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The Information Effect of FDA Approval Announcements on Pharmaceutical and Bio-Health Companies' Stock Prices

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-요약-

한국의 제약 및 바이오·헬스케어 기업들은 2000년대 초부터 FDA 승인을 신청하기 시작했다. 제약회사들은 국내 시장에서 제품을 판매하기 위해 의무적으로 FDA 승인을 받을 필요가 없으며, 승인 과정에 있어 많은 자원을 필요로 한다. 따라서 FDA 승인을 받기위한 투자는 합리적으로 보이지 않는다. 본 연구는 사건연구(event study) 방법론을 활용하여 유가증권 시장 및 코스닥 시장에 상장된 제약 및 바이오·헬스케어 기업들의 주가에 대한 FDA 승인 공시의 정보 효과를 분석하였다. 연구 분석 결과에 따르면, FDA 승인 공시에 대한 정보효과가 한국 주식 시장에서 작동하여 해당 기업의 주가를 유의하게 상승시키는 것으로 나타났다. 이는 미국 FDA 승인이 한국 제약 및 바이오·헬스케어 기업의 가치를 제고시키는 효과가 있다는 것을 시사한다. 또한, 중견 및 대기업보다는 중소기업에서, 코스피 시장보다는 코스닥 시장에서, 주가의 가격제한폭이 좁을 때 보다는 확대된 이후에 주가에 정보효과가 더 크게 반영되어 나타났다. 그리고 전통적인 제약산업보다는 바이오·헬스케어 산업인 경우, FDA 승인 공시에 주가는 더 민감하게 반응하는 것을 알 수 있다. 이상의 결과를 토대로 FDA 승인을 얻는 것이 기업의 주가에 긍정적 영향을 미친다는 것을 안 수 있었으며, 국내 기업들의 FDA 승인 신청이 고위험을 감수하며 높은 수익을 노리는 합리적인 투자에 해당함을 제시한다.

키워드 : FDA 승인 공시, 사건연구, 제약 및 바이오·헬스케어 기업, 정보효과

${\ensuremath{\mathbb I}}$. Introduction

Pharmaceutical and bio-healthcare companies have significant economic impacts and receive substantial

market attention. Between 2014 and 2018, the average annual growth rate of the global pharmaceutical and bio-healthcare market rose by over 5%, partly due to an increasingly aging population, especially in developed countries with strong drug development and high consumption (Korea Pharmaceutical and Bio-Pharma

^{*} 이 논문은 전남대학교 학술연구비 지원에 의하여 연구 되었음(과제번호: 2023-0491).

Manufacturers Association, 2019). Economies support the growth of pharmaceutical and related industries (Chen et al., 2021). For example, in the Declaration of Bio-Health National Strategic Vision 2019, the South Korean government singled out the pharmaceutical and medical precision machinery industries as the next "semiconductor industry" for Korea's future growth. Companies in these industries invest heavily in R&D to create competitive advantages and develop new safe drugs or effective medical devices ahead of their competitors (DiMasi et al., 2016). During the pandemic period, the share prices of biotech companies, especially so-called "COVID-19-themed stocks," were highly influenced by developmental news on COVID-19 vaccines. For example, Gilead Sciences, Inc. was a prime beneficiary of the trend, as its share rose by 2.6% when its experimental drug Remdesivir received the orphan drug designation from the FDA (Baccardax, 2020).

The European Medicines Agency (EMA) approves drugs to be marketed in the EU, while the US Food and Drug Administration (FDA) is the authoritative agency regulating drug safety in the US. Although the EMA and FDA oversee health concerns in different regions, the FDA seems to have more global impact. Furthermore, it receives and approves more drug review applications than the EMA. In the case of generic drugs, the EMA approved 15 applications in 2020 compared to 754 by the FDA (Ibrahim, 2022). Approval of a new drug or medical device undergoes heavy scrutiny to ensure safety, efficacy, and novelty. The FDA approves fewer than 50 new drugs per year. The R&D of a new drug could cost anywhere between USD 113 million to 6 billion (Rennane et al., 2022), and R&D spending as a share of revenue can exceed 25% on average (Congressional Budgetary Office, 2021). Receiving FDA approval can take an average of ten years of R&D investment, and this approval

is not guaranteed. Therefore, FDA product approvals reflect companies' capabilities and sustainability, which should be reflected either positively or negatively in company market evaluations (stock prices) (Bosch and Lee, 1994).

Korean companies' attempts to earn FDA approval with the expectation of increasing corporate value can have significant strategic consequences. Applying for an FDA review can involve substantial financial investment and resources for an extended period of approval processing time. News related to FDA approval or the prospect of approval process acceleration can strongly impact corporate value (DiMasi *et al.*, 2016; Hamill *et al.*, 2018). Therefore, the FDA approval process can be a gamble for smaller companies with limited resources.

Pharmaceutical and bio-healthcare industries in South Korea are notably experiencing steady growth (Korea Biomedicine Industry Association, 2018). While news regarding the FDA approvals of Korean companies can signal changes in company value, few studies have systematically analyzed the impact of FDA approval on the stock prices of local companies in South Korea. Assuming that markets are efficient (the efficient market hypothesis), this study aims to systematically verify Korean pharmaceutical and bio-healthcare companies' immediate stock price reactions to public FDA approval announcements (Sarkar and de Jong, 2006). The effect of a particular event, such as an FDA approval, on corporate value is assessed as the information effect of FDA approval announcements (Lo and Thakor, 2023). Event study methodology analyzes data to determine whether a stock price responds to an announcement abnormally (Budennyy et al., 2022; Hamil et al., 2018; Jeong and Lim, 2023).

The purpose of this study is to investigate the impact of FDA approvals on respective companies' stock prices in Korea. A new drug approval from the FDA can significantly impact a company's future strategic directions for two reasons (Cho, 2023). First, an FDA approval can positively adjust firms' stock prices due to increased financial expectations. FDA approval typically provides enough compensation for the considerable time and resources spent on obtaining the approval. Second, South Korean pharmaceutical and bio-healthcare industries strive to gain access to the global market; FDA approval is important for achieving this. A firm's FDA approval signals the company's R&D capabilities and financial sustainability, and our research shows the same applies to South Korean pharmaceutical and bio-healthcare companies. Therefore, this study provides strong academic evidence of the effects of FDA approval on corporate stock prices and assists South Korean pharmaceutical and bio-healthcare companies in establishing future strategic growth plans.

This study investigates (1) whether the information effect of FDA approval exists and varies significantly based on (2) company size (small vs. medium to large), (3) stock market (KOSDAQ vs. KOSPI), (4) stock price limit range (15% vs. 30%), and (5) industry (pharmaceutical vs. bio-healthcare). Existing studies utilizing event study methodology examined how firm characteristics, including firm size, membership to a specific stock exchange, and a firm's industry differentially caused stock prices to change when events occurred (Chaney et al., 1991; Chen et al., 2010; Masulis and Shivakumar 2002). Furthermore, the price limit level can influence the speed of a price adjustment following an event (Kyle, 1988). In general, small and medium-sized companies demonstrated more sensitivity to event announcements due to the asymmetricity of relevant information (Chen et al., 2010). Companies listed on the KOSDAQ, which is predominantly composed of small-sized companies, reacted more to announcements than those listed on the KOSPI

(Masulis and Shivakumar, 2002). Also, the relaxation of price limits, a governmental control of how much a stock price can change within a day, can make stock prices more reactive to an event (Kyle, 1988). Finally, companies in technology-intensive industries respond more significantly to events (Chaney *et al.*, 1991). Therefore, this study will evaluate whether the above company characteristics and governmental price limit regulations influence the volatility of the transnational information effects of FDA announcements.

The remainder of this paper is structured as follows. Section 2 presents the relevant literature, and Section 3 describes the propositions. The research methodology is discussed in Section 4, followed by an analysis of the results in Section 5. Finally, Section 6 concludes this paper.

$\ensuremath{\mathbbmm{I}}$. Literature Review

2.1 The Information Effect

Gaining FDA approval is recognized as a method for reducing future uncertainty and securing competitiveness (Sarkar and de Jong, 2006). An FDA approval announcement is considered a voluntary disclosure. These disclosures can have informational value by disseminating new information to the market, potentially influencing investment decisions (Dambra *et al.*, 2023). This informational effect is expected to influence the investment decisions of capital market participants. Previous studies have mainly analyzed the information effect of specific voluntary disclosures on stock prices (Ajinkya and Gift, 1984; Ball and Brown, 1968; Chan *et al.*, 1990; Lin *et al.*, 2020).

Ball and Brown (1968) verified the information effect of earnings disclosures on investors' decision-making, confirming a positive relationship between unexpected earnings and cumulative abnormal returns. Ajinkya and Gift (1984) discovered that management's disclosure of earnings outlooks caused stock market reactions. Predictions of positive earnings can result in correlated stock price reactions; however, negative earnings predictions bring adverse stock price reactions. In other words, voluntary disclosures of earnings predictions have an information effect.

