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The Cost of Paying Attention:

Cognitive Resource Scarcity and Investor Activity Around FDA Announcements

"...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)

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Abstract

In the summer of 2012, the FDA approved a pioneering drug for obesity, developed by Arena Pharmaceuticals (NASDAQ: ARNA). ARNA's stock price increased gradually in the preceding three months, from \$2 to \$11 on approval day. However, one month after FDA approval, Arena's stock price had declined by more than 30%, to \$7. What went wrong? Why did ARNA's stock price decrease after the 'good news' dissemination? Was this a specific case of ARNA, or did it reflect a general, intriguing, phenomenon?

To answer, we have collected a sample of FDA resolutions over a period from 2006 to 2014, consisting of 133 cases, 73 of which were approvals and the rest 60 were non-approvals.

Our findings bring about an interesting picture of price adjustments following the FDA announcements. In the cases where the FDA has not approved the drug application, as well as in the cases of approval, stock prices tended to decline after the announcement. The price decline after non-approvals was rapid (within a few days), while in the case of approvals it took longer (aprox. 30 trading days); the latter is especially puzzling as, ostensibly, it stands at odds with the nature of the released information.

Our paper's goal is to document this phenomenon, and suggest possible explanations for its existence. To the best of our knowledge, of the several studies which have investigated the effects of FDA resolution announcements for New Drug Application (NDA) and Biological Licensing Application (BLA) on stock prices, none has delved into the analysis of stock prices in the period subsequent to the FDA resolution.

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1. Introduction

Psychological aspects of decision making are playing an increasing role in economic modeling, adding positive aspects to the traditional, normative, approach based on the standard economic assumptions of rationality. Our primary interest is in analyzing investment patterns around FDA resolution on innovative firms representing the ‘new world’ of R&D firms, focusing on the pharmaceuticals industry.

Our research explores market conduct in one of the most fascinating and complex sectors within capital markets: the pharmaceutical sector .The pharmaceutical industry develops, produces, and markets drugs to be used as medication. It 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.

In the summer of 2012, the FDA has approved two obesity drugs. The date and time of the approvals were published on the FDA website several weeks before the announcement. Arena Pharmaceuticals (NASDAQ: ARNA) FDA approval on June 27, 2012, was followed by a closing price of \$11.4, and the approval for Vivus Inc. (NASDAQ: VVUS), on July 18, 2012, by a closing price of \$29. The stock prices of ARNA and VVUS have significantly appreciated in the few month before the FDA resolution, generating respective returns of about 400% and 142%, manifesting thereby a phenomenon we henceforth refer to as the ‘bio run-up.’ This is, however, only the first part of the empirical phenomenon story we document. The second, even more intriguing part regards the ex-post price conduct, which seem to be a puzzling anomaly. In the month subsequent to the FDA approval, ARNA’s price dropped to \$7.40 and VVUS’s to \$22, resulting in massive negative returns in the order of a quarter of the firms’ market capitalization. This phenomenon, which we dub the ‘bio run-down,’ is the main focus of our paper.

‘Bio run-up’ was recorded also in another event, which was described in Huberman and Regev (2001). A Sunday *New York Times* article, published on May 3, 1998, on the potential development of new cancer-curing drugs caused the stock price of EntreMed (NASDAQ: ENMD) to rise from \$12 at the Friday close, to Monday open at \$85 and close near \$52. Three weeks later, ENMD’s stock price was traded just above \$30, well above its pre *Times*’ cover, but still much lower than its post media-coverage related record. More than five months earlier, however, the journal *Nature*, and various popular newspapers, including the *Times*, had already reported the potential breakthrough in cancer research. Thus, the surge in ENMD’s share prices on May 4 occurred even though no genuinely new information had been presented on that date. Are those cases related? We think that the answer is ‘yes’, to wit, the interesting case brought by Huberman and Regev was not merely an occasional episode, but rather a manifestation of a much broader, systematic, phenomenon.

