Pharmaceutical product recall in China: challenges and negative public perceptions mitigations

Baoyang Ding (b.ding@sussex.ac.uk)
University of Sussex, School of Business, Management and Economic

Jia Fang
Shandong University, School of Health Management

Abstract

A pharmaceutical product recall is a systematic process that highlights a dangerous situation that requires timely and effective action to protect the public from harm. Through semi-structured interview and secondary recall data, this study provides an in-depth insight of the current drug recall situation in China. The social media facilitate pharma companies to conduct more proactive and responsive actions to solve recall events and in turn providing more transparent information to the publics. To conduct more effective recall, the awareness of recall, traceability of end users and the lack of regulations to encourage end-users to participate in recall are the main challenges to be addressed.

Keywords： Pharmaceutical product recall, public perception, challenges

Introduction

The number of pharmaceutical product recall events increased after 2004 due to the more strict regulations (Hall et al., 2016). The attention and spread of public recall events directly affects consumer attitudes, but also leads to significant impacts on corporate image and reputation (Lee et al., 2015; Hsu and Lawrence, 2016). If the drugs result in life-threatening consequences, pharmaceutical manufactures risk massive financial loss due to compensations and lawsuits, rather than the direct costs of collecting defects from distributors and end-customers (Chen et al., 2009; Thirumalai and Sinha, 2011). Thus, implementing pharmaceutical product recall plays a pivotal role for consumers, pharmaceutical manufacturers and the whole pharmaceutical industry. Pharmaceutical product recall ensures patients can obtain safe medication and protects the consumers' legal rights by controlling the utilisation and expansion of defective medicines (Nagaich and Sadhna, 2015).

A crucial issue within the pharmaceutical recall process is to understand the public perception of product recall rather than just altering the reality of the product-harm crisis (Ketchen et al., 2014; Hsu and Lawrence, 2016). Although there is an extensive

literature that illustrates how product recall events influence the focal company and stakeholders, there is a minimal effort to investigate on how to alleviate the negative impacts (see Zavyalova et al. 2012; Ni et al., 2014). A better matched response strategy will lead to more positive post-crisis public perceptions. In this manner, the prevalent social media (i.e. Facebook, Twitter, WeChat, etc.) offer pharma companies a timely, direct and interactive communication forum with the public and demonstrate their competence in handling the crisis. On the other hand, the focal company cannot completely control all information due to the inherent open and interactive feature of social media (Lee et al., 2015).

A pharmaceutical product recall is a systematic process that highlights a dangerous situation that requires timely and effective action to protect the public from harm. Therefore, the main purposes of this study are to investigate:

1) What are the influences on recall management caused by the social media;
2) What challenges are existed in current recall management system;
3) How pharmaceutical companies choose appropriate countermeasures to mitigate negative public perceptions through social media post drug recall.

The paper is organised as follows: the literature review containing factors influencing recall strategies, risk mitigations and related theories are explained in Section 2. The the methodology of this study is described in Section 3. Section 4 outlines the findings based on the interviews and secondary recall data from Chinese CFDA. Finally, Section 5 presents the limitations and contributions of this research.

Literature review

Given the serious impacts on companies, investors and consumers, recent researches investigate how to mitigate the negative impacts caused by product recalls. In the context of the pharma industry, based on the recall event of the Japanese drug Maalox®, Kuroyama (2003) analyses the time spent on different entities and the cost during the recall process, and suggests that it is crucial to establish a perfect information system that can ensure the information flow exchange among different participants and thus reduce the recall costs and also enhance the efficiency of recalls. In addition, Kumar et al. (2009) conduct a qualitative research focusing on how to manage risks during drug recall processes. They utilise the DMAIC (define, measure, analysis, improve and control) process to establish a framework that directs the responsibility of different actors in the pharmaceutical recall system. According to this research, transparent and effective communication flow is crucial for preventing potential miscommunication and perception errors.

With the exception of the pharma industry, the management scholars conducted some research on other industries. For example, Ni et al. (2014) indicate that the retailers that employ a refund remedy strategy experience greater negative financial impacts than those who use a product exchange or repair strategy, which is in line with the research of Davidson and Worrell (1992). Alternatively, Zavyalova et al. (2012) illustrate that technical actions contribute more to reducing negative media coverage of the firm involved in recall events, while ceremonial actions are more effective at reducing the negative spill-over effect for innocent companies in same industry. Although the

existing studies investigate the effectiveness of certain strategies in certain crisis conditions (i.e. Coombs and Holladay, 2009; Claeys et al., 2010; McDonald et al., 2010), they all use scenario-based experiments rather than testing the response strategies in the real world product recall crisis issues.