Chan *et al.* (1990) regarded patent applications as an output of firms' R&D activities and analyzed the information effect of patent application announcements. Their empirical analysis showed a positive stock price reaction to R&D investment disclosure, indicating patent application disclosures' significant information effect on the stock market. Furthermore, Lin *et al.* (2020) examined stock price reactions to patent acquisition disclosures, representing a firm's unique technological capabilities. The patent acquisition news of KOSDAQ companies resulted in positive reactions, confirming a significant positive information effect.

When disclosures of firm-specific events, such as FDA approvals, cause significant stock price reactions, it can be interpreted as an information effect. Event study is a methodology used to analyze the impact of firm-specific events, such as dividends, rights issues, mergers, and earnings announcements, on stock prices (Gigante *et al.*, 2023; MacKinlay, 1997). A seminal research paper utilizing event study methodology is that of Fama *et al.* (1969), who analyzed the information effect of stock split announcements, providing evidence for the efficient market hypothesis. An information effect refers to the impact of a firm's disclosed information's reflection in stock prices; immediate stock price reactions to new information can be observed in an efficient market.

2.2 The Importance of FDA Approval

The US Food and Drug Administration (FDA) is

an agency within the US Department of Health and Human Services that regulates food, drugs, biological products, medical devices, electronic products emitting radiation, cosmetics, veterinary products, and tobacco products. Among the many regulated products, new human drugs, biological products, medical devices, human cells, tissues, and cellular and tissue-based products must gain FDA approval before they can be transported or distributed across state lines. The FDA only provides approval when a company proves its product is safe to use and manufacture and is effective for its intended purpose with minimal risks. Even with identified side effects, the FDA can approve the product if these side effects are minimal and the benefits outweigh the risks. As a US governmental agency, the FDA outlines 361 public health-related regulations and provides health information to the public.

Obtaining FDA approval is important for drug companies as it can signal their corporate value to the market and alleviate the adverse selection and moral hazard problems in markets with information asymmetry. Investors may face difficulties entrusting their funding to pharmaceutical and bio-healthcare companies due to a lack of guiding information. Investment in R&D comprised more than 25% of in 2018 2019 companies' revenues and (Congressional Budgetary Office, 2021). Furthermore, successful products take an average of ten years to maneuver the R&D period and FDA approval process and only a fraction of the medicines or devices applying for FDA approval actually receive it. Chacko et al. (2001) investigated the influence of FDA approval or rejection announcements and the uncertainty of drugs' future profitability (Brown and Warner, 1985). Their study predicted that the future value of a drug with FDA approval would be reflected positively in its company's stock.

Similarly, stock prices of all listed Korean companies showed a suddenly rising tendency upon their FDA approvals. For example, HLB's stock price plunged when it failed to obtain FDA approval, whereas Hironic's stock price sharply increased after approval (Ahn and Kim, 2018).

2.3 The Impact of FDA Approval on Corporate Market Value

Event methodology can be utilized when a stock return exhibits an information effect from an announcement. This effect occurs when the impact of information disclosure (an event) is immediately reflected on the market, demonstrating a positive (+) abnormal return (Bursztynsky and Kolodny, 2022; Lin *et al.*, 2023). Chan *et al.* (1997) viewed an event as a necessary tool for value creation. Thus, economic value is achieved when the average abnormal return is positive (+) immediately after an announcement.

Some notable events studied for their informational effects include the announcement of R&D cooperation through partnership agreements (Gigante et al., 2023; Masulis and Shivakumar, 2002) and the adoption of enterprise-wide information systems (Bang et al., 2001; Ji and Yu, 2022). For example, Bang et al. (2001) examined whether ERP adoption announcements influenced the corporate value of 33 companies. They found no significant information effect of ERP adoption information. Among the companies, early ERP adaptors (13 companies) demonstrated no informational effect following the announcements, but the followers (20 companies) experienced adverse effects on their stock prices. ERP adoption is resource-intensive, and multiple companies in South Korea have failed to adopt it. Therefore, the market has not been favorable towards ESG adoption news. Like ERP adoption, companies making long-term IT investments influencing their corporate future value can use event study methodology to view an investment's impact on this value (Bang *et al.*, 2001).

Most previous studies using event study methodology in the pharmaceutical and bio-healthcare industries viewed the impact of event occurrences on the stock prices of companies listed in the US or Europe. Several studies focused on the effect of multinational pharmaceutical companies' partnerships with other bio companies (Chan *et al.*, 1997; Gigante*et al.*, 2023; Reddy *et al.*, 2019). Researchers also investigated the impact of partnership agreements at different stages in the R&D process. Due to the lengthy R&D duration of the pharmaceutical and bio industries, the results of each clinical trial determine whether a new product can be released (Simoens and Huys, 2022; Yashiro *et al.*, 2022). FDA approval-related studies are shown in <Table 1>.

The announcements of the FDA's decisions regarding new products can have global impacts. For example, the FDA's decision (approval/rejection) profoundly affects the corporate value of Korean companies. The stock price of Celltrion, Inc. increased sharply after announcing that their drug received FDA approval (Kim and Lee, 2018). However, a negative announcement can adversely affect corporate value. For example, Helixmith Co., Ltd.'s stock plunged to its lowest level for two consecutive days when it was made known that its product failed a clinical trial, making it harder for them to obtain FDA approval (Lee, 2019).

All studies in Table 1 examined how FDA approval impacted corporate value domestically within the US; none of these studies systematically researched to find out how foreign companies' FDA approvals impact their markets transnationally.

송유정·이상근·박소라

Author(s) (year)	Research summary
	The impact of governmental regulations on corporate activities and the measurement
Bosch and Lee (1994)	of market responses to FDA approval/rejection in the drug industry
	The impact of new products' FDA approval success/failure and an analysis of corporate
Sharma and Lacey (2004)	performance
0.1	The categorization of the FDA approval process into different stages and the determination
Sarkar and de Jong (2006)	of factors influencing FDA approval impact and the final approval in each stage
\mathbf{D} -the metal \mathbf{n} at \mathbf{n} (2011)	Depending on the positive or negative nature of FDA announcements, the initial
Rothenstein et al. (2011)	announcements had different influence trends on stock prices
Dingel and Chay (2017)	Large mergers increase the new drug FDA approval rate per dollar of R&D spending
Ringel and Choy (2017)	by 1.83 times the average
Hamill et al. (2018).	The abnormal returns of companies listed on the NYSE after FDA approval announcements
Hammi <i>et al</i> . (2018).	and the impact on the after-market values of the companies
Gunn (2019)	Classification of media channels used for FDA approval announcements
Kliger et al. (2021)	Negative post-event returns are observed after FDA approvals; investors seek abnormal
Kiigei <i>ei ui</i> . (2021)	returns at the time of FDA announcements, not after the announcements
Wu et al. (2021)	Firms' significant options trading, especially smaller firms, under FDA evaluation before
wu ei ai. (2021)	evaluation meetings and report generation preparations for the meetings
	The effect of FDA approval on stock price cumulative abnormal returns in Taiwanese
Chen et al. (2021)	pharmaceutical and biotech companies was significant, particularly for the phase 3 stage.
Cheff e_i u_i . (2021)	However, there were no abnormal returns for FDA announcement events in the Taiwanese
	stock market.
Budennyy et al. (2022)	A prediction model of stock market reactions to clinical trial announcements is presented.
Budennyy er ur. (2022)	Negative announcements tend to have a stronger reaction.
Aparicio et al. (2024)	Finetuned large language models to find out what made inflection points in biotech
- Aparicio er ur. (2024)	stocks; an event-based strategy according to firm size is suggested

(Table 1) Research Related to FDA Approvals

III. Research Propositions

FDA approval influences stock prices. For instance, the stock price of Regeneron, a leading biotechnology company in the US, has risen about 29 times since its first new drug was approved by the FDA in 2008, reaching an all-time high in 2015. As another example, in April 2018, Philip Morris International Inc.'s stock price dropped by 15% when the FDA rejected its claim that the IQOS tobacco device reduces the risks and harmful effects of smoking. However, the stock price bounced back by .75% immediately after Philip Morris won FDA approval to sell the device.

According to a 2021 report by the Congressional Budgetary Office, obtaining FDA approval signifies the global marketability of domestic drugs or medical devices. Developing a new drug costs USD 1,065 million on average, and of that amount, USD 690 million is the sunk cost of the failed drugs factored within the cost of successful drug development. In addition, based on further research on new drug R&D costs, only 16 out of 100 drugs passed a phase III drug trial and obtained FDA approval (DiMasi *et al.*, 2016). Therefore, earning FDA approval can be considered the culmination of all the endeavors and resources invested and is an objective measure of the future fruitfulness of an investment.

Korean companies have begun to attempt to obtain FDA approval in addition to the Korean Ministry of Food and Drug Safety's approval. In 2003, LG Life Sciences' antibacterial drug Factive was the first Korean drug to receive FDA approval. This study investigates whether an FDA announcement affects corporate value in South Korea.