Several studies have investigated the effect of FDA announcements on stock prices of pharmaceutical companies. However, to the best of our knowledge, none of them has delved into the analysis of the stock prices in the post-approval period. This study fills this gap, documenting the intriguing stock price pattern we have described above.

Mainstream 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; Fischbacher and Gächter, 2010; and reference therein), but do attention deficits play a role in real market situations? And if they do, then to what extent?

We suggest that the stock price surge before, and decline after, FDA resolution may be in line with scarcity of cognitive resources among market investors. According to this suggestion, investors’ attention rises towards the FDA resolution, and declines afterwards. Investigating the phenomenon

of limited attention in financial markets has threefold merit: in real markets, the behavior of actual investors is investigated; they may learn from their own, as well as others' experience; and market prices may wash out individual violations of rationality.

The pharmaceutical industry is subject to a demanding set of regulations regarding the development of new pharmaceutical products, which should 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 filing of an Investigational New Drug (IND) 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 successful completion of Phase III testing, either NDA, or BLA, is submitted to the FDA. NDAs and BLAs are the most common FDA regulatory drug approvals, whether chemically or biologically based. 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 have been 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.

In this study, we focus on the announcements of the FDA decisions whether to approve firms' NDA/BLA applications. 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, nor focused on small size innovative firms. This study fills this gap, and by doing so, documents an intriguing stock price pattern in the weeks surrounding the FDA announcements.

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 focus on post event market reaction. Furthermore, they did not target the small, innovative, firms which are focused on the development of new drugs or bio products representing the tip of innovation and the future of pharmaceuticals industry.

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.

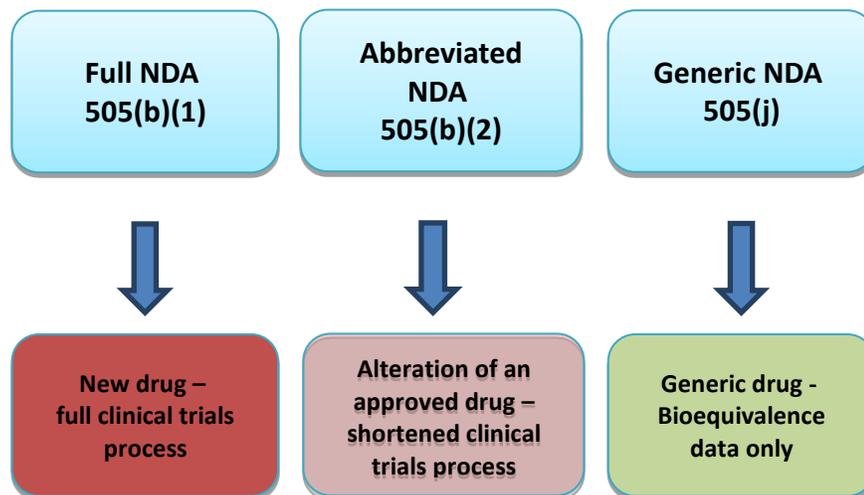
³ The magnitude of the cumulative abnormal return is somewhat unclear in the publicly available version of the working paper.

2. The long road until FDA resolution

FDA announcements follow a long, costly road. Once a firm has developed a molecule and finished the pre-clinical (non-human) trials and Phase 1 to assure safety, it may proceed to the next important milestone, Phase 2 and, subsequently, Phase 3, which are compulsory seminal milestones toward approval. In the next section we describe the most common regulatory path and the economic meaning of the FDA resolution in which drugs are been filed.

Section 505 of the Food Drug and Cosmetic Act (the Act) describes three types of new drug applications(see Figure I): 505(b)(1), an application that contains full reports of investigations of safety and effectiveness; 505(b)(2), a similar application , in which 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.