In addition, extant researches mainly centre on durable products (i.e. consumer products, automobile, toys, electronic products, medical devices, etc.) and inadequate researchers focus on perishable products (i.e. food, pharmaceutical products, etc.). For the pharmaceutical industry, the majority of the research investigates the tangible impacts on shareholder wealth and financial performance through the event-study method (see i.e. Dowdell et al., 1992; Dranove and Olsen, 1994; Cheah et al., 2007). Therefore, the research about pharmaceutical product recall is still incomplete.

To understand how public perceptions of pharmaceutical product recalls are generated, there are two theories have been demonstrated suitable for product recall processes. First, the Attribution Theory explains how individuals make causal attributions for the events, products or services they experience (Heider, 1958; Folkes, 1984; Weiner, 1986). Developed by the two dimensional factors (internal, external) proposed by Heider (1958), Weiner (1980) established a model to predict individual attribution of causality based on three dimensions: locus, controllability, and stability. Locus means the causes of an event are internal or external. Controllability refers to whether the causes of the event are controllable or not. Stability refers as whether the causes of the event are occasionally or temporary, or are stable and permanent (Folkes, 1984; Weiner, 1986; Coombs and Holladay, 1996). This theory was used to investigate the perception of the crisis responsibility of product quality failures or product harm events in management researches (Folkes, 1984; Siomkos, 1999; Klein and Dawar, 2004; Commbs, 2014). In particular, Coombs (2007) illustrates that the three dimensions of the Attribution Theory shows significantly high predictive validity for analysing unexpected and negative outcomes of the product recall process. Rooted by the Attribution Theory, Situational Crisis Communication Theory (SCCT) was developed by Coombs's (1995) prior research. He concentrates on how crisis managers can select appropriate response strategies fitting specific crisis situations in order to manage organisational reputation. Based on the SCCT (Coombs and Schmidt, 2000; Coombs, 2007), the level of crisis responsibility leads to a direct impact on public perception of the firm's reputation. When the public have higher level attributions of crisis responsibility, they tend to develop negative impressions of the organisation involved in the crisis, which in turn directs the future behaviours and actions of the public towards the firm (Coombs and Holladay, 1996). The perceptions of crisis responsibility are proven to be adjusted by two factors: severity and crisis history. However, these two theories have not been employed in pharmaceutical industry yet.

Methodology

To understand the pharmaceutical product recall more comprehensively, this study choose China, the second largest pharmaceutical market, as the objective. First, the drug recall data were collected from Chinese CFDA official website. These secondary archive data contains drug information, company information, recall time, reasons,

quality problems, batch information, corrective reactions and punishment. The time span of the recall data is from 2010 to present.

Semi-structured interviews reflected 'real world' issues which are not available in secondary sources. The preliminary study used qualitative data collected through semi-structured interviews, either in person or online. Sampling design for the study is based on the selection criteria such as 1) risk or consequences of recall; 2) Firm Size; 3) Products type including generic drugs or research-based new drugs; and 4) the function of supply chain member either manufacturer or distributors. As per the above sampling design, twelve interviewees from China were selected to collect evidence through semi structured interviews with either supply chain managers and/or quality managers. The open-ended interview outline includes five aspects: recall management systems: impacts of social media; influencing factors of public perceptions; mitigation strategies; challenges. Finally, the qualitative data were coded via QSR NVivo 11 software.

Findings

Summary of Chinese pharmaceutical product recall data

Compared with the USA and UK where published the drug recall in detail, Chinese recall data are not all published to the public. Since 2010, there were only 16 records of pharmaceutical product recall. Through screening the report of drug inspections from CFDA official website, we found another 56 recall events happened in the past four years. Unlike western countries, most records of product recall are mandatory recalls, while only seven of them were conducted voluntarily by involved companies. Among them, only one Chinese domestic organization implement voluntary recall, the remaining were all western companies (i.e. Bayer, GSK, Boehringer Ingelheim, Sandoz, etc.). The mandatory recall events were found by external stakeholders, such as randomly inspection by CFDA, routine inspection by local CFDA, complaints report by customers. Due to the complexity in herbal medicine production, 19 recall events were occurred in traditional herbal decoction pieces and Chinese patent drugs.