According to the efficient market theory, price adjustments follow FDA announcements, reflecting the newly gained information effect (Bosch and Lee, 1994). The Efficient market theory emphasizes the reliance on collective market valuations for corporate value when important assumptions about future states change due to an event (Brown and Warner, 1985). The FDA approval of a new product causes a significant wealth effect demonstrating the efficient market theory (Bosch and Lee, 1994; Sharma and Lacey, 2004; Torabzadeh et al., 1998). Bosch and Lee (1994) found that FDA approval of drugs, food, and other items resulted in significantly upwards stock market reactions. Sharma and Lacey (2004) determined that both the success and failure of new product approval by the FDA caused significant market reactions. Therefore, Proposition 1 is suggested as follows.

Proposition 1: FDA approval announcements positively (+) increase a company's stock price.

Small drug companies are active in drug development. Since 2009, a third of new drugs approved by the FDA were from small-sized companies. Roughly 20% of drugs in phase III trials were initiated by medium to large companies (IQVIA, 2019); the remainder were either from small companies or acquired by bigger companies before phase III. While small companies' participation in drug development is significant, investors do not have enough information to make funding decisions. The adverse effects of information asymmetry can have a differential impact based on the size of a company (Barry and Brown, 1984). Arbel *et al.* (1983) argued that less information is available from smaller companies because they receive less attention on the stock market. As small companies' stocks lack enough information to build certainty in valuation, the risks associated with these stocks tend to be compensated with higher returns, demonstrating the small firm effect. In stock markets, asymmetric information exists across companies and between internal and external stakeholders (Bohmann and Patel, 2022; Javid and Malik, 2016). This asymmetry adversely affects selection problems, causing potential investor losses (Hsiao and Wu, 2022; Petrov and Schantl, 2023). Furthermore, information asymmetry may cause investors to experience information constraints, negatively influencing stock market liquidity.

Several prior studies report greater stock price reactions for smaller companies upon announcing an event (Chen et al., 2010; Kliger et al., 2021; Rasoulian et al., 2023; Torabzadeh et al., 1998; Wu et al., 2021). Smaller companies are more innovative and strategically aggressive, leading to stronger firm performance than larger firms (Weinzimmer et al., 2023). Due to the firm size effect, the impact of information is stronger for smaller companies because less information is available; thus, they experience higher information asymmetry in the market (McWilliams and Siegel, 1997; Tripathi and Mukhopadhyay, 2020). Furthermore, smaller firms have fewer products in the pipeline, and their corporate value is more concentrated on these products (Torabzadeh et al., 1998). Therefore, stock price reactions to FDA approval announcements are expected to be more significant for smaller companies. Hence, we present the following proposition.

Proposition 2: Smaller companies' stock prices experience a sharper increase due to FDA approval announcements than medium or large-sized companies.

To illustrate the characteristics of stock markets in South Korea using an analogy, the Korean Composite Stock Price Index (KOSPI) and the Korea Securities Dealers Automated Quotation (KOSDAQ) can be compared with the New York Stock Exchange (NYSE) and the National Association of Securities Dealers Automated Quotations (NASDAQ).respectively KOSPI stocks are typically from large companies, whereas the KOSDAQ lists small and medium-sized companies and ventures with high growth potential and technical skills. KOSDAQ and NASDAQ stocks are considered highly similar because the companies listed on the two markets are mostly advanced technology venture companies with high growth potential. Therefore, KOSDAQ stocks tend to show more growth potential and KOSPI more stability.

Masulis and Shivakumar (2002) compared the immediacy of stock price responses to new information between NYSE, AMEX, and NASDAQ stocks. The results showed that stock price reactions are comparatively faster for NASDAQ stocks, suggesting that these stocks can handle news more efficiently. Ivanov et al. (2014) also observed the influence of market structure, noting that the transaction time of stocks slowed when companies moved from the NASDAQ to the NYSE. Correspondingly, companies listed on the KOSDAQ may handle new information more efficiently than those on the KOSPI. Furthermore, KOSDAO-listed pharmaceutical and bio-healthcare companies demonstrate many characteristics of smaller companies, as discussed in Proposition 2. Therefore, this study suggests that stock prices react to FDA approval announcements more sensitively when listed on the KOSDAO rather than the KOSPI. Thus, we propose the following.

Proposition 3: KOSDAQ stock prices react more sensitively to FDA approval announcements than KOSPI stock prices.

A price limit system strictly enforces the price range within which a stock can fluctuate in a single trading day. Currently, several Asian countries, including South Korea, China, Taiwan, and Japan, and some European countries, have implemented this system. These limits have the advantage of reducing investment risk by enforcing a cooling-off period for overreacting investors, making it easier for erratic stock prices to return to equilibrium and reducing stock price volatility (Ma et al., 1989; Zhang et al., 2023). However, price limits could slow the establishment of new equilibrium prices by decreasing the speed of new information being reflected on the stock market. Additionally, a price limit system could reduce supply, hindering not only the liquidity of the stock market but also market efficiency (Fama, 1987).

South Korea's price limit range was relaxed from 15% to 30% on June 14, 2015, to maintain market stability and enhance future sustainability. In the domestic market, the relaxation of the price limit range increases market efficiency – faster reflections of corporate value give rise to investors' market participation (Lee and Hyung, 2022).

Investors can react more quickly to new information in a market with a relaxed price limit (Kyle, 1988). For example, investors reacted more sensitively to information when observing the market after the regulation correction in 2015, resulting in larger price responses. Thus, short-term stock price reactions to favorable information, such as FDA approval, became greater. Additionally, price limits can cause a magnet effect, accelerating prices toward their limits (Zhang *et al.*, 2023). A price range of +/- 30% should magnet the accelerating stock prices closer to the 30% range than the 15% price limits. Therefore, this study presents the following proposition.

Proposition 4: Stock price reactions to FDA approval announcements became greater after the relaxation of the price limit in 2015.

Industry is an important factor in determining the reaction level to an announcement. The bio-healthcare industry has been gaining more momentum in obtaining research funds. According to a report published by the US Congressional Budgetary Office (2021), all research projects funded by the National Institute of Health between 2010 and 2016 involved an aspect of biotechnology (Galkina Cleary et al., 2018). The medical biotechnology industry is developing new therapy methods using cells or microorganisms through molecular engineering techniques, making the industry more technology-dependent (Khan, 2020). The industry has promised to correct congenital diseases; however, completing this project requires a considerable investment. Similarly, Moderna, who produced the first mRNA-based vaccine approved to protect against COVID-19, engaged in over ten years of mRNA delivery platform developmental efforts and invested over two million dollars in gaining approval for the vaccine to be marketed in 2020 (Clifford, 2021).

Several characteristics of the bio-healthcare industry make it both attractive and risky for investment. First, the bio-healthcare industry is primarily comprised of small and medium-sized venture companies, which can respond flexibly and quickly to environmental changes. Small companies' stocks react to an event more sensitively than large companies (Chen *et al.*, 2010; Kliger *et al.*, 2021; Rasoulian *et al.*, 2023; Wu *et al.*, 2021). In the case of South Korea, there are four subindustry classifications underneath the pharmaceutical industry. Among them, medical chemical com-

pound & antibiotics (MCCA) manufacturing and biological substance (BS) manufacturing are considered part of the biotechnology industry. The traditional pharmaceutical industry comprises drug product (DP) manufacturing and Chinese medicine (CM) manufacturing. In 2019, among MCCA companies, 52.1 % were small venture capital companies, and 33.3% were small and medium-sized companies. For BS, 71.1% were venture capital companies. For BS, 71.1% were venture capital companies. Only 32.5% of DP and 40.6% of CM companies were venture capital companies (Shin *et al.*, 2021). These numbers show a higher percentage of smaller and venture capital companies belong to the biotechnology industry.

The companies within these industries are technology- and knowledge-intensive. Furthermore, the bio-healthcare industry is technology-dependent and carries out high-risk and high-yield projects (Shkolnykova and Kudic, 2022; Yashiro *et al.*, 2023). The 2020 Korean drug industry analysis report shows that the biotechnology industry spent a higher percentage of its revenue on R&D. In 2019, BS spent 15.3% of its revenue on R&D, followed by MCCA at 9.5%, DP at 6.5%, and CP at 3.0%. Therefore, bio-healthcare companies invest more in R&D and depend more on drug development projects' uncertain success than the traditional pharmaceutical industry, suggesting that bio-healthcare companies in Korea are characterized by more information asymmetry.