Figure I: FDA drugs developments regulatory pathways:



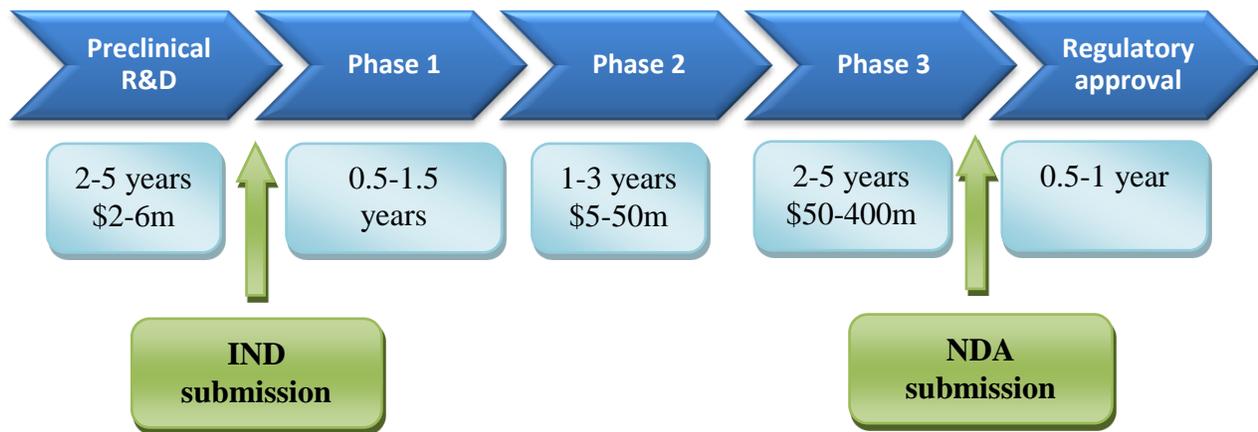
Clause 505(b)(1) is the regular, full process pathway of clinical drug development, employed for new drug applications. Generally, the drug development pathway consists of three clinical phases, and a drug must meet success criteria at each of them before moving on to the next one.

The main goals of Phase 1 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 dosage; Phase 3 is in larger scale, focuses on drug effectiveness, in comparison with current 'gold standard' treatment. 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 specific drug, disease and 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 Figure II.

Figure II: Drug development 505(b)(1) pathway: costs and duration.



3. Testable Hypotheses

Our primary focus is on investment patterns upon market reaction to ‘good news.’ The picture emerging from the data we observe proposes that toward the FDA announcement, the investors increase their attention to the firm under scrutiny, causing thereby a ‘bio run-up’. We further observe that the intensity of the ‘bio run-up’ depends on the preceding milestone – Advisory Committee (AdvC) – which takes place about two months before FDA resolution. Advisory committees meet only to discuss the most controversial or innovative products, or products whose underlying information is not clear-cut. Although the AdvC merely provides the FDA with recommendations, it seems to play an essential role the formation of the FDA decision.

We suggest that the attention-grabbing property of the seminal milestone 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, are part of the causes for the market appreciation of the submitting firms’ stocks.

Ex post event, we see that the stock prices revert towards the price level before the FDA announcement, for the cases of non-approvals, as well as for the approvals.

Observing the stock prices around announcements, we hypothesize as follows:

H1: Pre-event attention: FDA upcoming resolution of the NDA/BLA ignites a period of investor attention to the stocks of the submitting firm, thereby, causes:

- (i) an upward trend in cumulative abnormal returns; and
- (ii) increased trading activity, manifested by positive abnormal trading volume.

H2: Post-event diminishing attention: FDA resolution of the NDA/BLA, either in the form of approval, or non-approval, snuffs out the period of investor attention to the stocks of the submitting firms, thereby, causes:

- (i) slow reversion towards the former prices in case of NDA/BLA approval; and
- (ii) rapid reversion to the former prices in case of NDA/BLA non-approval.

