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Quantifying Reputational Risk in MedTech: The Impact of Notoriety Bias on Stock Volatility and Adverse Event Reporting

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Abstract: Quality control and reputational risk management are critical factors for medical device manufacturers. This paper investigates the phenomenon of "Notoriety Bias", a situation where the volume of adverse event reports (MDR) is driven by media attention rather than solely by product failure rates. Using the 2021, Philips Respironics, ventilator recall as a case study, we analyze the temporal relationship between three variables: (1) the external shock (Recall event), (2) consumer reaction (FDA MAUDE database reports), and (3) capital market reaction (stock price volatility). Methodologically, the study employs STL decomposition and ARIMAX modeling to quantify the structural break in reporting, and Granger Causality tests to verify the direction of information flow. These findings are contrasted with an Event Study of abnormal stock returns. The results reveal a significant temporal decoupling: while the capital market reacts immediately (efficient market hypothesis), the consumer reaction (reporting spike) exhibits a significant lag of 10–12 months. The study demonstrates the utility of OpenFDA Big Data for modeling corporate risk dynamics.

Keywords: MAUDE; adverse event; ARIMAX; Granger causality

JEL Classification: M21; L1; G17

1. Introduction

Quality control and reputational risk management are paramount for manufacturers in the healthcare sector. A robust quality culture is essential not only for ensuring patient safety but also for saving costs and protecting a brand's reputation. In the medical device industry, postmarket safety surveillance is crucial given the limitations of premarket evidence. A central tool for this surveillance in the United States is the Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. While this system allows for the detection of safety issues, it relies on passive reporting from external individuals and organizations, making it susceptible to inaccuracies, incompleteness, and reporting biases.

A critical challenge in passive surveillance is discerning whether a surge in adverse event reports reflects a genuine increase in device failures or is driven by external factors such as media attention—a phenomenon known as "notoriety bias". Notoriety bias is a selection bias

where a case has a greater chance of being reported if the subject is exposed to a factor known or thought to cause the event, often triggered by safety alerts or media coverage. Conversely, recent investigations have revealed significant issues with late reporting; nearly a third of manufacturer reports to the MAUDE database are not submitted within the required 30-day window, with some delayed by more than six months. This raises the question: to what extent does the volume of adverse event reports correlate with actual product failure versus public awareness and corporate reporting delays, and how does this dynamic interact with the company's market value?

While the financial impact of product recalls on shareholder wealth is well-documented, with studies confirming significant negative stock market reactions to recall announcements, the temporal relationship between the financial shock and the regulatory reporting surge is less understood. Existing research has examined the impact of product recalls on stock prices across various sectors, finding that the automotive and pharmaceutical industries experience significant losses due to high regulation and hazard levels. However, there is a need to quantify the specific lag between the immediate capital market reaction and the potentially delayed consumer and regulatory reaction manifesting in surveillance databases.

This study aims to quantify the magnitude and delay of notoriety bias using the 2021 Philips Respironics ventilator recall as a case study. By employing advanced time-series analysis, we seek to model the structural breaks in reporting and contrast them with market volatility to better understand the decoupling of financial and regulatory risks.

Spontaneous reporting systems like FAERS and MAUDE are fundamental to pharmacovigilance but face challenges such as underreporting and stimulated reporting. Historically, the "Weber Effect" suggested that adverse event reporting peaks at the end of the second year after regulatory approval and then diminishes. However, Hoffman et al. (2014) analyzed modern reporting patterns and found little evidence of this trend, suggesting that reporting counts tend to increase over the first three quarters and then remain constant.

More recently, attention has shifted to "notoriety bias" or stimulated reporting triggered by safety alerts and media coverage. Neha et al. (2021) define this as a bias where exposure to a factor known to cause an event increases the likelihood of reporting. While their study on the FAERS database found that overreporting due to notoriety bias did not consistently alter signal strength for all drugs, they noted that specific safety alerts could drive increased reporting. The influence of media is further highlighted by Al-Ali et al. (2022), who noted that media attention regarding rare adverse events post-vaccination contributed to widespread hesitancy and controversy, suggesting a link between public publicity and the perception of risk. Furthermore, Everhart et al. (2025) highlight the prevalence of late adverse event reporting in the medical device sector, noting that late reports are often released in large batches, which can obscure the timely identification of safety concerns.