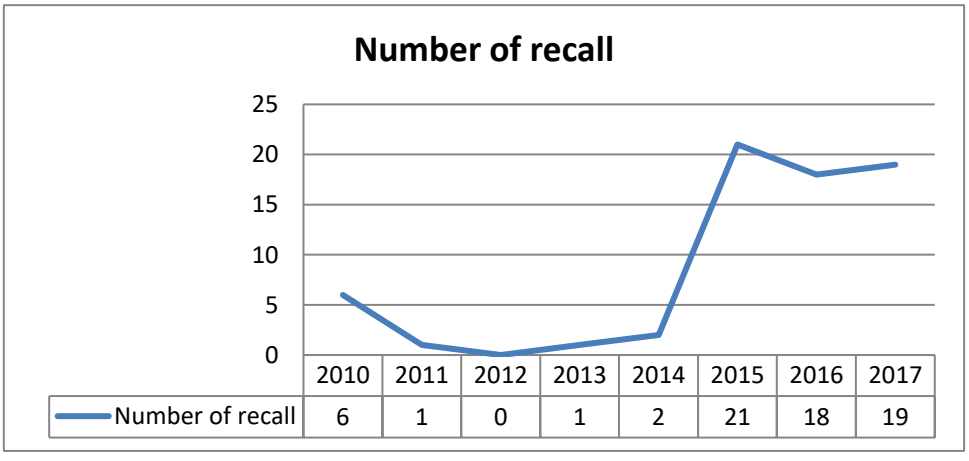

Figure 1 Number of recall happened every year in China (since 2010)

As shown on Table 1, the most common reason of pharmaceutical recall is data missing/fraud issues. According to the recall announcements and quality inspection reports, involved pharma companies deliberately missed records of important quality control point, and even changed the original data to meet quality standard of either raw material or final product test. The second largest reason is the non-observance of standard production procedures. Since pharmaceutical production procedures are approved before being launched, any tiny changes in production process need post-approval, which is both time-consuming and expensive. There are 19 events due to the changes of production procedures without approval by regulatory agent. They added unapproved materials, used disqualified manufacturing equipment and changed qualified person without permission. In addition, exceeding the standard of quality control test in production process is also common. Given most Chinese pharma manufacturers are still under batch-based production, the quality management is always off-line rather than the "on-line" test without disruption in continuous production. In the randomly inspection reports, the products from eight companies cannot meet the quality standards including stability, impurity, sterility, endotoxin, microbiology indicators. The other issue is raw material problems. Seven companies did not manage their raw material suppliers properly. They used counterfeit raw materials or defective raw materials to reduce cost, and the audit of supplier is ineffective. Besides, there is another reason "Good Manufacturing Practice (GMP) accreditation", which means companies manufacture drugs out of the scope of GMP accreditation, with expired GMP accreditation or even without GMP accreditation. The last reason is contamination, which is caused by cross contamination or production environment.

Table 1 The reasons of recall

Reason	Number
Data missing/fraud	25
Non-observance of standard production procedures	19
Exceeding standards of quality control test	12
Raw materials issues	7
Issue false invoice	4
GMP accreditation	3
Contamination	2

In terms of the punishment, the companies forced to mandatorily recall their defective products and companies voluntarily recalled their products were all punished by CFDA. As for mandatory recalls, the GMP accreditations of all involved companies have been abolished by CFDA. Meanwhile, the responsible persons were punished. The violation practices were investigated by judicial department. For voluntary recalls, although they would not be withdrawn the GMP accreditations, they still need to suspend production to rectification.

Current management system of product recall

Generally, the recall management systems in different companies were established based on the documents and guidelines including "Chinese CFDA management on drug recall", Chinese cGMP, EU GMP, US GMP, ICH Q7 and ICH Q9. Although not all interviewed companies experienced product recall before, they all have proactive management system to deal with product recall. The interview data inform that all companies conduct 'mock recalls' at least every two years to guarantee their recall system operate effectively. Although the "mock recalls" were only paper-based without returning the products from end-users, all procedures and time limits are completely consistent with the CFDA regulations. The virtual physical flows of several best-selling products are simulated within the mock processes, from manufacturer to distributors. All interviewees confirmed that the mock recalls can assist them to identify potential risks in recall management, and thereby continuing improving the weakness of recall management system. Under current circumstance, product recall is mainly operated by quality management department and supported by procurement, supply chain management, sales and customer service department. As a systematic process, recalls rely on the high level of coordination and communication between different entities within company and across the pharmaceutical supply chain. All interviewees state that the current recall system can satisfy the requirement of CFDA, no matter for time limit or traceability. The only thing is the support from downstream distributors. Given manufacturers lack sufficient control of second-tier distributors and end-retailers, the effectiveness of recall are highly depended on the support from these end users.

