Evaluating the Center for Drug Evaluation and Research Drug Recall Trend from January 2018 to August 2023

USC Mann
Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences

Se Jin Park, PharmD, MS Candidate in Regulatory Science
Project Advisor: Dr. Eunjoo Pacifici, PharmD, PhD

Project #797

OBJECTIVES

- To review and identify the drug recall trend and compare with previous studies.
- To evaluate the recall termination status.

BACKGROUND

- Drug recall is an essential tool for keeping the public safe from potentially dangerous products.
- A recall can be mandated by the Food and Drug Administration (FDA) or voluntarily initiated.
- Recalls are terminated when the FDA determines that appropriate corrective actions are performed.
- Recalls are categorized into three different recall classifications (Class I, II, and III), with Class I representing those with the highest risk (serious health problems or even death).
- FDA updates the recall status utilizing the Enforcement Report to track on a weekly basis and displays recall information (termination status, recall reason, product quantity, risk classification, recall method, distribution pattern, recall initiation date, classification date, and termination date).

METHODS

- Weekly FDA Enforcement Reports were downloaded and compiled from January 2018 to August 2023.

All reports (Biologics, Cosmetics, Devices, Drugs, Food, Tobacco, Veterinary) **N = 38,629** → Filtered recall reports (Drugs only) **N = 7,955** → Filtered terminated drug recall reports **N = 5,306**

- Recall information were categorized and grouped for analysis.

RESULTS

- 10 countries were involved in the recall process.
- 7,893 recalls were voluntarily done, 29 recalls were enforced by the FDA, and 33 recalls were not classified.
- Initial notification methods included e-mails, letters, press releases, telephones, and other methods.
- Over 500 recalling firms were involved in the process.
- 64% of US (nationwide or part of the US), 100% of Non-US (foreign country(s)), 81% of worldwide, and 57% of unknown distributions were terminated.
- 66% of recalls due to adulteration (CGMP deviation, potency discrepancies, packaging/product problems), 83% due to labeling (any issues to with labeling), and 77% due to regulatory deviation (marketed without an approved NDA/ANDA) were terminated.

RESULTS, CONT.

Figure 1. Drug recall status comparison from January 2018 to August 2023

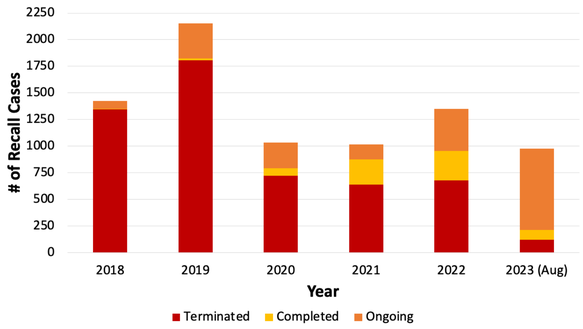


Figure 2. Monthly drug recall trend (combined years from January 2018 to August 2023)

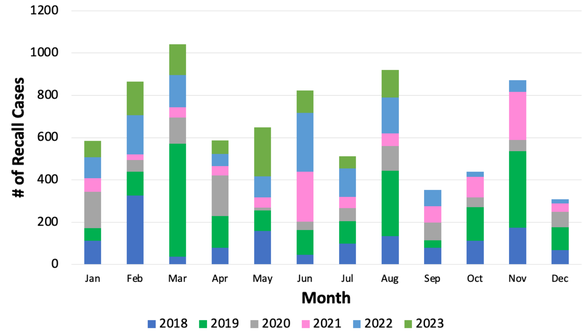


Figure 3. Drug recall classifications (comparison of terminated and non-terminated drug recalls)

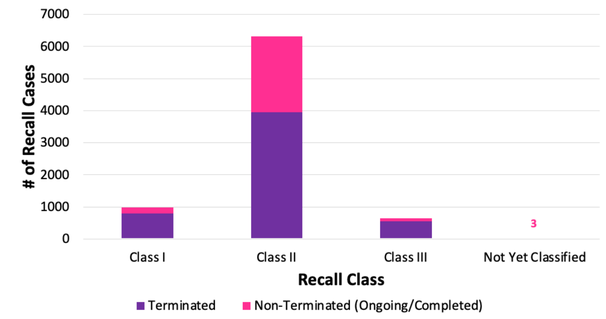


Figure 4. Drug recall distribution pattern (comparison of terminated and non-terminated drug recalls)