Finally, industries with varying characteristics can cause investors to react to an event differently. For example, industries demonstrated varying adverse reactions to security breach announcements (Tweneboah-Kodua *et al.*, 2018). Chaney *et al.* (1991) compared different industries' market reactions to new product launch announcements and concluded that the more technology-oriented an industry is, the stronger the reaction to the announcement. Therefore, as the bio-healthcare industry is more technologically oriented, it has stronger market responses

In short, the traditional pharmaceutical industry differs from the bio-healthcare industry in inducing different stock market behaviors. The bio-healthcare industry comprises more small and medium-sized companies than the traditional pharmaceutical industry. Furthermore, the bio-healthcare industry invests more revenue into R&D, increasing its risk and success potential more than the pharmaceutical industry. Thus, the stock prices of bio-healthcare companies should react more strongly to FDA approval announcements than those of the pharmaceutical industry; therefore, we make the following proposition.

Proposition 5: The stock price reaction to FDA approval announcements in the biotechnology and healthcare industry is more significant than in the traditional pharmaceutical industry.

\mathbb{N} . Methods

4.1 Event Study Methodology

Event study methodology is often used to identify the existence of an information effect (Fama *et al.*, 1969). In an efficient market, investors in the capital market make timely use of all available information to determine corporate value. Thus, a company's stock price reflects new information about its business activities (Chen *et al.*, 2021). Event study effectively identifies changes in corporate value resulting from business activities by observing stock price reactions (Jeong and Lim, 2023). In other words, it provides researchers with a useful tool for learning about the relationship between a company's business activities and its value creation (Mc Namara and Baden-Fuller, 2007). This study adopted event study methodology for the data analysis. This methodology estimates an event's impact on corporate value, namely, its information effect, by measuring the company's stock price changes (price-earnings ratio) in the short period immediately following an event (the event period) (Ding *et al.*, 2018). However, the fluctuation range in the stock price over a period could be partly based on a company's internal risk. Accordingly, it is necessary to single out the abnormal return (the price change over the event period due to the information effect) by subtracting it from the price-earnings ratio (Mc Namara and Baden-Fuller, 2007).

Therefore, this study estimates the abnormal return over a short period (the event period) immediately after an FDA approval announcement (the event) and verifies the statistical significance of the estimated abnormal return (Brown and Warner, 1985). The normal return (the expected price-earnings ratio in the absence of FDA approval announcements) is required to calculate an abnormal return and is computed using the following market model regression formula.

$$R_{it}^* = \alpha_i + \beta_i R_{mt} + \epsilon_{it} \tag{1}$$

 R_{it}^* represents the price earnings rate of company i on day t, and R_{int} represents the market return on day t. The KOSPI or KOSDAQ index from the same period is used to identify the market return. α_i refers to the estimated regression constant, and β_i is the regression coefficient of company i for the estimation period before the occurrence of each event. ϵ_{it} refers to the error term of company i on day t. Regression formula (1) is used to calculate the company's price-earnings ratio from 60 days (-60) to one day (-1) prior to the day the FDA approval information was first released to the press (the event period).

 $\hat{\alpha}_i$ and $\hat{\beta}_i$ are used to calculate the normal return on day t, a day within the event period. Then, the abnormal return on that day can be calculated by subtracting the normal return from the price-earnings ratio. The event window demonstrates an event's total impact on the stock price (market value) over a particular period. The event window varies by situation: it can be set to begin (i) the day of the event (0); (ii) one day (-1) prior to the event, and run until one day (+1) after the beginning of the event; (iii) five days (-5) prior to the event, and run until five days (+5) after the beginning of the event; or (iv) ten days (-10) prior to the event, and run until ten days (+10) after the beginning of the event. However, in the stock market, where various events occur daily, increasing the estimation window may make it more difficult to isolate a particular event's impact on the price-earnings ratio from other external interferences (Lee et al., 2014; Mc Namara and Baden-Fuller, 2007). For this study, the event period (estimation window) is limited to the day of the event to best identify the impact of the FDA approval announcements under examination. The abnormal return on the event period, day t, is computed with the following Formula (2).

$$AR_{it} = R_{it} - (\hat{\alpha}_l + \hat{\beta}_l R_{mt}) \tag{2}$$

Formula 3 predicts the average abnormal returns during the event window by dividing the abnormal return of a single company (the result of Formula 2) by the number of sample companies (N) on day $t. AAR_{it}$ represents the average abnormal return on day t, i.e., the average abnormal return on the day of the event.

$$AAR_{it} = \frac{1}{N} \sum_{i=1}^{N} AR_{it}$$
(3)

To test the significance of abnormal returns on each trading day, we conducted a t-test and presented the test statistic as follows:

$$t = \frac{AR}{\sqrt{\frac{1}{60} \sum_{t=-60}^{-1} (R_{it} - R_{it}^{*})^{2}}}$$
(4)
$$t - value = \frac{1}{N} \sum_{i=1}^{N} t$$
(5)

In addition, as shown in Formula 6, a two-sample t-test was performed to examine the average abnormal return between different groups to verify Propositions 2 to 5. t_s is the t distribution with the degree of freedom (n_1+n_2-2) , and n_1 and n_2 refer to the sample size of groups 1 and 2, respectively. $S_{\overline{x_1}-\overline{x_2}}$ represents the standard deviation of the test statistic, whereas $(S_n)^2$ denotes the distribution of the entire sample (n_1+n_2) .

$$t_{s} = \frac{\overline{x}_{1} - \overline{x}_{2}}{S_{\overline{x}_{1} - \overline{x}_{2}}} = \frac{\overline{x}_{1} - \overline{x}_{2}}{\sqrt{\frac{(S_{1})^{2}}{n_{1}} + \frac{(S_{2})^{2}}{n_{2}}}}$$
(6)

4.2 Data Collection

1

This study compiled companies listed on the KOSPI and KOSDAQ of the Korea Exchange (KRX) that received FDA approval announcements from 2003 to 2022. The summarized event study procedure is shown in <Figure 1> below.

In the initial data collection stage, this study used a big news data server called Bigkinds (https://www. bigkinds.or.kr/) provided by the Korea Press Foundation (KPF). All announcements containing the keyword "FDA approval" in their titles were selected as candidates.

For the second stage, the timing of the FDA announcement was double-checked. Using the list of

Stage 1	Stage 2	Stage 3	Stage 4
Identifying events Search for "FDA approval" based on the news big data system provided by Korea Press Foundation	Set the event period Set the initial disclosure of "FDA approval" the event date.	Use the event study methodology to compute t-value > Statistically test for significance by estimating the average abnormal return of the firm in the event period minus the normal return. > Proposition 1	Conduct t-test on the independent sample Compare AAR between two groups Proposition 2-5

(Figure 1) Data Collection Process

candidate announcements from the first stage, we searched media content (newspapers, etc.) to determine the precise timing of the FDA approvals. When multiple announcements were made for a single event, the date of the earliest report was chosen as the announcement date. This step is carried out to control for the impact of exploitation by informed market participation when an unexpected information disclosure is made prior to the official FDA announcement. This process is in place to ensure the reliability and validity of the research results by identifying the maximum impact of a particular event on the company's market value.

We set the day of the FDA approval announcement (t = 0) as the event period. Furthermore, we set 60 days as the estimation period, covering 60 days (t

= - 60) prior to the announcement until one day (t
= - 1) before the announcement to statistically verify the impact of the event (Kwon and Han, 2017; Mathur *et al.*, 1997).

In the third stage, event study methodology was used to calculate the stocks' average annual returns (AAR) related to the FDA announcements. The calculated AAR tests the significance of the event's impact (Proposition 1).

The final step, stage 4, was conducted to test Propositions 2 through 5 by subdividing the entire sample into meaningful sample groups representing the required characteristics. <Table 2> summarizes the propositions, sample characteristics, and sample size to test the appropriate proposition. The current

Proposition	Sample characteristics	Sample size	Percentage (%)
P1: FDA announcement impact	Total sample	91	100
D2. EDA approximant impact by firm size	Medium to large	36	42
P2: FDA announcement impact by firm size	Small	55	58
P3: FDA announcement impact by Korean stock	KOSPI	29	32
market index	KOSDAQ	62	68
D4. EDA approximation for an interval	15% (before June 14, 2015)	36	40
P4: FDA announcement impact by price limit level	30% (after June 15, 2015)	55	60
P5: FDA announcement impact by industry	Pharmaceutical industry	38	42
classification	Bio-healthcare industry	53	58

(Table 2) Sample Size by Proposition

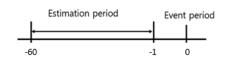
research categorized company size according to Act 2 of the South Korean Framework Act on Small and Medium Enterprises. Companies are classified as small-sized when their annual revenue is less than KRW 12 billion (about USD 9.2 million) with ten or fewer full-time employees. The total number of sample events is 91, which is comparable to similar studies utilizing event study methodology (Bosch and Lee, 1994; Kwon and Lee, 2017; Rothensten et al., 2011). For example, Rothensten et al. (2011) used 59 FDA clinical trial approval results for an event study analysis. Also, noticeable differences in paired sample sizes (e.g., 29 KOSPI companies vs. 62 KOSDAQ companies) are accepted in analyzing and comparing events' impacts (Bosch and Lee, 1994; Kwon and Lee, 2017).