The impacts on recall management caused by social media

The evidence suggests that social media forced pharma companies to conduct more effective and timely response strategies to drug recall. All the companies been interviewed have independent departments (i.e. public relation department, information management department, customer service department) to collect and analyse the information from various social media platforms to analyse potential side-effects or other safety issues in a proactive way. Meanwhile, companies will more scrupulous for their actions, and with proactive awareness to understand their own problems. For example, one interview states that she obtains a disclosure of quality problems of the packaging material suppliers from Wechat, which thus assist her to start inspections on their products proactively and ensure the disqualified batch of packaging material will not influence the production. In addition, the other two interviewees also benefit from the social media, since they have a discussion group in which the quality managers from different companies will communicate the latest quality documents, notices and reports every day and thereby avoiding checking the CFDA official website.

It is noteworthy that one interviewee stated that the transparency of the information from social media helps customers to evaluate the responsibility of focal company more rationally. Typically, in China, drug recall is regarded as a disastrous event. Even once incident will penalise and make the company to stay out from the group medicine bidding list. Therefore drug recall is a serious issue for Chinese companies especially for products such as injection and blood product manufacturers which are always at high risk. To some extent, the diversified information from social media alters the

attitude of publics towards the companies that voluntarily recalled their defective products. Although the response speed will be faster, all interviewees deem that the complaints or pressure form social media will not affect their decision making for implementing a recall. They all believe that the quality is the only factor to be considered.

Influencing factors of public perceptions

According to the attribution theory and SCCT, we defined several factors may influence the public perceptions of a drug recall event. First we refer to the detection locus of recall as internal or external in accordance with whether defects occurred within the boundaries of pharmaceutical supply chain or not (Klein and Dawar, 2004). Second, we chose the controllability of recall, in which controllable causes refers to the pharmaceutical manufacturer that has the ability, but fails to prevent the defects from being exposed to customers, while uncontrollable causes means the pharmaceutical manufacturer is incapable of influencing the appearance of defective products. In addition, stability refers to whether the reasons causing product recall are likely to recur in the future. If the company provides a corrective action, whether causes are intentional or not, it manifests a "signal" that the company "intends to correct the situation" in order to prevent future occurrence of this defect. Besides, we choose crisis history, when a pharmaceutical company experiences similar product recalls, the public is prone to intensify negative evaluations of the company, which leads to more serious impacts on the company's corporate reputation and brand image. Last, the response strategy (denial, non-voluntary response, voluntary response) are selected.

Through brief scenario-based questions, the respondents provided their opinions about these factors. First, in terms of the detection locus, all respondents believe mandatory recall due to external inspections will generate more negative perceptions. For the second factor, controllable reasons will attract more negative perceptions. Since every step should be controllable in a good company, uncontrollable factors will lead to higher risks. Meanwhile, if the recall is caused by the focal company rather than suppliers or distributors, it will generate more negative public perceptions. Next, as for the stability, they believe companies with corrective actions will attract less negative public perceptions. In terms of the crisis history, it is a controversial factor. Most interviewees state that this depends on different situations. Two interviewees deem that unlike other industries, customers are not very familiar with the quality history of a pharma company, which means they cannot distinguish the differences due to the access to quality report data. One interviewee also claims that even if the company has high reputation of quality history, the product recall is still a disaster. The other respondent argues that if there is one product has been recalled several times, it means the chaotic quality management in that company, while the company that experienced slight quality problems in turn will identify the risks and thus improving their quality management system. Last, for recall strategy, despite that all respondents believe that voluntary recall will attract less negative perceptions, it is noteworthy that voluntary recall will still incur negative public perceptions due to the awareness of drug recall in China.

