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FDA Advisory Committee (AdCom) Voting Outcomes on Drug Approvals Effect on Sponsor

Firms' Stock Prices

<u>Abstract</u>

This project investigates whether FDA Advisory Committee (AdCom) voting outcomes on drug approvals significantly affect sponsor firms' stock prices. By examining stock price movements for four companies including Johnson and Johnson, Geron Corporation, Novo Nordisk and Merck Shark & Dohme LLC, we came to the conclusion that Adcom decisions have little to no long- term effect on firm valuations. However, short-term fluctuations are arguably immediately visible following the outcome decision, suggesting a temporary market response. The company with lower overall stock prices exhibited a more pronounced effect due to the Adcom decision compared to other larger and more established companies. This indicated that the size of a company may be a large factor in determining whether stock prices were significantly affected. Overall, our findings indicate that while FDA AdCom outcomes may briefly affect investor behavior, stock prices generally return to the pre-event trajectory.

<u>Introduction</u>

The FDA plays a crucial role in determining which new drugs reach the market, and these decisions can have significant financial consequences for the stock holders of the companies involved. Advisory Committee (AdCom) meetings are particularly important because they publicly review and recommend whether a new drug should be approved, often serving as an early signal of how the FDA might rule. Financial markets tend to react to such regulatory signals since they directly influence firms' future revenues and investor expectations. Understanding how strongly and how quickly these reactions occur provides insight into how efficiently markets incorporate public health policy decisions into asset prices. By connecting the outcomes of FDA meetings to corresponding stock price data, we can assess whether investors will buy, sell, or keep their shares in a given firm.

Our midterm project is aimed at understanding the relationship between FDA Advisory Committee voting outcomes on drug approvals and the firms' corresponding stock price fluctuations. Our aim is to look at long term stock term fluctuations (60-day range, 30 days before and after) for each firm. Our null hypothesis is as follows: firms' FDA Adcom decisions have no impact on stock price fluctuations. Our alternative hypothesis is as follows: firms who received a positive outcome from the FDA Adcom had a relative increase in stock price and firms who received a negative outcome from the Adcom had a relative decrease in stock price.

We aim to study correlation between FDA Adcom and firms' relative stock prices because it gives us insight as to how relevant a tentative drug approval is for stock holders in a

given firm. We manually curated the dataframe below and utilized the relevant categorical and numerical variables: Voting outcome, Date, and Sponsor ticker.

We utilized the yfinance library which helps us scrape the relevant data for our analysis to identify the timeframes. We analyzed a timeframe of 30 days before and after the voting outcome to gauge general stock fluctuations and determine the impact of the Adcom outcome on a given stock.

Method

We began by manually collecting data from the FDA Advisory Committee meeting pages. Each entry represented one meeting and contained the following information:

- AdCom Committee name

- Date of the meeting or vote

- AdCom Center (either CBER for biologics or CDER for drugs)

- Sponsor name and ticker symbol

- Voting Outcome (1 for positive outcome, 0 for negative outcome)

- Whether the drug was for a rare disease

- Whether it was a first-in-class drug

- Therapeutic area (e.g., oncology, infectious disease)

- Drug name

In Google Colab, we imported the file with a simple pandas command that reads it directly from its GitHub link.

After loading, we cleaned the data by converting the "Date" column into datetime format and dropping any rows that lacked essential fields such as the sponsor ticker or voting outcome. This ensured that only complete, analyzable records remained.

To measure the market's reaction to these FDA events, we used the Yahoo Finance API via the yfinance Python library. For each company in our FDA dataset, we pulled 60 days of stock data: 30 days before and 30 days after the AdCom decision date.

The code looped through each company, using its ticker symbol to extract daily opening and closing prices for the specified window. The historical data was retrieved using the yf.Ticker() function.

For example:

- If a company's AdCom decision occurred on March 15, 2024, the script collected stock data from February 14 to April 14.
- Both "Open" and "Close" prices were stored in a list along with the company name, voting outcome, and event date.

A few tickers returned errors such as "No data found, symbol may be delisted." These cases are common in pharmaceutical research because many biotech companies merge, change names, or get delisted after key trials. Despite these issues, we successfully collected data for several major publicly traded companies including Geron (GERN), Johnson & Johnson (JNJ), Novo Nordisk (NVO), and Merck (MRK).

Once the valid stock data was collected, we compiled all the lists into a single pandas DataFrame containing columns for Prices, Company Name, Outcome, and Date. This unified dataset allowed us to easily analyze and visualize price trends around FDA decisions.

Analysis

To visualize the data, we used matplotlib to create a figure with four subplots, two showing positive AdCom outcomes and two showing negative outcomes. Each subplot displayed the company's daily Open and Close stock prices, with a red dashed line marking the event date (the day the FDA decision occurred).

The main title of the figure was:

"Positive (Left) vs. Negative (Right) Outcomes Effect on Prices."

The resulting plots clearly illustrated differences between approval and denial outcomes:

● **Geron Corporation (Positive Outcome):** After a favorable AdCom decision, Geron's stock price increased significantly, showing a strong market response.

● **Novo Nordisk (Negative Outcome):** Following a negative recommendation, Novo Nordisk's stock price fell noticeably in the days after the decision.

● **Johnson & Johnson (Positive Outcome):** The movement was more muted. As a large, diversified company, individual drug outcomes had less impact on its overall valuation.