4. Literature overview

The inevitability of limited attention in relation to the vast amount of information available makes attention an important factor in agents' learning and decision-making processes. The literature analyzing the economic consequences of agents' attention is rapidly growing. Sims (2003) modeled agents' attention constraints to explain consumption and price stickiness. Hirshleifer and Teoh (2003, 2005) analyzed firms' accounting disclosure policy and the resulting price dynamics in the presence of inattentive investors. Gabaix, et al (2005) studied agents' directed attention in response to economic incentives.

Barber and Odean (2005) studied how salient events can capture investors' attention and affect their stock buying and selling decisions. Attention seems to be a crucial factor in investors' reaction to information. When investors pay less attention to a company's stock, they are more likely to fail to fully incorporate the information into the stock prices. Consequently, there might be a more pronounced post-announcement drift as this information later becomes reflected in the stock prices. Post-earnings announcement drift has been documented by a large number of empirical studies, e.g., Ball and Brown (1968) and Bernard and Thomas (1989). They found that buying stocks with recent good earnings news, while simultaneously shorting stocks with recent bad earnings news, can generate positive profits that are unrelated to risk. Attention is also a necessary condition for investors to overreact to any information. This may generate, for instance, positive autocorrelation of stock returns at short horizons (Jegadeesh and Titman, 1993; Moskowitz and Grinblatt 1999; Hirshleifer and Hong 2003) and the post-earnings announcement drift (Watts 1978, Bernard and Thomas 1989). 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 seminal milestones 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 et 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

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).

5. Data and Analysis

Our data consist of all 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 the first quarter of 2014. 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 133 events, of which 73 are of cases which were approved by the FDA (henceforth 'approvals'), and 60 not approved ('non-approvals'); the non-approvals consist of 53 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 the FDA 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 $t=-300, \dots, +50$, to calculate daily (logarithmic) returns. We employ two return benchmarks: the (i) Healthcare index, and (ii) S&P 500 index; and two calculation methods: 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 $t=-300, \dots, -60$ 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 68 approvals and 59 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 $t=-300, \dots, +50$, normalize each series' by subtracting the mean and dividing by the standard deviation calculated over $t=-300, \dots, -60$, and average across all events in each subsample for each day relative the NDA/BLA announcement dates.

Pre-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 $t=-250,\dots,+50$, 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 $t=-50,\dots,+50$, 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 16.68%, significant at the 1% significance level, possesses the two month from 50 days before the approval till the day after; on the day following the event, the average abnormal return is 4.33% (significant at 1%).⁵

In the case of the non-approvals (Table 2 and Figure 4) there is weak evidence of a positive CAAR of roughly 4% or more, depending on the specification of the abnormal return, taking place from two month till a fortnight before the event. 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, -19.80% (in the order of -20% across all specifications), takes place.

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.

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 (-9.73% in the Healthcare/Reg specification, and over -10% in the other specifications) . Interestingly, while more than a 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 decline surrounding the announcements takes place till 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.

6. Discussion

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.

In this sense, we reveal an intriguing phenomenon reflecting the investment patterns within the innovative pharmaceuticals industry. We document a robust 'bio run-up' pattern before FDA resolutions. An interesting related specific case was recorded by Huberman and Regev (2001). Importantly, we observe an intriguing phenomenon after the FDA resolutions, which to the best of our knowledge, is documented for the first time: all stock prices, regardless whether they belong to the approvals, or non-approvals, subsample, decline after the resolution, with only differences in decay intensity.

The documented 'bio run-up' may be a result of investors' selective attention and their tendency to overweight rare events. The role of probability weighting functions is that positively skewed security returns may be overpriced, and thus earn negative average excess returns (Barberis and Huang, 2008). The result, in a nutshell, is due to the sub-additivity of the probability weighting functions, causing overweighting of the tails of the distribution they are applied to.