4.3 Event Study Setting

The day of an FDA approval announcement (t =0) is set as the event period for measuring the impact of an announcement (t = 0). The impact of a particular event on a company's market value should be at its maximum on the date the event is announced. A total of 60 days, covering 60 days (t = -60) prior to the announcement until one day (t = -1) before the announcement, is chosen as the estimation period to verify the statistical significance of an event's impact (Mathur et al., 1997; Kwon and Han, 2016). This estimation period covers the time prior to the occurrence of an event affecting a stock price. It is important to set a reasonable estimation period as normal returns are calculated using a company's stock price data, and insufficient data may lead to an inaccurate estimation. The event period is when a specific event is considered to impact stock prices. If the event period is too short, it will be difficult to discern the persistence of the information effect. Conversely, if the event period is

too long, the true information effect of the disclosure cannot be fully verified due to the confounding effects of stock price fluctuations caused by other events or exogenous factors.

Therefore, this study sets a 60-day estimation period as a conventional duration of an estimation period as used in similar event studies. Figure 2 illustrates the model's event period and estimation period.



(Figure 2) Event Period and Estimation Period

V. Results

5.1 Results of Testing the Impact of FDA Announcements.

<Table 3> presents the average abnormal returns of 91 FDA approval announcement events and the statistical significance of the impact of the FDA approval announcements using a t-test. The results show that the average abnormal return of the entire sample was 0.179% (t (91) = 2.114, p<.05) on the day of the event. That is, the stock price of the companies included in the study sample increased by 0.179%, on average, on the day of an FDA approval announcement. This increment is abnormal and statistically significant.

(Table 3) Average Abnormal Return Due to FDA Approval Announcements.

Sample size (n = 91)	AAR	t-value
	0.179%	$t = 2.114^{**}$ p = 0.000

Notes: *p<0.1, **p<0.05, ***p<0.01.

5.2 Results of Testing the Impact of FDA Announcements by Firm Size

This study classified companies listed on the Korea Exchange (KRX) into two groups, small-sized companies, and large and medium-sized companies, and compared the impact of FDA approval announcements between the groups. The companies in this study were divided into these groups according to Act 2 of the South Korean Framework Act on Small and Medium Enterprises.

<Table 4> presents the impact of FDA approval announcements on each group. The average abnormal return after FDA approval announcements was 0.281% for small-sized companies (t (55) = 2.239, p < .01) and 0.023% (t (36) = 1.729, p < 0.1) for medium and large-size companies. The result of the two-sample t-test indicates that the difference in average abnormal returns between the two groups was statistically significant (t (91) = 4.821, p = 0.000).

5.3 Results of Testing the Impact of FDA Announcements by Korean Stock Market Index

This study investigated the impact of FDA approval announcements on KOSDAQ- and KOSPI-listed companies separately. As shown in <Table 5>, immediately after FDA approval announcements, the average abnormal return of companies listed on the KOSDAQ was 0.251% (t (62) = 4.537, p<.01). In contrast, the return of companies listed on the KOSPI was 0.025% (t (29) = 1.798, p<.10). The two-sample t-test result shows the difference in average abnormal returns was statistically significant (t (91) = 3.769, p = 0.000). Therefore, Proposition 3 is supported, as the results show that KOSDAQ-listed stocks brought more abnormal returns than KOSPI-listed stocks.

5.4 Results of the Impact of FDA Announcements by Level of Price Range Restrictions

On June 15, 2015, stock price limits in the South

(Table 4) Average Abnormal Returns Due to FDA Approval Announcement Based on the Firm Size

	Sample	AAR	t-value	Two-sample t-test
	Large and medium $(n = 36)$	0.023%	1.729*	$t = -4.821^{***}$
By firm size	Small $(n = 55)$	0.281%	4.931***	p = 0.000

Notes: **p*<0.1, ***p*<0.05, ****p*<0.01.

(Table 5) Average Abnormal Returns Due to FDA Approval Announcement Based on the Stock Price Index

	Sample	AAR	t-value	Two-sample t-test
By stock price	KOSPI (n = 29)	0.025%	1.798^{*}	$t = -3.769^{***}$
index	KOSDAQ (n = 62)	0.251%	4.537***	p = 0.000

Notes: p < 0.1, p < 0.05, p < 0.01.

Limi	•			
S	ample	AAR	t-value	Two-sample t-test
By price range	15% (n = 36)	0.172%	2.847***	t = -1.846*

0.184%

(Table 6) Average	Abnormal	Returns	Due to	FDA	Approval	Announcement	Based	on Price
Limits								

	*	**	***
Notes	n < 0.1	n < 0.05	<i>p</i> <0.01.
rous.	p .0.1,	$p \sim 0.05$,	$p \sim 0.01$

restriction

30% (n = 55)

	Sample	AAR	t-value	Two-sample t-test
By industry	Pharmaceutical industry (n = 38)	0.031%	1.950*	$t = -4.390^{***},$
classification	Bio-healthcare industry (n = 53)	0.285%	4.894***	p = 0.000

Notes: **p*<0.1, ***p*<0.05, ****p*<0.01.

Korean stock market were relaxed from 15% to 30%. This study divided the sample into two groups based on the FDA approval announcement date. As presented in Table 6, the average abnormal return due to FDA approval announcements when the price limit was 15% was 0.172% (t (36) = 2.847 p<.01). In comparison, the average abnormal return due to FDA approval announcements at price limits of 30% was 0.184% (t (55) = 4.199, p < .01). The two-sample t-test results show that the difference in average abnormal returns was statistically significant at the 10% level (t (91) = -1.846, p<.10). Consequently, Proposition 4, stating that "the stock price reaction to FDA approval announcements became greater after the expansion of the price limits in 2015" is supported.

5.5 Results of Testing the Impact of FDA Announcements by Industry Classification

This study compared the impact of FDA approval announcements between industries by dividing the sample into two groups based on industry: the traditional pharmaceutical industry and the bio-healthcare industry. The average abnormal returns due to the FDA approval announcements of companies in the bio-healthcare industry and the traditional pharmaceutical industry were 0.285% and 0.031%, respectively, and the corresponding t-values were 4.894 and 1.950. Both were statistically significant at the .01 level and .10 level, respectively, as shown in <Table 7>. The two-sample t-test results indicate that the difference in average abnormal returns between companies in the two industries was statistically significant (t (91) = 4.390, p = 0.000). Therefore, Proposition 5, which states that "stock price reactions to FDA approval announcements in the bio-healthcare industry are greater than the traditional pharmaceutical industry," is supported.

4.199***

p = 0.068

VI. Discussion

6.1 Summary and Implications

This study examined the impact of FDA approval on the corporate value of pharmaceutical and bio-healthcare companies listed on South Korean stock exchanges by measuring the abnormal return of a stock

price on the day of an FDA approval announcement using event study methodology.

The results reveal that the abnormal return of a company's stock price significantly increased (+) on the FDA approval announcement day, denoting that FDA approval increases corporate value. Therefore, Proposition 1 is supported. Although the FDA is a US agency, its approval announcements signal the potentially unacknowledged value of Korean pharmaceutical and bio-health companies.

Propositions 2, 3, and 5 proved to be statistically significant. The impact of FDA approval announcements on stock price is greater on small companies than on medium and large companies, on KOSDAQ stocks than on KOSPI stocks, and on stocks belonging to the bio-health industry than in the traditional pharmaceutical industry. For Proposition 2, the results that the abnormal returns of small-sized companies were, on average, 0.258% higher than medium and large companies suggest the tendency for smaller companies to have a greater market reaction to FDA approval announcements. The ripple effect of information seems stronger for smaller companies, causing them to react more sensitively to an event, resulting in effecting returns. Similarly, the analysis of the results shows that the average abnormal returns of KOSDAQ-listed companies were 0.226% higher than that of KOSPI-listed companies. Therefore, Proposition 3 is proven with statistical significance. KOSDAQ-listed stocks seem to be affected by price-related information relatively quickly and are more sensitive to FDA approval announcements In terms of Proposition 5, both pharmaceutical and bio-health companies were demonstrated to react to FDA announcements with abnormal returns. However, the FDA approval announcements of companies in the bio-healthcare industry have a greater impact than in the traditional pharmaceutical industry because the bio-healthcare industry is dominated by technology-oriented venture companies that engage in high-risk and high-return projects.

