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Correlations Between Management Behaviors and Financial Indicators with FDA Compliance Leading to Medicine Shortages

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Abstract

A series of Food and Drug Administration (FDA) interventions and enforcement actions against pharmaceutical manufacturers in the past 5-6 years led to medicine shortages in the United States.

- The manufacturing shortfalls made essential medicines unavailable for the treatment of patients.
- Manufacturing shortfalls implied that quality management and manufacturing systems were not empowered or adequately staffed to support the critical functions of the pharmaceutical firms.

Problem

The general problem investigated in this study was a significant increase in the number of pharmaceutical firms cited for noncompliance with federal quality guidelines.

- In the first three years of the Obama Administration, the number of warning letters issued to pharmaceutical firms for manufacturing and quality problems increased to 49 letters. (Nguyen, Seoane-Vazquez, Rodriguez-Monguio, & Montagne, 2013).
- In comparison, the FDA only issued nine warning letters in the last three years of the George W. Bush Administration (Nguyen, Seoane-Vazquez, Rodriguez-Monguio, & Montagne, 2013).
- In a letter dated October 31, 2011, the FDA indicated that about 54% of drug shortages were a result of manufacturers' quality issues (FDA, 2011).
- The lack of compliance with Current Good Manufacturing Practices (CGMP) led to pharmaceuticals manufacturing facility closures, loss of revenues, certain penalty fees, loss of reputation, and significant investments to address remediation of their non-conformances to the FDA regulations. (Asotra, Cossin, & Yacobi, 2012).

Purpose

Determine to what extent, if any, management behavior and financial indicators were correlated with the compliance of FDA regulations leading to medicine shortages.

Relevant Literature

- The level of sustainability depends on the degree of change that management embraces and accepts (Asotra, Cossin, & Yacobi, 2012).
- As emphasized by Woodcock (2012), manufacturing shortfalls implied that quality management and systems were not empowered or properly staffed.
- Historical trends of drug shortages represented an increase from 61 shortages in 2005 (Barlas, 2014) to 251 shortages in 2011 (FDA, 2013).

Theoretical Framework

The **theory of planned behavior** (TPB) was used to frame the behaviors of the pharmaceutical managers (Ajzen, 1991).

- Central point of TPB -- a direct relationship between intention and actual behavior.
- TPB highlights -- behavior could be explained and behaviors are not difficult to predict.

For this study, the intention of management to comply with the regulations of the FDA, as well as with the financial limitations, created an excellent scenario to examine with the TPB.

Research Questions

RQ 1: To what extent, if any, do management behaviors correlate to compliance with FDA regulations at the pharmaceutical firms in the USA?

RQ 2: To what extent, if any, do financial indicators correlate to compliance with FDA regulations at the pharmaceutical firms in the USA?

RQ 3: To what extent, if any, do financial indicators impact compliance with FDA regulations at the pharmaceutical firms in the USA?

Procedures

I selected to conduct a quantitative study.

- correlations
- regression line analyses

Study Variables

- Independent Variables: Management Behaviors and Financial Indicators
- Dependent Variable: Compliance with FDA Regulations
- Treatment: FDA Intervention
- Scenarios: Pre-FDA and Post-FDA Intervention

Participants

- 1144 members of the International Society of Pharmaceutical Engineers (ISPE) with job titles representing management positions.
- Participants from public pharmaceutical companies in the United States.

Data Collection

The complete responses from 21 participants through 133 Likert-type scales and scaled ranges were the input to the data analysis.

Data Analysis

Correlations, aggregate comparison and Cronbach's alpha were utilized. ANOVA, *t* tests, Durbin-Watson statistics, and collinearity statistics supported the examination of the assumptions to establish the generalization of the findings.

Findings

- The FDA intervention had a favorable influence on the participants' behaviors increasing the level of compliance.
- The TPB provided linear regression models to predict behavior reinforcing that management could modify behaviors to enhance future compliance.
- Behaviors and financial indicators correlated with compliance of the firm with the FDA regulations.
- The financial indicators contributed to the impact on compliance in the regression model only during the Pre-FDA intervention.

Limitations

- Only 21 out of 1144 ISPE invitees completed the survey, possibly due to apathy for surveys, internet firewalls, and the sensitivity of the topic of compliance in the pharmaceutical industry.
- The length of the survey with 133 questions also impacted the participation.

Conclusions

Consumer

Having a high level of compliance with the FDA regulations reduces investments and compliance expenses minimizing interruptions in the supply of essential pharmaceutical drugs.

Stockholders

The significant correlation between stockholders' equity and compliance, in both pre-FDA and post-FDA interventions, signaled the relevance of the firm's compliance and the investors' expectations.

Management

The behaviors and the decision-making processes of the pharmaceutical manager could reinforce the presence of effective quality systems eliminating or minimizing medicine shortages.

Pharmaceutical Firm

The lack of compliance could impact the reputation and the performance of the firm negatively.

Social Change Implications

- The main potential social impact was to avoid having medicine shortages.
- The risk of affecting the patient health could be minimized or eliminated by avoiding medicine shortages.
- The study was directed to encourage managers of pharmaceutical organizations to operate and behave with a clear approach to compliance.

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