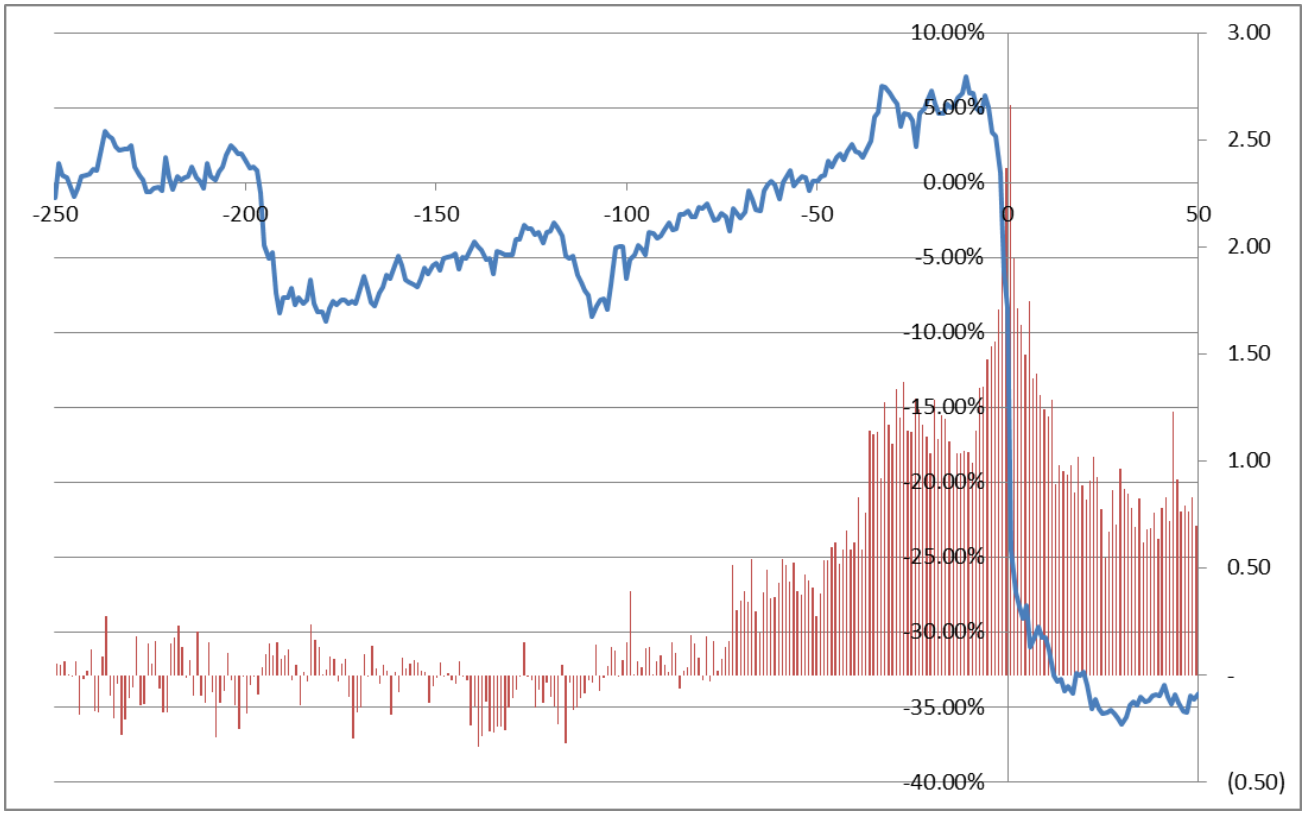


Figure 3: CAARs and abnormal daily volume statistics around NDA/BLA approvals, for t=-50,..,+50.