Exploration of the effect of limited attention and overweighting of rare events in financial markets has several merits. First, in real markets, as compared to laboratory experiments, investors may learn from their own experience and from market dynamics, which may erase individual violations of rationality; second, investors' market decisions involve real money in substantial amounts, relatively to common laboratory explorations; lastly, we reveal fascinating market conduct in one of the most complex sectors within capital markets: the pharmaceutical sector.

Maybe even more intriguing than the 'bio run up' phenomenon is the 'bio run-down' pattern we reveal in this study. We portrait a short description of drug development process which indicates that FDA approval announcements are the 'holy grail' of drug development firms, scientifically and financially, especially for a small size innovative firm. The approval represents the end of R&D and the transition to sales with lower risk.⁶

⁶ In most cases, patents are granted for 20 years + 5 years extensions from initial R&D phases.

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, they commonly take place in the market. We, however, aimed at questioning whether limited attention has an impact on the processing of seminal events such as FDA resolutions.

We have found that the attention hypothesis, and the abovementioned features of prospect theory were corroborated by the data. Specifically, the attention-grabbing property of the FDA resolutions, along with investors’ tendency to overweight the small chances of huge gains by small R&D firms filing for NDAs/BLAs, may explain the stock price behavior around the FDA announcements.

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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	16.68%	3.57	15.76%	3.32	16.69%	3.46	16.94%	3.61
-40 to 1	42	16.29%	3.88	15.22%	3.57	16.10%	3.71	16.15%	3.83
-30 to 1	32	12.35%	3.37	11.51%	3.09	12.33%	3.26	12.44%	3.38
-10 to 1	12	8.02%	3.57	7.69%	3.38	7.32%	3.16	8.08%	3.58
-2	1	1.08%	1.66	1.14%	1.73	0.91%	1.36	1.03%	1.59
-1	1	0.83%	1.28	0.75%	1.14	1.02%	1.52	0.97%	1.49
0	1	1.25%	1.93	1.16%	1.76	1.17%	1.75	1.06%	1.62
1	1	4.33%	6.68	4.29%	6.53	3.73%	5.58	4.32%	6.64
2	1	-2.83%	-4.37	-2.77%	-4.21	-2.76%	-4.13	-2.67%	-4.11
3	1	-1.16%	-1.78	-1.17%	-1.78	-1.20%	-1.80	-1.15%	-1.77
2 to 10	9	-6.76%	-3.48	-6.71%	-3.40	-7.54%	-3.76	-6.71%	-3.44
2 to 20	19	-7.82%	-2.77	-7.87%	-2.75	-8.83%	-3.03	-7.95%	-2.80
2 to 30	29	-8.70%	-2.49	-9.19%	-2.59	-10.94%	-3.04	-9.82%	-2.80
2 to 40	39	-8.77%	-2.17	-9.33%	-2.27	-11.36%	-2.72	-9.96%	-2.45
2 to 50	49	-9.73%	-2.15	-10.56%	-2.29	-12.05%	-2.57	-10.24%	-2.25

2 to 10	9	-6.76%	-3.48	-6.71%	-3.40	-7.54%	-3.76	-6.71%	-3.44
11 to 20	10	-1.06%	-0.52	-1.16%	-0.56	-1.29%	-0.61	-1.24%	-0.60
21 to 30	10	-0.88%	-0.43	-1.32%	-0.63	-2.11%	-1.00	-1.87%	-0.91
31 to 40	10	-0.07%	-0.04	-0.14%	-0.07	-0.43%	-0.20	-0.15%	-0.07
41 to 50	10	-0.96%	-0.47	-1.23%	-0.59	-0.68%	-0.32	-0.28%	-0.14