To statistically model the impact of external shocks—such as a recall announcement—on time-series data, this study draws on the foundational work of Box and Tiao (1975). Their methodology for "Intervention Analysis" provides a framework for analyzing whether a specific event (intervention) causes a step change or a pulse in a stochastic process, allowing researchers to distinguish between noise and actual structural shifts in data. This approach

allows for the modeling of dynamic responses, such as immediate step changes or gradual "ramp" responses following an intervention.

The study's financial analysis is grounded in the efficient market hypothesis, which posits that an efficient market reacts instantaneously to new information, such as a product recall, by adjusting stock prices. Bernon et al. (2018) employed event study methodology to confirm that product recalls generate negative stock market reactions, with the magnitude of the loss influenced by the industry sector and the hazard level of the product. Specifically, recalls involving severe hazards (Class I) lead to greater reductions in share price due to perceived litigation costs and reputational damage. Similarly, Kim and Noh (2025) found that delayed recall decisions can lead to substantial negative stock returns, emphasizing the market's sensitivity to the timing and management of safety issues.

2. Methodology

The primary data source for this study is the Manufacturer and User Facility Device Experience (MAUDE) database, managed by the U.S. Food and Drug Administration (FDA). This passive surveillance system aggregates Medical Device Reports (MDRs) from mandatory reporters (manufacturers, importers) and voluntary reporters (healthcare professionals, patients) under 21 CFR Part 803. To ensure data integrity and reproducibility, raw data were not manually exported but acquired programmatically via the “openFDA API” (`https://api.fda.gov/device/event.json`). This RESTful API allows for precise server-side filtering and structured JSON output. The extraction strategy employed the `search` parameter to filter records by manufacturer and date range, utilizing pagination (`limit`, `skip`) to bypass the default 1000-record query limit.

The analysis focuses on Philips Respironics as a case study, specifically examining the impact of the June 2021 Class I Recall regarding sound abatement foam degradation. The observational period spans from January 1, 2018, to December 31, 2023.

The dependent variable is the aggregate monthly count of adverse event reports. A critical methodological decision was to utilize the `date_received` (the date the FDA received the report) rather than the `date_of_event` (when the incident occurred). This distinction is vital for analyzing "Notoriety Bias," as `date_received` reflects the temporal reaction of the public and reporters to external stimuli (media coverage, recalls), whereas `date_of_event` is subject to "back-filling" bias and does not accurately capture the reporting behavior triggered by the recall news.

2.1. Statistical Framework

To isolate the underlying signal from noise, the time series was decomposed using STL Decomposition (Seasonal and Trend decomposition using Loess). We assessed the series for three components: Trend, Seasonality, and Residuals. The strength of the trend and seasonality were calculated to determine the necessity of seasonal adjustment in subsequent modeling.

The core analysis employs the Box-Jenkins methodology (ARIMA) to model the baseline reporting behavior. Stationarity was verified using the Augmented Dickey-Fuller (ADF) test.

Where non-stationarity was detected (unit root presence), the series was stabilized via differencing.

To quantify the impact of the recall, we utilized Intervention Analysis (ARIMAX). The recall event was modeled as an exogenous binary variable. Two intervention functions were considered:

- Pulse Function: Represents a temporary shock.
- Step Function: Represents a structural break or permanent shift in reporting levels.

To address the potential delay between the recall announcement and the surge in reporting, we performed a Lag Analysis. Multiple ARIMA models were fitted with intervention delays ranging from 0 to 12 months. The optimal lag was selected by minimizing the Akaike Information Criterion (AIC) to prevent overfitting and identify the most statistically probable reaction time.