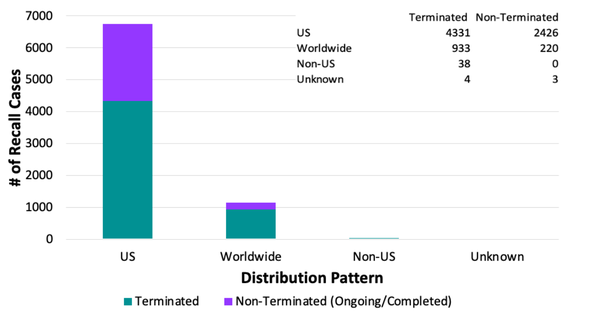


Figure 5. Drug recall reason (comparison of terminated and non-terminated drug recalls)

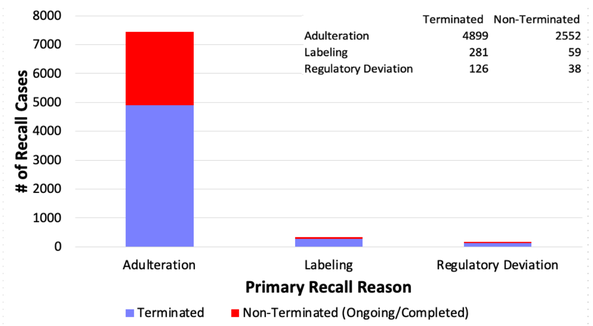
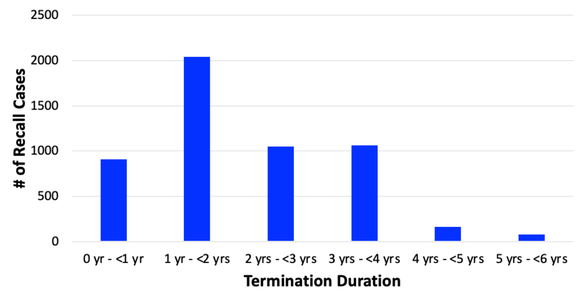


Figure 6. Drug recall termination duration pattern



CONCLUSION & FUTURE RESEARCH

- The drug recall trend analysis from various years (2004 to 2011, 2012 to 2014, 2016 to 2018, 2009 to 2019, and this study) indicates that the most common recall reasons are adulteration and mislabeling.
- Over the past years, adulteration remains to be the most common reason for drug recall and the challenge that pharmaceutical companies need to address and correct.
- This project will be further conducted to analyze more information on the drug recall including product formulation, route of administration, prescription vs non-prescription, and type of distributors/ manufacturers.
- This project may potentially include a larger data set for a more complete trend analysis.

LIMITATION/DISCLAIMER

- Data categorizations and analysis are based on the author's interpretations of the FDA Enforcement Reports.

REFERENCES

1. FDA's Role in Drug Recalls. FDA. https://www.fda.gov/drugs/drug-recalls/fdas-role-drug-recalls. Updated September 29, 2023. Accessed September 7, 2023.
2. Wang B, Gagne JJ, Choudhry NK. The epidemiology of drug recalls in the United States. *Arch Intern Med*. 2012;172(14):1109-1110. doi:10.1001/archinternmed.2012.2013
3. Hall K, Stewart T, Chang J, Freeman MK. Characteristics of FDA drug recalls: A 30-month analysis. *Am J Health Syst Pharm*. 2016;73(4):235-240. doi:10.2146/ajhp150277
4. Eissa M. Drug recall monitoring and trend analysis: a multidimensional study. *Global Journal on Quality and Safety in Healthcare*. 2019;2(2): 34-39. doi.org/10.4103/JQSH.JQSH_3_19
5. Gollamudi, V. Review of drug and biologics recalls: 2009 through 2019. *Eastern Michigan University*. 2020. https://commons.emich.edu/cgi/viewcontent.cgi?article=2425&context=theses. Published July 7, 2020. Accessed September 7, 2023.
6. Enforcement Reports. FDA. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports. Updated December 12, 2022. Accessed September 7, 2023.
7. Enforcement Report Information and Definitions. FDA. https://www.fda.gov/safety/enforcement-reports/enforcement-report-information-and-definitions. Updated May 12, 2023. Accessed September 7, 2023.

ACKNOWLEDGEMENT

- Special thanks to Dr. Eunjoo Pacifici for supporting this project.