Furthermore, after the stock price limits in the South Korean stock market expanded from 15% to 30% in

No.	Summary	Analysis results			Two-sample t-test
INO.		Grouping by	AAR(%)	t-value	p
P1	FDA approval announcements \rightarrow Increase in stock price	Entire sample(n=91)	0.179	3.664***	<i>p</i> = 0.000
P2	Small companies > Strong medium-sized and large	Medium and large(n=36)	0.023	1.729*	<i>p</i> =0.000.
	companies	Small(n=55)	0.281	4.931***	
Р3	KOSDAQ > KOSPI	KOSPI(n=29)	0.025	1.798	<i>p</i> =0.000
		KOSDAQ(n=62)	0.251	4.537***	
P4	After the change in price limits	15%(n=36)	0.172	2.847***	<i>p</i> =0.068
P4	> Before the change	30%(n=55)	0.184	4.199***	
P5	Bio-healthcare industry > Pharmaceutical industry	Pharmaceutical Industry(n=38)	0.031	1.950 [*]	m =0.000
		Bio·Healthcare Industry(n=53)	0.285	4.894***	<i>p</i> =0.000

(Table	8>	Analysis	Results
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Notes: **p*<0.1, ***p*<0.05, ****p*<0.01.

2015, the impact of FDA approval on corporate value increased (Proposition 4), possibly due to the magnet effect of price limits. As this effect exists in the South Korean stock market, the short-term stock price reactions to favorable information like FDA approval announcements became greater after the expansion of price limits in 2015. While the difference is small, the results demonstrate that price limit regulation in the stock markets can prohibit the short-term realization of potential stock value.

6.2 Limitations and Directions for Future Studies

This study has several limitations. First, it only targeted the pharmaceutical and bio-healthcare industries. However, companies in other industries, such as food and manufacturing, can also obtain FDA approval. Thereby, future studies should be expanded to non-pharmaceutical industries to test the international influence of FDA approval in countries outside the US, including South Korea.

Second, the study's results can be more generalizable by comparing data from other countries. This study obtained data on 91 companies listed on the KOSPI or KOSDAQ. Compared to countries such as the US and Japan, the South Korean pharmaceutical and bio-health industries are young, with fewer companies and FDA approvals. While the current sample size enabled group comparisons for the proposed propositions, more robust analysis results could be produced, given better statistical power. Thus, conducting a comparative study of countries with similar backgrounds could support the propositions better. In future studies, the event study methodology procedure employed in this study can be referenced to measure the increased value of non-US companies due to their long-term sustainable R&D and FDA approvals.

Thirdly, this research is limited as the only way to measure the changed value of drug companies is by observing stock prices at the time of an FDA approval announcement. Nonetheless, this study is contributive because it is the first to reveal whether FDA approval announcements affect the values of internationally located companies in the pharmaceutical and bio-healthcare industries using event study methodology. The methodology used in this study to verify the effectiveness of FDA approval announcements in Korean stock markets can be used in other studies on related topics.

Finally, this study analyzed how a specific event (FDA approval) influenced stock prices using event study methodology. The results of the analysis showed a significant relationship between FDA approval announcements and stock price changes. However, the interpretation and use of the study results must be made discretionally as it did not examine all factors influencing the market. Additional factors could influence stock prices along with events, such as R&D investment size, the general stock market environment, firms' financial stability and growth potential, and the competition's FDA approval status. Thus, future studies can investigate the influence of factors not included in the current study to provide a more realistic picture of the effects of transnational information.

This research has both academic and practical implications. Academically, the transnational impact of FDA approval has been proven using the event methodology. This study is the first known attempt to reveal the relationship between FDA approval announcements for Korean companies' medical products and their stock prices on two Korean stock markets. Furthermore, our research investigated FDA approvals concerning various company characteristics and governmental restrictions (price limits) within a new drug development context, providing a potential framework for analyzing industry-specific information effects using event study methodology.

This study has several practical implications. First, the results show that companies can benefit from international certifications or approvals due to information effects across national boundaries. Until now, it has generally been considered that most of the corporate value created by FDA approval is reflected in the stock market before the actual announcement. However, as with the case discussed in Aparicio *et al.* (2024), abnormal stock responses can still occur following FDA announcements. Furthermore, the informational effect is realized transnationally in South Korea.

Secondly, the study demonstrates that smaller companies with less market visibility have a better chance of gaining recognition with a recognized international certification. Therefore, South Korean stock market investors must set different event-based trading strategies based on firm size. Finally, smaller companies obtaining FDA approval should determine how to market their product. The South Korean drug market comprises roughly 1.3% of the global market, compared to the US's 41%. Thus, South Korean pharmaceutical companies' global presence and asset size are not comparable to global giants (Kim, 2022). Therefore, given the South Korean market size and the capabilities of its pharmaceutical industries, it might be realistic for smaller South Korean pharmaceutical and bio-health companies to obtain access to the resources and markets of large global drug companies through strategic alliances and M&As.

References

 Ahn, B. J. and M. Kim, "Hironic's acne treating laser device approved by FDA", *PULSE by Maeil Business News Korea*, 2018.09.18., Available at https://pulsenews.co.kr/view.php?year=2018& no=588630.

- [2] Ajinkya, B. B. and M. J. Gift, "Corporate managers' earnings forecasts and symmetrical adjustments of market expectations", *Journal of Accounting Research*, 1984, pp. 425-444.
- [3] Aparicio, V., D. S. Gordon, G. Huayamares, and Y. Luo, "BioFinBERT: Finetuning Large Language Models (LLMs) to Analyze Sentiment of Press Releases and Financial Text Around Inflection Points of Biotech Stocks", arXiv preprint, Vol.arXiv:2401.11011, 2024, Available at https:// arxiv.org/ftp/arxiv/papers/2401/2401.11011.pdf.
- [4] Arbel, A., S. Carvell, and P. Strebel, "Giraffes, institutions and neglected firms", *Financial Analysts Journal*, Vol.39, No.3, 1983, pp. 57-63., https://doi.org/10.2469/faj.v39.n3.57.
- [5] Baccardax, M., "Gilead Sciences jumps higher after FDA gives Coronavirus treatment 'orphan drug' Status", TheStreet, 2020.03.24., Available at https://www.thestreet.com/investing/gilead-ge ts-fda-orphan-drug-status-for-coronavirus-treat ment.
- [6] Ball, R. and P. Brown, "An empirical evaluation of accounting income numbers", *Financial Accounting and Equity Markets*, Routledge, 2013. pp. 27-46.
- [7] Bang, J. W., J. S. Kim, M. B. Lee, and S. H. Kim, "The Impact of ERP Implementation Announcement on the Market Value of the Firm", *Asia Pacific Journal of Information Systems*, Vol.11, No.3, 2001, pp. 185-208.
- [8] Barry, C. B. and S. J. Brown, "Differential information and the small firm effect", *Journal of Financial Economics*, Vol.13, No.2, 1984, pp. 283-294, https://doi.org/10.1016/0304-405X(84) 90026-6.
- [9] Bohmann, M. J. and V. Patel, "Informed options trading prior to FDA announcements", *Journal*

of Business Finance and Accounting, Vol.49, No.7-8, 2022, pp. 1211-1236, https://doi.org/10. 1111/jbfa. 12600.

- [10] Bosch, J. C. and I. Lee, "Wealth effects of Food and Drug Administration (FDA) decisions", *Managerial and Decision Economics*, Vol.15, No.6, 1994, pp. 589-599.
- [11] Brown, S. J. and J. B. Warner, "Using daily stock returns: The case of event studies", *Journal of Financial Economics*, Vol.14, No.1, 1985, pp. 3-31.
- [12] Budennyy, S., A. Kazakov, E. Kovtun, and L. Zhukov, "New drugs and stock market: how to predict pharma market reaction to clinical trial announcements", arXiv Scholarly Paper, 2022, Available at http://arxiv.org/abs/2208.07248.
- [13] Bursztynsky, J. and L. Kolodny, "Tesla stock closes down more than 12% after Musk's Twitter deal", CNBC, 2022.04.26, Available at https:// www.cnbc.com/2022/04/26/tesla-stock-falls-mo re-than-9percent-after-musks-twitter-deal.html.
- [14] Chacko, G., P. Tufano, and G. Verter, "Cephalon, Inc. Taking risk management theory seriously", *Journal of Financial Economics*, Vol.60, No.2-3, 2001, pp. 449-485.
- [15] Chan, S. H., J. W. Kensinger, A. J. Keown, and J. D. Martin, "Do strategic alliances create value?", *Journal of Financial Economics*, Vol.46, No.2, 1997, pp. 199-221, https://doi.org/10.101 6/S0304-405X(97)00029-9.
- [16] Chan, S. H., J. D. Martin, and J. W. Kensinger, "Corporate research and development expenditures and share value", *Journal of Financial Economics*, Vol.26, No.2, 1990, pp. 255-276, https://doi.org/10.1016/0304-405X(90)90005-K.
- [17] Chaney, P. K., T. M. Devinney, and R. S. Winer, "The impact of new product introductions on the market value of firms", *Journal of Business*,

1991, pp. 573-610.