To verify the directionality of information flow, specifically, that the recall event predicts the reporting surge and not vice versa, we employed the Granger Causality test based on Vector Autoregression (VAR). The test evaluates whether past values of the recall binary variable provide statistically significant information for forecasting future reporting volumes beyond what is contained in the history of variable itself. Robustness was checked by testing lag lengths of 1 to 18 months to ensure results were not artifacts of arbitrary lag selection.

All data processing and statistical analyses were conducted in R version 4.5.1 using following packages:

- Data Acquisition & Manipulation: `httr` and `jsonlite` for API interaction; `tidyverse` (`dplyr`, `lubridate`) for data aggregation.
- Modeling: `forecast` package for ARIMA/STL; `lmtest` and `tseries` for residual diagnostics (Ljung-Box test) and stationarity testing.
- Causality: `vars` package for VAR and Granger testing.

Model adequacy was rigorously validated by analyzing residuals to ensure they approximate white noise (Ljung-Box Q-test, $p > 0.05$).

3. Results

To isolate the underlying drivers of the incident reporting volume, we performed an STL decomposition (Seasonal and Trend decomposition using Loess) – see figure 1. The analysis quantified the strength of the trend (*FT*) and seasonal (*FS*) components on a scale of 0 to 1. The results indicate a strong trend component ($FT = 0.74$), confirming that the time series is driven primarily by long-term directional shifts and external shocks rather than random noise. Conversely, the seasonal component was found to be weak ($FS=0.19$). This suggests that the dynamics of reporting for Philips Respironics are not significantly influenced by administrative cycles or calendar effects, justifying the focus of the subsequent ARIMA modeling on trend and intervention variables.