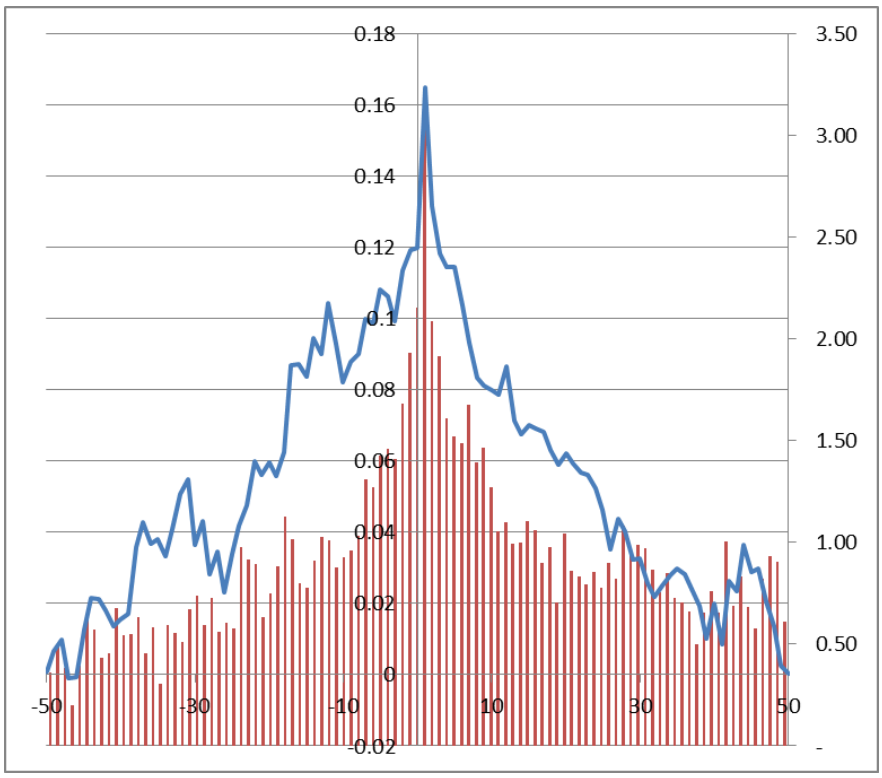
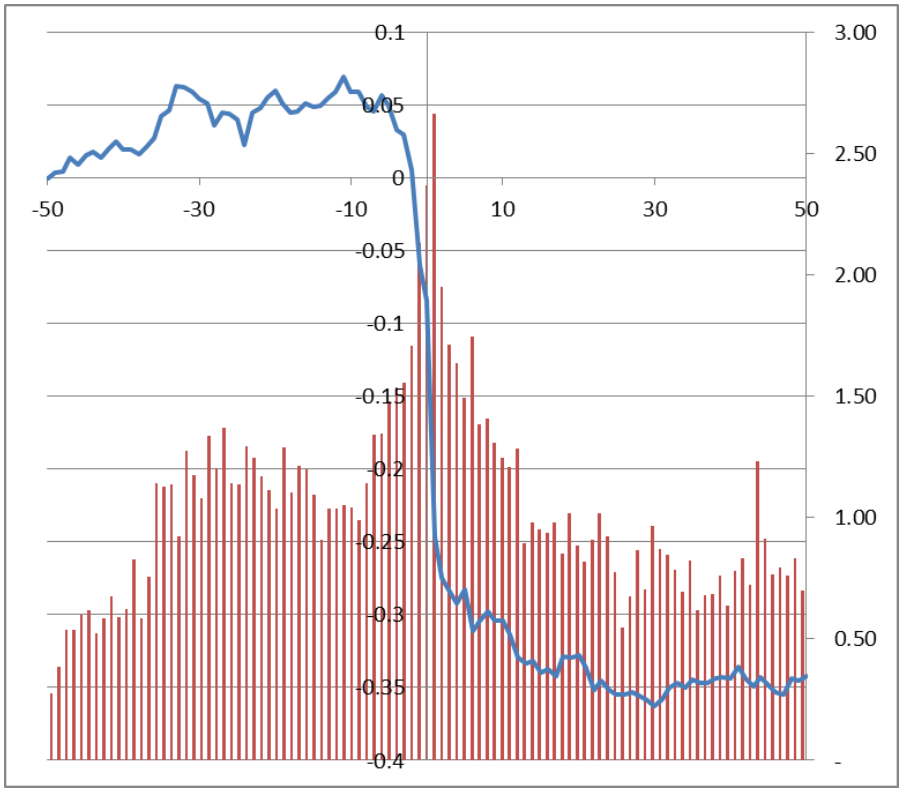
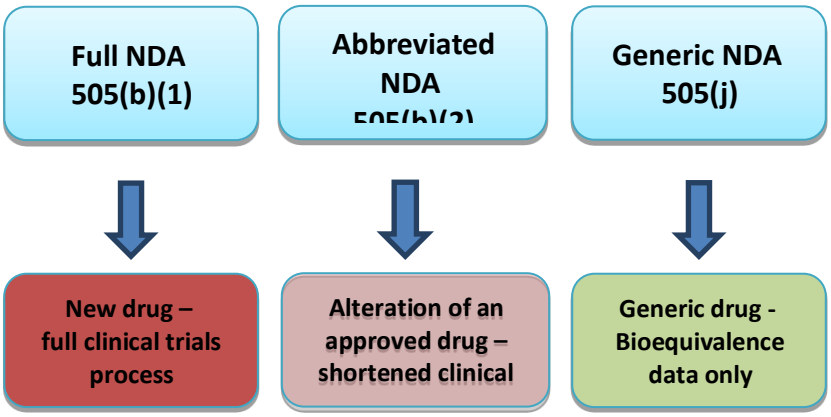


Figure 4: CAARs and abnormal daily volume statistics around NDA/BLA non-approvals, for t=-50,..,+50.



Appendix B: New drug application (NDA) pathways under FDA guidance

Section 505 of the Food Drug and Cosmetic Act (the Act) describes three types of new drug applications: 505(b)(1), an application that contains full reports of investigations of safety and effectiveness; 505(b)(2), an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference; and 505(j), an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product.



Clause 505(b)(1) is the regular, full process pathway of clinical drug development, employed for applications of a new drug. Generally, the drug development pathway consists of three clinical phases, and a drug must meet success criteria at each of them before moving on to the next one.

Phase 1: main goals are to assess safety and tolerability, and explore how the drug behaves in the body (how long it stays in the body, how much of the drug reaches its target, etc.). This phase is often conducted in healthy volunteers.

Phase 2: main goals are to evaluate whether the drug appears effective in patients, to further explore its safety, and to determine the best dose.

Phase 3: large studies involving 500 to 5,000 or even more patients, depending on the disease and the study design. Very large trials are often needed to determine whether a drug can prevent bad health outcomes. Often the goal is to compare the effectiveness, safety, and tolerability of the test drug with another drug or a placebo.

The size, duration, costs and number of trials of each clinical phase may vary according to the drug, the disease and the regulatory pathway. If the candidate drug shows clear benefits and acceptable risks in phase 3, the company may file an NDA, requesting regulatory approval to market the drug. Regulators review data from all studies and decide whether the drug's benefits outweigh any risks it may have. The range of costs and duration of drug development in the 505(b)(1) pathway are depicted by the following figure.