● **Merck Sharp & Dohme (Negative Outcome):** The stock showed a downward trend following the event, but eventually stabilized, indicating partial market correction after initial disappointment.

This visual comparison highlighted how market size and company dependence on a single product influence the magnitude of stock price reactions.

Positive (Left) vs. Negative (Right) Outcomes Effect on Prices
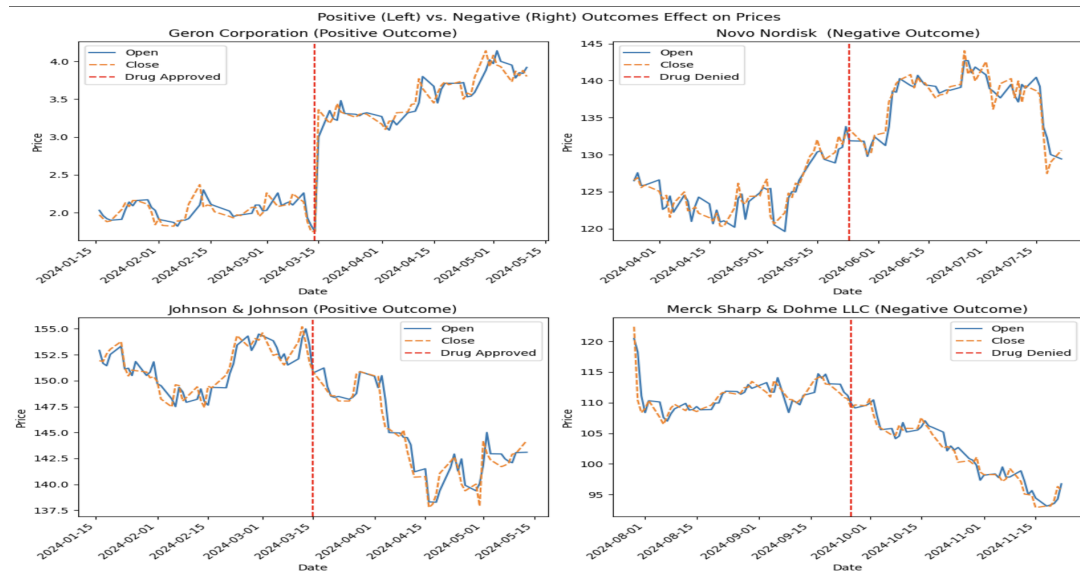
Outliers

During our analysis, we also examined potential outliers. In our graphical data, Geron Corporation is classified as an outlier visually.

Geron Corporation exhibited a dramatic short-term increase in stock price immediately following the positive AdCom decision, rising by over 20% within two trading days. This spike was significantly higher than typical daily fluctuations. Throughout the 30 days after the announcement, Geron Corporation stock prices maintained the elevated price point, demonstrating a long-term effect of Geron Corporation's valuation.

Conversely, Merck Sharp & Dohme showed a temporary sharp decline immediately after its negative outcome with a quick rebound within a week. This short reaction suggests that while

investors initially responded negatively to the decision, long-term valuation of Merck Sharp & Dohme was not affected.

These observations illustrate how the size of the company could play a major role in determining whether stock prices were influenced in the long-term. While Geron Corporation's stock prices were around $2 before the drug decision, Novo Nordisk's was around $125, Johnson & Johnson at $152.5 and Merck Sharp & Dohme at $110. Larger companies like Johnson & Johnson, Novo Nordisk and Merck Sharp & Dohme are likely less affected by a single drug decision due to diversified portfolios.

Overall, the presence of Geron Corporation as an outlier supports the conclusion that FDA AdCom outcomes can trigger short-term volatility driven by market psychology as well as more long-term effects in smaller firms, while larger firms typically demonstrate more market stability.

Conclusion

This project demonstrated how correlation decisions may have immediate, observable effects on financial markets. By constructing our FDA AdCom dataset and connecting it with market data through the yfinance API, we are able to visualize how investor sentiment changes around the time of regulatory announcements.

Takeaways from this analysis:

1. **Building the dataset manually was a valuable experience.** It showed the realities of working with incomplete and unstructured public data, including missing tickers, inconsistent formatting, and delisted stocks.

2. **FDA decisions have influence in the market.** A positive committee vote tends to boost investor confidence and drive stock prices up, while a negative vote can cause temporary or sustained declines.

3. **Company size and diversification matter.** Large pharmaceutical firms, with many ongoing products, experience smaller relative movements than small biotech companies that depend on one or two key drug approvals.

4. **APIs make this type of analysis accessible.** The finance library allows anyone to pull market data for hundreds of companies through scraping and conducting meaningful time-series analyses.

There is potential for a follow-up to this project to delve deeper into the many confounding variables, such as size of the firm and overall stock market trends influencing the firms. We could also test whether variables like therapeutic area, first-in-class designation, or rare-disease status explain differences in stock reactions.

It showed how open-source tools and publicly available data can be used to study the interaction between FDA regulatory outcomes and investor behavior. Beyond technical skills, it provided practical insight into how analysts combine datasets from completely different domains to understand cause-and-effect relationships in real markets.

References:

Data was taken from FDA Adcom Meeting PDFs.

https://www.fda.gov/advisory-committees/advisory-committee-calendar