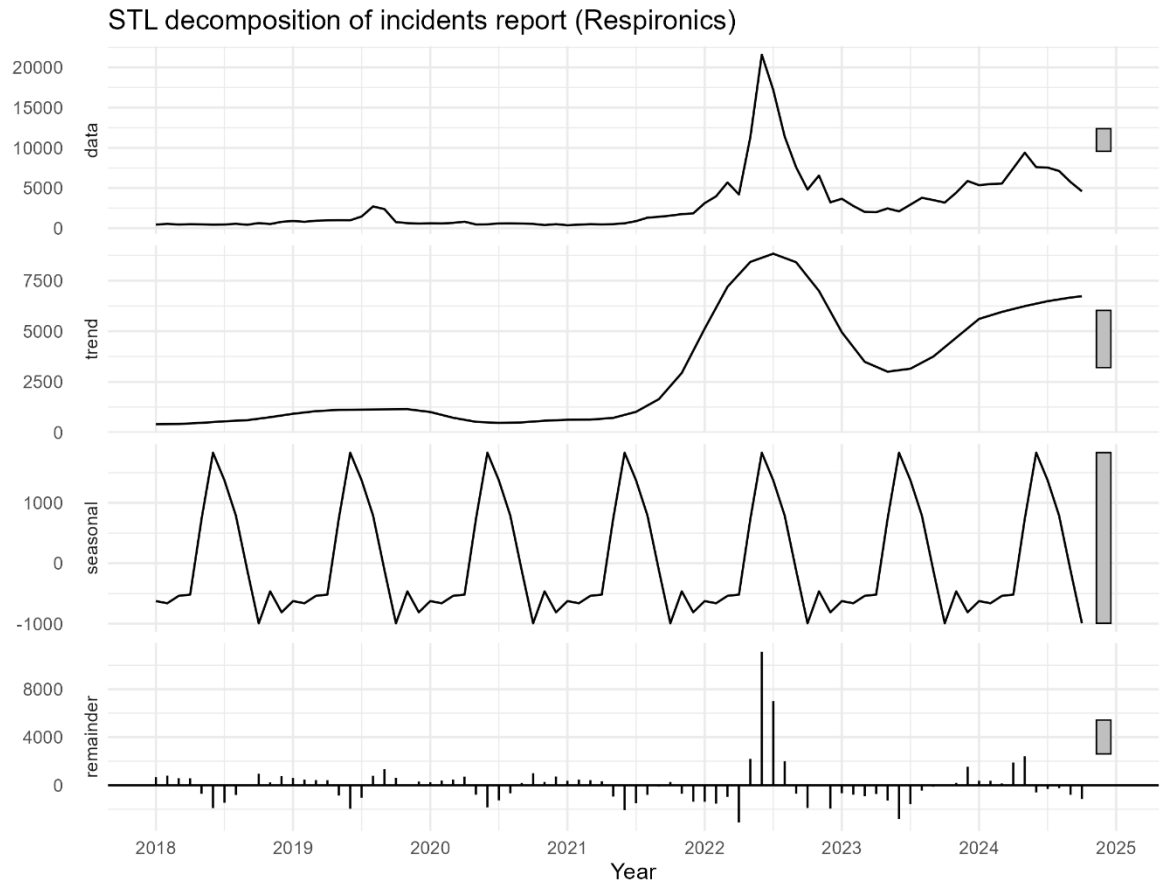

Figure 1. STL decomposition of incident report for Respironics company

3.1. Intervention Analysis

The Delayed Notoriety Bias We utilized an ARIMAX model to test the hypothesis that the Class I Recall announcement (June 2021) acted as an immediate structural break (Step Function) in the reporting volume. The initial model (Table 1) estimated a positive intervention coefficient of approximately 2,328 additional reports per month following the recall. However, this immediate impact was not statistically significant ($p \approx 0.09$). While the residual diagnostics (Ljung-Box $Q = 10.2$, $p > 0.05$) confirmed the model's technical validity, the lack of significance suggests that the "Notoriety Bias" did not manifest immediately in the MAUDE database.

Table 1. Intervention model parameters estimation

Parameter	Estimate	Std. Dev.	Z-value	Pr > |z|
ar1	0.65	0.11	5.84	5e-09
ma1	0.59	0.13	4.4	9e-06
Intercept	1800	1030	1.75	0.08
xreg	2328	1363	1.71	0.0í

To address the potential temporal decoupling, we conducted a Lag Analysis, fitting models with intervention delays ranging from 0 to 12 months. The optimization criterion was the minimization of the Akaike Information Criterion (AIC). We saw three important areas of assessed lag (see fig. 2):

- Immediate Impact (Lags 0–3): The intervention variable remained statistically insignificant (p>0.05).
- Onset of Significance (Lag 4): A statistically significant increase in reporting was first detected with a 4-month lag (p = 0.010).
- Peak Model Fit (Lag 11): The model achieved the lowest AIC (1,426.95) and the highest statistical significance (p < 0.001) at a lag of 11 months.