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	3.82%	0.88	6.42%	1.44	6.56%	1.43	6.93%	1.55
-40 to -11	30	1.04%	0.28	3.56%	0.92	3.62%	0.91	3.68%	0.95
-30 to -11	20	-0.65%	-0.21	1.27%	0.40	0.13%	0.04	1.27%	0.40
-20 to -11	10	1.17%	0.54	1.77%	0.79	1.19%	0.52	1.75%	0.78
-10 to -1	10	-12.22%	-5.63	-11.72%	-5.27	-12.82%	-5.58	-11.50%	-5.14
-10 to -0	11	-15.20%	-6.68	-14.64%	-6.28	-16.14%	-6.70	-14.51%	-6.18
-10 to 1	12	-35.00%	-14.72	-34.84%	-14.30	-36.22%	-14.40	-35.23%	-14.37
-2	1	-2.37%	-3.45	-2.23%	-3.17	-2.23%	-3.08	-2.23%	-3.15
-1	1	-6.40%	-9.32	-6.15%	-8.74	-6.80%	-9.37	-6.09%	-8.60
0	1	-2.98%	-4.35	-2.92%	-4.15	-3.32%	-4.57	-3.02%	-4.26
1	1	-19.80%	-28.85	-20.20%	-28.72	-20.08%	-27.66	-20.72%	-29.28
2	1	-3.07%	-4.47	-2.88%	-4.09	-3.17%	-4.37	-2.83%	-4.00
3	1	-1.96%	-2.85	-1.89%	-2.68	-2.05%	-2.82	-1.93%	-2.73
4	1	-0.19%	-0.27	-0.22%	-0.31	-0.39%	-0.54	-0.34%	-0.48
1 to 3	3	-24.83%	-20.89	-24.96%	-20.50	-25.30%	-20.13	-25.48%	-20.78
4 to 10	7	-2.06%	-1.13	-1.70%	-0.91	-2.01%	-1.05	-2.21%	-1.18
11 to 20	10	-2.05%	-0.95	-2.13%	-0.96	-2.87%	-1.25	-2.37%	-1.06
21 to 30	10	-3.90%	-1.80	-3.77%	-1.70	-3.86%	-1.68	-3.60%	-1.61
31 to 40	10	0.89%	0.41	0.71%	0.32	0.63%	0.28	0.75%	0.34
41 to 50	10	2.91%	1.34	3.17%	1.43	2.88%	1.26	3.29%	1.47