Mitigation strategies

First, company should take more active actions to publish the reasons of recall and explain the products, how company control the quality during manufacturing process and hazards of defective products. Second, company should enhance the disclosure of information thereby reducing the potential public panic caused by recall events. The countermeasures used by Chinese companies include establishing special risk management groups to communicate with the public, timely disclosure and clarification through both official social media platforms and SFDA or other third party authorities, stopping production to consolidate the plant, compensation, and cooperation with medical institutions to decrease clinical side-effects, etc.

If the safety issue is relatively minor, companies can implement actions to solve it. But when they consider the potential impact caused by halt production even for over one month, company feels panic to the mass media and social media. Two respondents state that a number of manufacturers tend to mitigate the impacts of defective products through withdrawing the products under the table rather than informing CFDA.

Challenges for recall management

Based on the feedbacks from twelve interviewees, we identified three main challenges. First, the recognition of product recall events in China is totally different from western countries. The understanding of publics and even governments still need to be improved. Not only the publics cannot understand the meaning of recall, but the downstream distributors and retailers also do not understand the regulations clearly, which thus inhibit the effective communications. Due to the specific situation of pharmaceutical production, mass media cannot understand the entire issue, and thereby exaggerating the facts to attract more focus and even distort the facts. The media cannot illustrate the facts of recall and even add fuel to the fire, which constrains companies to conduct product recall in a positive way. Therefore, most pharma company in China will work as “fire fighters”, and they have to avoid the negative impacts on them. Even for some foreign companies, they still consider these factors.

The second issue is traceability. Due to the specific distribution system, Chinese manufacturers can barely control the second-tier and third-tier distributors, albeit with the national electronic supervision code, which to some extent affects the response efficiency. The end-users, small clinics and small pharmacies still do not have enough equipment to guarantee the operation of electronic code. Although the internal collaboration and cooperation is not a problem in pharma companies, the unexpected factors from external stakeholders have great influence on recall implementation. Some end-use retailers do not cooperate with manufacturers, for instance, they do not provide the receipt of recall products or certificates of products. In this way, manufacturers’ ability to control distributors is still poor, which will affect the evaluation of recall speed.

In addition, the regulations of pharmaceutical product recall are still incomplete. One interviewee said that the regulation of recall process is clear, but the classification of recall is ambiguous. How to determine the class of recall is not very clear in the real-world operation, because the response time to recall is determined by the class of

recall (Class I 24 hour, Class II 48 hours, Class III 72 hours). Besides, as the development of drug distribution in China, the more strict regulation and formal operation will assist the management of downstream distributors. However, there is no shirking responsibility that distributors must try their best to complete the recall, given that the main responsible agent is manufacturers.

Conclusion

This research investigated the pharmaceutical product recall management in China through semi-structure interview and secondary recall data from CFDA official website. According to the recall data, most recalls occurred in China are mandatory recall forced by CFDA. Generally, the recall management is mainly operated by quality management department and supported by other departments within organization. Chinese companies arrange the routine "mock recall" to test the effectiveness of their recall management system and identify potential risks through this process. As the development of social media, the transparent information motivates pharma companies to response recall events more proactively and faster. Meanwhile, most Chinese companies built their own social media management team to collect the feedbacks and complaints from different platform and communicate with their customers more effectively. Under the social media circumstance, the recalls caused by controllable reasons, detected by external inspections and the main responsible body is the focal company will generate more negative public perceptions. To conduct more effective recall event, there are three main challenges to be addressed, which are recognition of recall events, traceability of end users and the lack of regulations encourage the engagement in recall events, especially for distributors and retailers.

In terms of the contributions, since existing studies investigate the effectiveness of certain strategies in certain crisis conditions (i.e. Claeys et al., 2010; Liu et al., 2011) all use scenario-based experiments, this research provides in-depth insights of the current drug recall situation in China. Second, given the unique nature of pharma supply chains and regulations, it is difficult to directly use experiences that have been obtained from other industries. Besides, this research fulfils the need for more mitigation approaches studies of product recall (Wowak and Boone, 2015). In addition, this study will also advance the Attribution Theory and Social-mediated Crisis Communication Model and help to validate these two theories in pharmaceutical industry. Future research will analyse the real-world data of public perceptions of drug recall event from social media platforms and investigate how to choose appropriate strategy to mitigate negative public perceptions in different conditions.