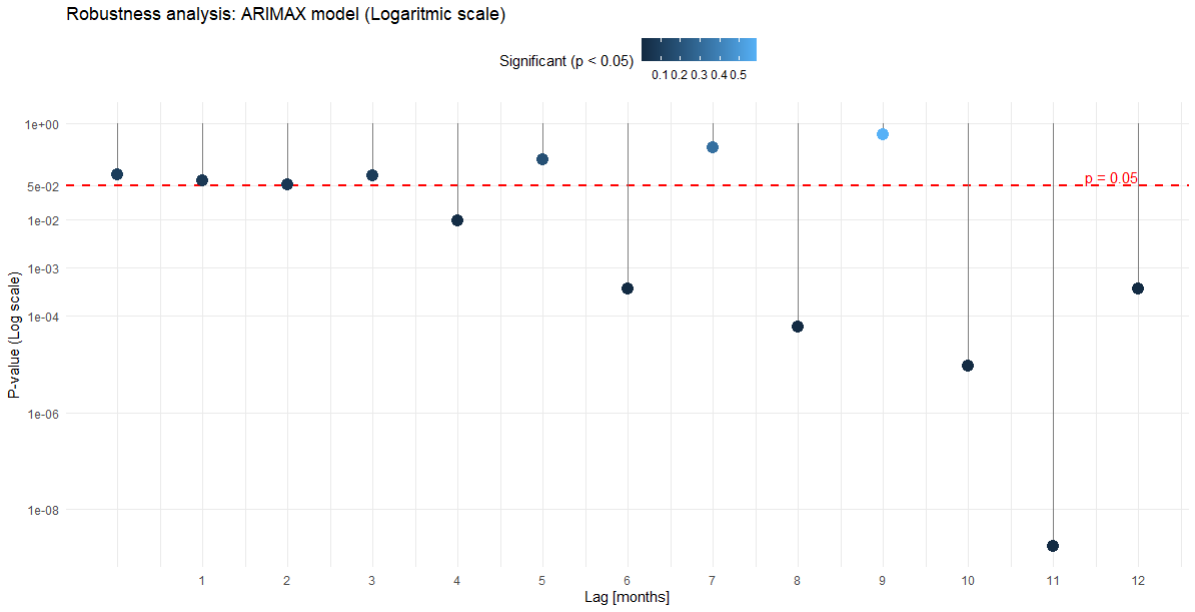

Figure 2. Robustness analysis ARIMAX model

This analysis reveals that while the recall eventually triggered a massive surge in reporting (Notoriety Bias), there was a substantial latency period. The structural break in the data is most accurately modeled as occurring nearly a year after the public announcement.

3.2. Causality and Information Flow

To robustly verify that the recall event serves as a predictor for the reporting surge (and not merely a coincident trend), we employed the Granger Causality test based on Vector Autoregression (VAR). A robustness analysis was performed for lag lengths $k \in \langle 1,18 \rangle$ months to rule out arbitrary lag selection artifacts (Figure 3).

- Short-term (1–9 months): The null hypothesis (H0: Recall does not Granger-cause Reporting) could not be rejected (p>0.05).
- Long-term (10+ months): The relationship becomes statistically significant at Lag 10 (p<0.05) and highly significant for lags 11–18 (p<0.01). This confirms a causal, predictive relationship where the recall news drives the volume of adverse event reports, but strictly with a delay of approximately 10 months.