- [18] Chen, Y. J., Z. Y. Feng, Y. P. Li, and H. W. Huang, "The economic consequences of US FDA new drug approvals: Evidence from Taiwan pharmaceutical and biotech companies", *Innovation*, Vol.23, No.3, 2021, pp. 354-374.
- [19] Chen, Z., D. S. Dhaliwal, and H. Xie, "Regulation fair disclosure and the cost of equity capital", *Review of Accounting Studies*, Vol.15, 2010, pp. 106-144, https://doi.org/10.1007/s11142-009-91 15-6.
- [20] Cho, H. S., "Global Competition in Pharmaceutical- and Bio-technology and Korea's Strategy", *Journal of Social Science*, Vol.62, No.2, 2023, pp. 137-158, https://doi.org/10.22418/ JSS.2023. 4.62.2.137.
- [21] Clifford, C., "How the Moderna Covid-19 mRNA vaccine was made so quickly", CNBC, 2021. 07.03., Available at https://www.cnbc.com/20 21/07/03/how-moderna-made-its-mrna-covid-va ccine-so-quickly-'noubar-afeyan.html.
- [22] Congressional Budget Office, "Research and development in the pharmaceutical industry", 2021, Available at https://www.cbo.gov/publication/ 57126.
- [23] Dambra, M., B. Schonberger, and C. Wasley, "Creating visibility: Voluntary disclosure by private firms pursuing an initial public offering", *Review of Accounting Studies*, 2023, pp. 1-50, https://doi.org/10.1007/s11142-023-09763-y.
- [24] DiMasi, J. A., H. G. Grabowski, and R. W. Hansen, "Innovation in the pharmaceutical industry: new estimates of RandD costs", *Journal of Health Economics*, Vol.47, 2016, pp. 20-33, https://doi.org/10.1016/j.jhealeco.2016.01.012.
- [25] Ding, L., H. K. Lam, T. C. E. Cheng, and H. Zhou, "A review of short-term event studies in operations and supply chain management",

International Journal of Production Economics, Vol.200, 2018, pp. 329-342, https://doi.org/10. 1016/j.ijpe.2018.04.006.

- [26] Fama, E. F., "Perspectives on October 1987, or, what did we learn from the crash?", Center for Research in Security Prices, Graduate School of Business, University of Chicago, 1988.
- [27] Fama, E. F., L. Fisher, M. C. Jensen, and R. Roll, "The adjustment of stock prices to new information", *International Economic Review*, Vol.10, No.1, 1969, pp. 1-21.
- [28] Galkina Cleary, E., J. M. Beierlein, N. S. Khanuja, L. M. McNamee, and F. D. Ledley, "Contribution of NIH funding to new drug approvals 2010-2016", *Proceedings of the National Academy of Sciences*, Vol.115, No.10, 2018, pp. 2329-2334.
- [29] Gigante, G., A. Cerri, and G. Leone, "The impact of mergers and acquisitions on shareholders' value: an empirical study of pharmaceutical companies", *Managerial Finance*, 2023, https://doi.org/ 10.1108/MF-01-2022-0015.
- [30] Gunn, M., "When an FDA drug approval makes mainstream news: The announcement of zulresso, a media case study", *Journal of Commercial Biotechnology*, Vol.24, No.4, 2019.
- [31] Hamill, P. A., M. Hutchinson, Q. M. N. Nguyen, and M. Mulcahy, "FDA approval announcements: Attention-grabbing or event-day misspecification?", *Economics Letters*, Vol.170, 2018, pp. 171-174, https://doi.org/10.1016/j.econlet.2018 .06.024.
- [32] Hsiao, Y. C. and M. H. Wu, "Does Partner Asymmetry Facilitate Innovation Speed? Organizational Learning and Social Exchange Perspectives", *IEEE Transactions on Engineering Management*, 2022, https://doi.org/10.1109/TEM .2022.3228562.
- [33] Ibrahim, S., "Comparing FDA and EMA decisions

for market authorization of generic drug applications covering 2017-2020", Office of Generic Drugs, 2022.

- [34] IQVIA, "The changing landscape of research and development", 2019, Available at https://www .iqvia.com/insights/the-iqvia-institute/reports/the -changing-landscape-of-research-and-development.
- [35] Ivanov, P. C., A. Yuen, and P. Perakakis, "Impact of stock market structure on intertrade time and price dynamics", *PLoS One*, Vol.9, No.4, 2014, p. e92885, https://doi.org/10.1371/journal.pone. 0092885.
- [36] Javid, A. Y. and H. Malik, "Performance and capital structure of IPOs in Pakistan from 2000 to 2015", *Financial Innovation*, Vol.2, 2016, pp. 1-19, https://doi.org/10.1186/s40854-016-0032-y.
- [37] Jeong, A. Y. and J. H. Lim, "The impact of blockchain technology adoption announcements on firm's market value", *Journal of Information Systems*, Vol.37, No.1, 2023, pp. 39-65, https:// doi.org/10.2308/ISYS-2021-038.
- [38] Ji, P. and G. Yu, "Preemptive or Catch Up? Performance Differences under Enterprise Digital Transformation", Asia Pacific Journal of Information Systems, Vol.32, No.3, 2022, pp. 564-579, https://doi.org/ 10.14329/apjis.2022.32.3.564.
- [39] Khan, F. A., "Biotechnology Fundamentals Third Edition", CRC Press, 2020.
- [40] Kim, B. and E. Lee, "U.S. FDA approves Celltrion's HIV-1 treatment", PULSE by Maeil Business News Korea, 2018.11.19., Available at https://pulsenews.co.kr/view.php?year=2018and no=724614.
- [41] Kim, M. S., "How to Build South Korean Bio-Medical Industry's Competitive Force," DigitalBizOn. 2022.05.25., Available at http:// www.digitalbizon.com/news/articleView.html?i dxno=2330334.

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- [42] Kliger, D., T. Rothman, and S. Mousavi, "Pharmaceutical Lottery Stocks: Investors' Reaction to FDA Announcements", 2021, Available at https://doi.org/10.2139/ssrn.3911774.
- [43] Korea Biomedicine Industry Association, "Strategic information for global market penetration of biomedical drugs", 2018, Available at https://www.kobia.kr/bbs/board.php?tbl=notice&mode=VIEW&num=173.
- [44] Korea Pharmaceutical and Bio-Pharma Manufacturers Association, Pharmaceutical industry data book, 2019, Available at https://www.kpbma.or .kr/library/publications/list?b_category=2&start =0 &search_txt=.
- [45] Kwon, H. and H. Lee, "The Impact of Alliance on Market Value of the Bio-pharmaceutical Firm in Korea", *Journal of the Korea Academia-Industrial Cooperation Society*, Vol.18, No.7, 2017, pp. 149-161, https://doi.org/10.5762/KAI S.2017.18.7.149.
- [46] Kwon, S. M. and C. H. Han, "Empirical investigation on information breach effect on the market value of the firm: Focused on source and long term performance", *Journal of Society for e-Business Studies*, Vol.21, No.2, 2017, https:// doi.org/10.7838/jsebs.2016.21.2.081.
- [47] Kyle, A. S., "Trading halts and price limits", *Review of Futures Markets*, Vol.7, No.3, 1988, pp. 426-434.
- [48] Lee, E. and N. Hyung, "Widening price limit effects on volatility: Using portfolio return and EGARCH Model. The Korean Data Analysis Society", Journal of The Korean Data Analysis Society, Vol.24, No.6, 2022, pp. 2229-2246. https://doi.org/10.37727/jkdas.2022.24.6.2229.
- [49] Lee, H. S., "Successive failures throw Korean bioindustry's drug-developing ability into question", *Korea Biomedical Review*, 2019.09.26.,

Available at http://www.koreabiomed.com/news/ articleView.html?idxno=6509.

- [50] Lee, H. S., "Successive failures throw Korean bioindustry's drug-developing ability into question", *Korea Biomedical Review*, 2019.09.26., Available at http://www.koreabiomed.com/news /article View.html?idxno=6509.
- [51] Lee, S. M., Y. Noh, D. Choi, and S. J. Rha, "The effect of ISO 14001 on equity structure", *Industrial Management and Data Systems*, Vol.114, No.6, 2014, pp. 979-991, https://doi.org/10.1108 /IMDS-01-2014-0021.
- [52] Lin, C., R. Morck, B. Yeung, and X. Zhao, "What do we learn from stock price reactions to China's first announcement of anti-corruption reforms?", *The Journal of Finance and Data Science*, Vol.9, 2023, 100096, https://doi.org/10.1016/j.jfds.202 3.100096.
- [53] Lo, A. W. and R. T. Thakor, "Financial intermediation and the funding of biomedical innovation: A review", *Journal of Financial Intermediation*, 2023, 101028, https://doi.org/10.10 16/j.jfi.2023.101028.
- [54] Ma, C. K., R. P. Rao, and S. Sears, "Limit moves and price resolution: The case of the treasury bond futures market", *The Journal of Futures Markets* (1986-1998), Vol.9, No.4, 1989, pp. 321.
- [55] MacKinlay, A. C., "Event studies in economics and finance", *Journal of Economic Literature*, Vol.35, No.1, 1997, pp. 13-39.
- [56] Masulis, R. W. and L. Shivakumar, "Does market structure affect the immediacy of stock price responses to news?", *Journal of Financial and Quantitative Analysis*, Vol.37, No.4, 2002, pp. 617-648, https://doi.org/10.2307/3595014.
- [57] Mathur, L. K., I. Mathur, and N. Rangan, "The wealth effects associated with a celebrity endorser: The Michael Jordan phenomenon", *Journal*

of Advertising Research, Vol.37, No.3, 1997, pp. 67-74.