References

Claeys, A.S., Cauberghe, V. and Vyncke, P. (2010), "Restoring reputations in times of crisis: An experimental study of the Situational Crisis Communication Theory and the moderating effects of locus of control", *Public Relations Review*, *36*(3), pp.256-262.

Coombs, W.T. and Holladay, S.J. (1996), "Communication and attributions in a crisis: An experimental study in crisis communication", *Journal of public relations research*, *8*(4), pp.279-295.

Coombs, T. and Schmidt, L. (2000), "An empirical analysis of image restoration: Texaco's racism crisis", *Journal of Public Relations Research*,*12*(2), pp.163-178.

Coombs, W.T. and Holladay, S.J. (2001), “An extended examination of the crisis situations: A fusion of the relational management and symbolic approaches”, *Journal of Public Relations Research*, *13*(4), pp.321-340.

Coombs, W.T. (2007), “Protecting organization reputations during a crisis: The development and application of situational crisis communication theory”, *Corporate Reputation Review*, *10*(3), pp.163-176.

Coombs, W.T. (2014), “*Ongoing crisis communication: Planning, managing, and responding”*, Sage Publications.

Davidson, W.N. and Worrell, D.L. (1992), “Research notes and communications: The effect of product recall announcements on shareholder wealth”, *Strategic management journal*, *13*(6), pp.467-473.

Dowdell, T.D., Govindaraj, S. and Jain, P.C. (1992), “The Tylenol incident, ensuing regulation, and stock prices. *Journal of Financial and Quantitative Analysis”*, *27*(02), pp.283-301.

Dranove, D. and Olsen, C. (1994), “The economic side effects of dangerous drug announcements. *The Journal of Law and Economics”*, *37*(2), pp.323-348.

Folkes, V.S. (1984), “Consumer reactions to product failure: An attributional approach”, *Journal of consumer research*, 10(4), pp.398-409.

Heider , F. (1958), “The Psychology of Interpersonal Relations”, Wiley, New York .

Hall, K., Stewart, T., Chang, J., and Freeman, M. K. (2016), “Characteristics of FDA drug recalls: A 30-month analysis”, *American Journal of Health-System Pharmacy*, *73*(4), pp.235-240.

Hsu, L. and Lawrence, B., (2016). The role of social media and brand equity during a product recall crisis: A shareholder value perspective. *International Journal of Research in Marketing*, *33*(1), pp.59-77.

Ketchen, D.J., Wowak, K.D. and Craighead, C.W. (2014), “Resource Gaps and Resource Orchestration Shortfalls in Supply Chain Management: The Case of Product Recalls”, *Journal of Supply Chain Management*, 50(3), pp.6–15.

Klein, J. and Dawar, N. (2004), “Corporate social responsibility and consumers' attributions and brand evaluations in a product–harm crisis”, *International Journal of research in Marketing*, *21*(3), pp.203-217.

Kumar, S., Dieveney, E. and Dieveney, A. (2009), “Reverse logistic process control measures for the pharmaceutical industry supply chain”, *International Journal of Productivity and Performance Management*, 58(2), pp.188-204.

Kuroyama, Y. K., (2003), “Medical Institutions, Response and the Volume of Work Related to the Recall of Pharmaceutical Products from the Market”, *Japanese Journal of Pharmaceutical Health Care and Science*, 29(3), pp.287-293.

Lee, L. F., Hutton, A. P., and Shu, S. (2015), “The role of social media in the capital market: evidence from consumer product recalls”, *Journal of Accounting Research*, *53*(2), pp.367-404.

Liu, B.F., Austin, L. and Jin, Y. (2011), “How publics respond to crisis communication strategies: The interplay of information form and source”, *Public Relations Review*, *37*(4), pp.345-353.

Ni, J.Z., Flynn, B.B. and Jacobs, F.R. (2014), “Impact of product recall announcements on retailers′ financial value”. *International Journal of Production Economics, 153,* pp.309-322.

Siomkos, G.J. (1999), “On achieving exoneration after a product safety industrial crisis”, *Journal of Business & Industrial Marketing*, *14*(1), pp.17-29.

Weiner, B. (1986), “An attributional theory of achievement motivation and emotion”, In *An attributional theory of motivation and emotion* (pp. 159-190). Springer US.

Wowak, K.D. and Boone, C.A. (2015), “So many recalls, so little research: a review of the literature and road map for future research”, *Journal of Supply Chain Management*, *51*(4), pp.54-72.