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

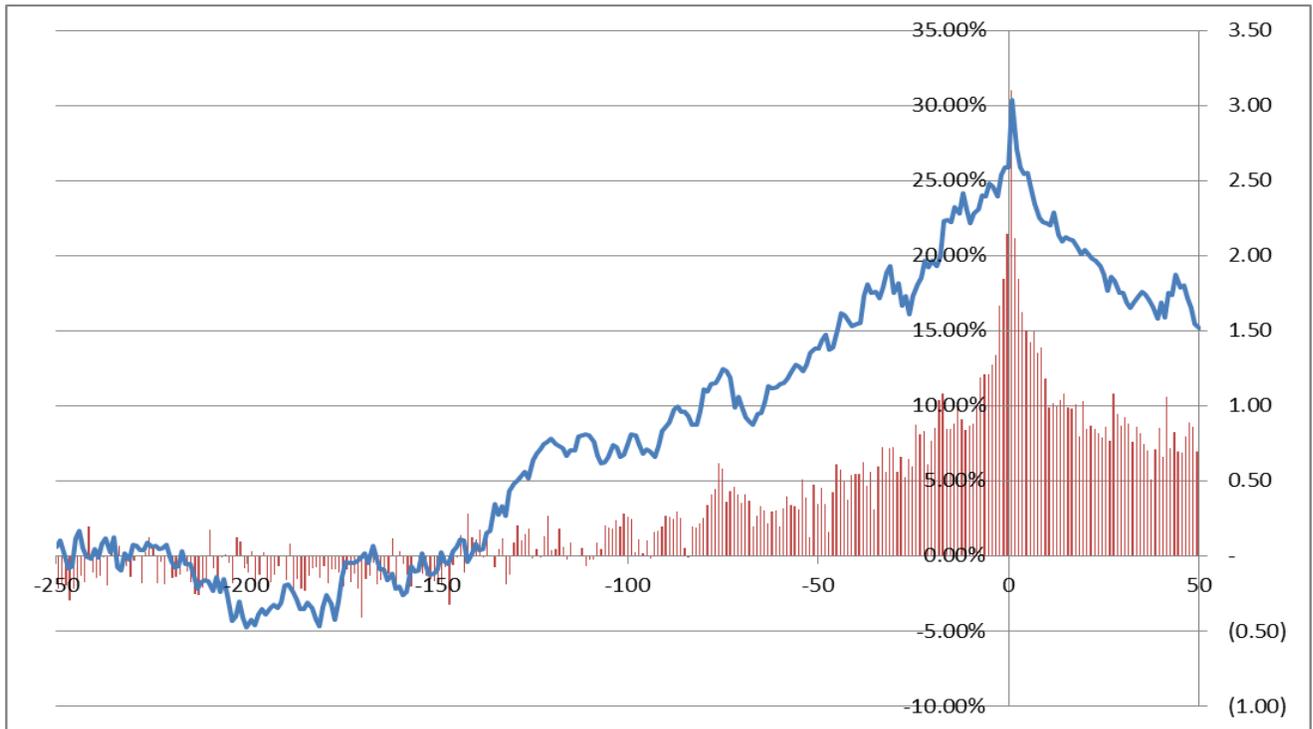


Figure 2: CAARs and abnormal daily volume statistics around NDA/BLA non-approvals, for $t=-250, \dots, +50$.