- [58] Mc Namara, P. and C. Baden-Fuller, "Shareholder returns and the exploration-exploitation dilemma: RandD announcements by biotechnology firms", *Research Policy*, Vol.36, No.4, 2007, pp. 548-565, https://doi.org/10.1016/j.respol.2007.02.012.
- [59] McWilliams, A. and D. Siegel, "Event studies in management research: Theoretical and empirical issues", *Academy of Management Journal*, Vol.40, No.3, 1997, pp. 626-657, https://doi.org/10.5465/257056.
- [60] Petrov, E., and S. Schantl, "Conversations Between Managers and Investors", 2023, https:// doi.org/10.2139/ssrn.4412167.
- [61] Rasoulian, S., Y. Grégoire, R. Legoux, and S. Sénécal, "The effects of service crises and recovery resources on market reactions: An event study analysis on data breach announcements", *Journal* of Service Research, Vol.26, No.1, 2023, pp. 44-63, https://doi.org/10.1177/1094670521103 6944.
- [62] Reddy, K., M. Qamar, and N. Yahanpath, "Do mergers and acquisitions create value? The post-MandA performance of acquiring firms in China and India", *Studies in Economics and Finance*, Vol.36, No.2, 2019, pp. 240-264, https://doi.org/10.1108/SEF-01-2018-0027.
- [63] Rennane, S., L. Baker, and A. Mulcahy, "Estimating the cost of industry investment in drug research and development: a review of methods and results", *INQUIRY: The Journal of Health Care Organization, Provision, and Financing*, Vol.58, 2021, 00469580211059731, https://doi.org/10.1177/00469580211059731.
- [64] Ringel, M. S. and M. K. Choy, "Do large mergers increase or decrease the productivity of pharmaceutical RandD?", *Drug Discovery Today*,

Vol.22, No.12, 2017, pp. 1749-1753, https://doi.org/10.1016/j.drudis.2017.06.002.

- [65] Rothenstein, J. M., G. Tomlinson, I. F. Tannock, and A. S. Detsky, "Company stock prices before and after public announcements related to oncology drugs", *Journal of the National Cancer Institute*, Vol.103, No.20, 2011, pp. 1507-1512. https://academic.oup.com/jnci/article/103/20/15 07/904625.
- [66] Sarkar, S. K. and P. J. de Jong, "Market response to FDA announcements", *The Quarterly Review* of Economics and Finance, Vol.46, No.4, 2006, pp. 586-597, https://doi.org/10.1016/j.qref.2005. 01.003.
- [67] Sharma, A. and N. Lacey, "Linking product development outcomes to market valuation of the firm: The case of the US pharmaceutical industry", *Journal of Product Innovation Management*, Vol.21, No.5, 2004, pp. 297-308, https://doi.org/10.1111/j.0737-6782.2004.00084.x.
- [68] Shin, Y. W., J. Y. Yun, H. J. Jeon, C. Y. Kim, J. H. Kim, and Y. R. Kim, "2020 Drug industry analysis report", Korea Health Industry Development Institute, 2021, Available at https ://www.khidi.or.kr/board/view?linkId=4886277 6&menuId=MENU00085.
- [69] Shkolnykova, M. and M. Kudic, "Who benefits from SMEs' radical innovations?empirical evidence from German biotechnology", *Small Business Economics*, Vol.58, No.2, 2022, pp. 1157-1185, https://doi.org/10.1007/s11187-021-00464-x.
- [70] Simoens, S. and I. Huys, "How much do the public sector and the private sector contribute to biopharmaceutical RandD?", *Drug Discovery Today*, Vol.27, No.4, 2022, pp. 939-945, https:// doi.org/10.1016/j.drudis.2021.11.027.
- [71] Torabzadeh, K. M., C. G. Woodruff, and N. Sen,

"FDA decisions on new drug applications and the market value of pharmaceutical firms", *American Business Review*, Vol.16, No.2, 1998, pp. 42-50.

- [72] Tripathi, M. and A. Mukhopadhyay, "Financial loss due to a data privacy breach: An empirical analysis", *Journal of Organizational Computing and Electronic Commerce*, Vol.30, No.4, 2020, pp. 381-400, https://doi.org/10.1080/10919392 .2020.1818521.
- [73] Tweneboah-Kodua, S., F. Atsu, and W. Buchanan, "Impact of cyberattacks on stock performance: A comparative study", *Information and Computer Security*, Vol.26, No.5, 2018, pp. 637-652, https://doi.org/10.1108/ICS-05-2018-0060.
- [74] Weinzimmer, L., C. A. Esken, E. J. Michel, W.C. McDowell, and R. V. Mahto, "The differential impact of strategic aggressiveness on firm per-

formance: The role of firm size", *Journal of Business Research*, Vol.158, 2023, 113623, https://doi.org/10.1016/j.jbusres.2022.113623.

- [75] Wu, Z., P. Borochin, and J. H. Golec, "Informed Options Trading Before FDA Drug Advisory Committee Meetings", University of Miami Business School Research Paper, 2021, 3825062, https://doi.org/10.2139/ssrn.3825062.
- [76] Yashiro, K., Y. Lim, S. Sengoku, and K. Kodama, "Recent trends in interorganizational deal networks in pharmaceutical and biotechnology industries", *Drug Discovery Today*, 2022, 103483, https://doi.org/10.1016/j.drudis.2022.103483.
- [77] Zhang, X., X. Li, J. Hao, and P. Li, "Price limit change and magnet effect: The role of investor attention", *Finance Research Letters*, Vol.53, 2023, 103577, https://doi.org/10.1016 /j.frl.2022. 103577.

Information Systems Review Volume 26 Number 1 February 2024

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Abstract

Korean pharmaceutical and bio-health companies began applying for FDA approval in 2000. However, drug companies in South Korea are not required to obtain FDA approval to market their products on the South Korean market, and the approval process is highly resource-intensive. This study utilizes event study methodology to examine the information effect of US FDA approval announcements on the stock prices of pharmaceutical and bio-health companies listed on South Korean stock markets. The study's results show that FDA approval announcements caused abnormal increases in corporate stock prices, indicating that these announcements have a transnational information effect on South Korean companies' value. Furthermore, the results show that the impact of FDA approval announcements on stock prices is greater for small companies than mid-sized and large companies and in bio and healthcare industries than in the traditional pharmaceutical industry. This impact is also more significant on the KOSDAQ (Korea Securities Dealers Automated Quotation) companies than the KOSPI (Korean Composite Stock Price Index) companies and after the expansion of stock price limits. These findings signal that the information effect is more significant when regulatory controls are weaker. The results also indicate that obtaining FDA approval brings above-normal returns for companies and that FDA application is a high-risk, high-return investment.

Keywords: FDA Approval Announcements, Event Study, Pharmaceutical and Bio-healthcare Industries, Information Effect

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서강대학교 경영대학에서 석사학위를 취득하였으며, 현재 동대학원에서 박사 과정에 재학 중이다. 주요 연구분야는 자발적 공시, 보고 적시성, 기업지배구조 등이다.



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현재 서강대학교 경영학부 정교수로 재직 중이다. 서강대학교 경영학과에서 학사 석사를, 미국 네브라스카 대학에서 경영학 박사를 취득했다. 그는 Journal of World Business, Information & Management, International Journal of Information Management, International Journal of Production Research 등을 포함 100편의 논문과 중앙일보 동아일보 등에 100여 편을 IT관련 컬럼을 기고해 왔다. 주요 연구분야는 블록체인, 메타버스 등으로 중국 칭화대학과 일본의 히도츠바시 대학에서 교환교수를 지냈다.



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미국 네브라스카 주립대에서 경영학 (경영정보)로 박사를 받고 Kean University, 제주대학교, 제주한라대학교에서 재직하였고, 2022년부터 전남대학교 경영학과에 교수로 재직 중이다. 기업의 윤리적인 기술사용, 기업의 ESG 활동이 이해관계자 들에게 미치는 영향 및 기업가치, 기업의 온라인/메타버스 활용과 HCI(Human computer interaction)에 관심을 갖고 연구와 교육을 수행하고 있고, 국내외 학술지에 20여 편의 연구결과를 발표하였다. Management, Journal of Electronic Commerce Research 등에 논문을 발표하였다. 주요 관심분야는 Cloud Computing, Technostress 등이다.

논문접수일:2023년 12월 13일 1차수정일:2024년 02월 04일 게재확정일: 2024년 02월 09일