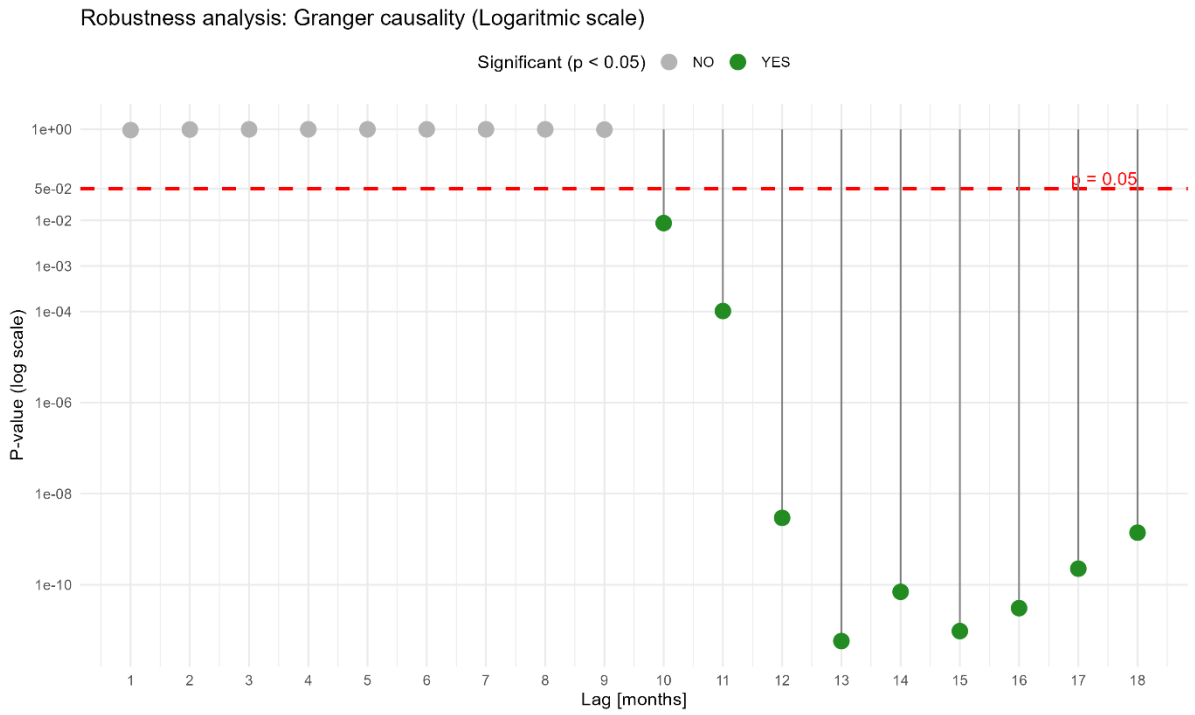

Figure 3. Granger test: Robustness analysis

The delayed reaction observed in the consumer/regulatory data stands in stark contrast to the capital market reaction. As illustrated in the comparative analysis (Figure 4), the cumulative returns of Philips stock decoupled from the S&P 500 market index immediately following the June 2021 announcement. While the financial markets priced in the reputational risk instantaneously (consistent with the Efficient Market Hypothesis), the "Notoriety Bias" in the FDA MAUDE database exhibited a significant inertia, materializing as a structural break only after the complex logistics of the recall and media cycle had fully permeated the patient and provider population.

Figure 4. Respironics recall effect on the financial markets (Phillips vs Market)

4. Discussion

The primary finding of this study is the significant temporal decoupling between the external shock (the Class I Recall announcement) and the manifestation of "Notoriety Bias" in regulatory data. While the recall was publicized in June 2021, the intervention analysis reveals that the structural break in adverse event reporting did not become statistically significant until approximately four months later, peaking with a lag of 10 months.

This contradicts the assumption that media attention drives an *immediate* panic-induced spike in reporting (a "Pulse" effect). Instead, the data suggests a "Step" effect with high inertia. The delay likely reflects the complex logistics of the medical device ecosystem: it takes time for information to permeate from manufacturers to healthcare providers and finally to patients. Furthermore, the 10-month lag aligns with the typical timeline for the formation of class-action lawsuits and intensified media cycles, which reinforce the "availability heuristic" – leading patients to attribute previously ignored symptoms to the recalled device long after the initial news breaks.

A critical insight emerges when contrasting the regulatory data with the capital market reaction. As illustrated in Figure 4, the cumulative returns of Philips stockholders decoupled from the S&P 500 index immediately following the June 2021 announcement. The financial markets, acting in accordance with the Efficient Market Hypothesis, priced in the reputational and litigation risk instantaneously.

In contrast, the FDA MAUDE database as a primary tool for post-market surveillance exhibited a "regulatory latency" of nearly a year. This discrepancy suggests that while capital markets are predictive and immediate, passive surveillance systems are reactive and sluggish. For risk managers, this implies that stock price volatility may serve as a leading indicator for future regulatory compliance burdens, whereas MAUDE data is a lagging indicator.

The interpretation of these findings is subject to limitations inherent in passive surveillance data. The most significant constraint is the absence of a "denominator" i.e. the total number of devices in use. Without sales or usage data, it is impossible to calculate the true Incidence Rate (absolute risk).

However, the magnitude of the relative increase in reports (from hundreds to tens of thousands per month) is so substantial that it cannot be attributed solely to a sudden degradation in manufacturing quality ten months post-recall. The sheer volume confirms that the signal is driven by behavioral changes in reporting (stimulated reporting) rather than a fundamental shift in device reliability. A secondary limitation is the single-case nature of the study; while the Philips Respironics case provides a clear example of Notoriety Bias, further research across multiple Class I recalls is necessary to generalize these temporal dynamics.

The study demonstrates that the MAUDE database is highly susceptible to Notoriety Bias, which can obscure genuine safety signals. A sudden, massive increase in reports may be an artifact of public attention rather than a new safety threat. Consequently, regulatory bodies and manufacturers should incorporate "media weighting" or time-series intervention

models when analyzing safety data during high-profile recalls, to distinguish between actual device failures and the noise generated by the notoriety of the event.

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Conflict of interest: none

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