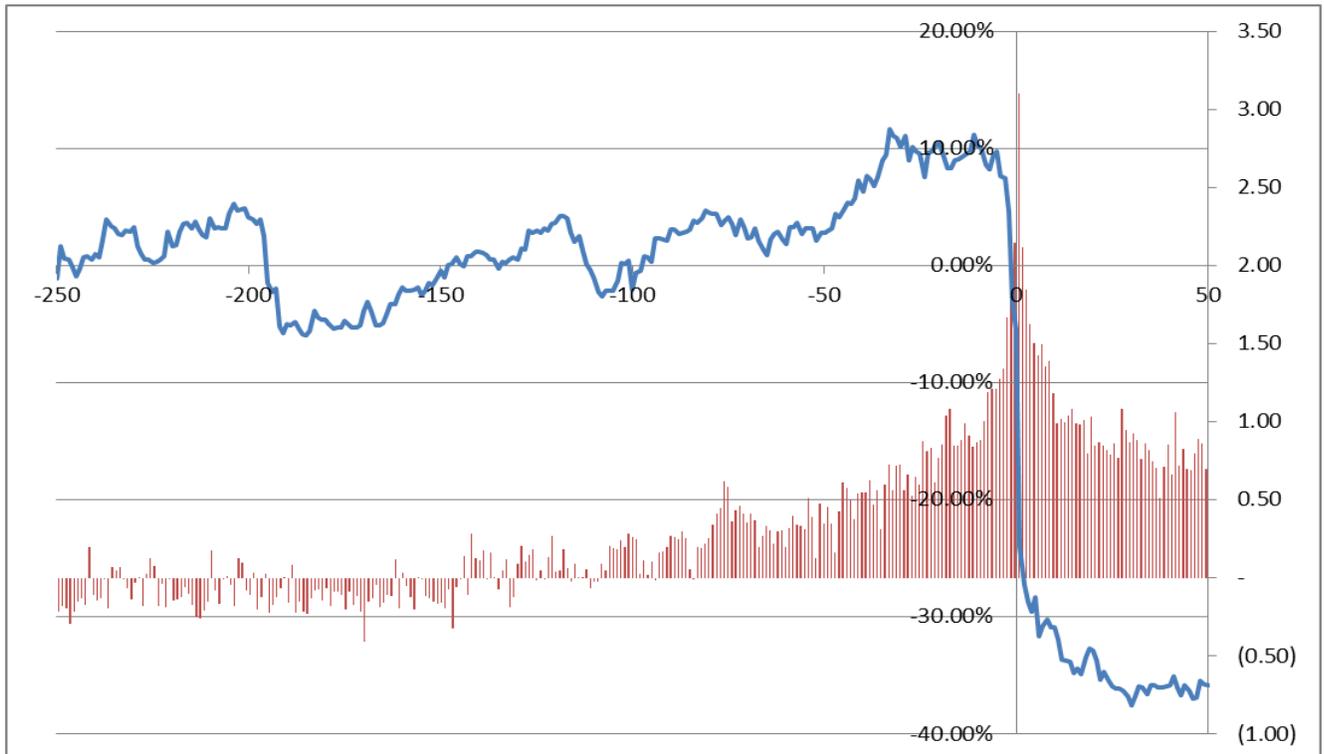


Figure 3: CAARs and abnormal daily volume statistics around NDA/BLA approvals, for $t=-50, \dots, +50$.

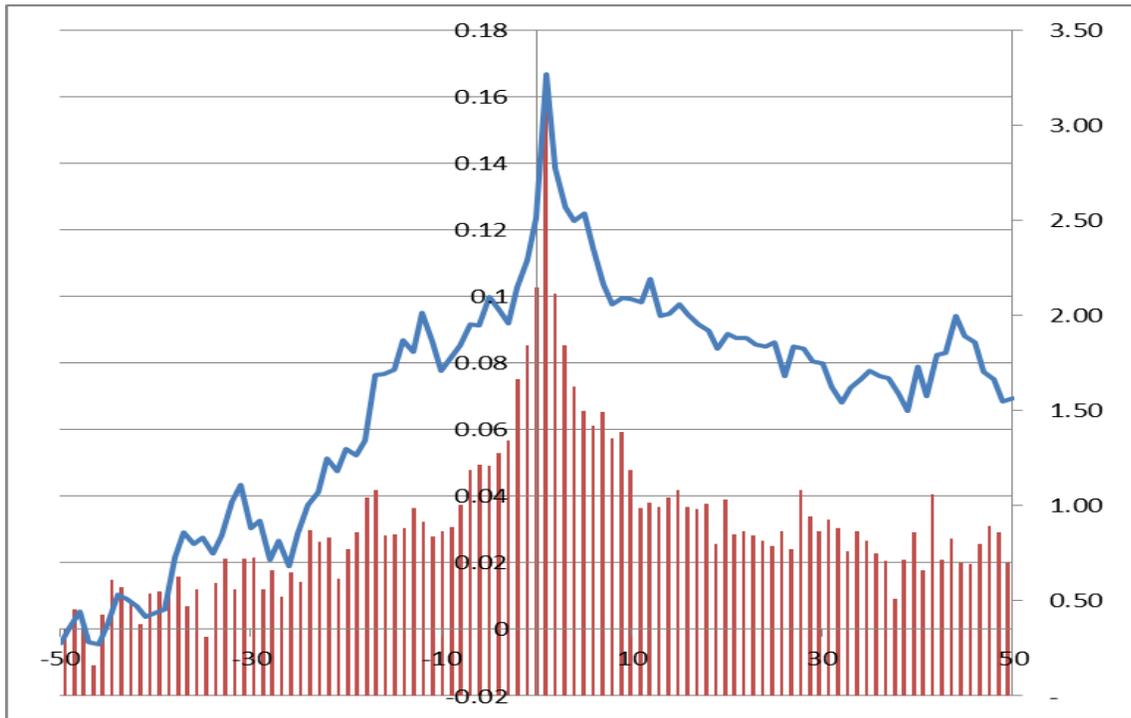


Figure 4: CAARs and abnormal daily volume statistics around NDA/BLA non-approvals, for $t=-50, \dots, +50$.

