Analysis of FDA-issued warning letters for fraudulent claims within the economic, clinical, and humanistic outcomes (ECHO) framework

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INTRODUCTION

- Amid the COVID-19 pandemic, a plethora of products emerged claiming to prevent, treat, mitigate, or cure the virus. However, many manufacturers have been found to make false and misleading claims about their products.
- The U.S. Food and Drug Administration (FDA) Office of Prescription Drug Promotion (OPDP), plays a crucial role in regulating pharmaceutical labeling and advertising. To safeguard consumers, the FDA swiftly issued warning letters (WLs) to manufacturers for making fraudulent claims regarding COVID-19.
- The purpose of this study was to analyze FDA-issued warning letters (WLs) from March 2020 to September 2023 directed at pharmaceutical manufacturers for making false or misleading claims regarding products intended to mitigate, prevent, treat, diagnose, or cure COVID-19.
- This study employed a content-analysis approach, focusing on these WLs within the economic, clinical, and humanistic outcomes (ECHO) framework.

METHODS

- All WLs available on the FDA website until September 2023 were systematically obtained. A data collection form (DCF) was developed based on relevant literature, and it was pilot tested on WLs issued in March 2020.
- Two researchers (DU and SA) independently applied the verified DCF to analyze WLs, collecting information such as product details, company name, promotional media type, target audience, number of violations, corrective actions taken, and current product status.
- Agreement between the two researchers was determined by kappa statistic of 80% or higher.
- Discrepancies between the researchers were resolved through discussion with two additional researchers to ensure consensus.
- Edits were made to the DCF as needed, and the final DCF was used to analyze the remainder of the warning letters.

RESULTS

- Between March 2020-September 2023, there was a total of 227 WLs. Out of those claims, we evaluated 218 post-pilot. Of these 218, 36 claims contained product images within the FDA-Warning Letter, yielding a percentage of 16.5% with product images. There were 182 warning letters that did not contain product images: yielding a percentage of 83.5%.
- Figure 1 shows categories of the products. The majority of products in these WLs were drugs (n=140; 64.2%), followed by medical devices (n=52; 23.9%), food and beverages (n=14; 6.4%), dietary supplements (n=7; 3.2%), and others (n=5; 2.3%).
- Approximately 45.2% of WLs reported claims on social media platforms and websites and about 44.2% of WLs reported claims on website. (Figure 2).

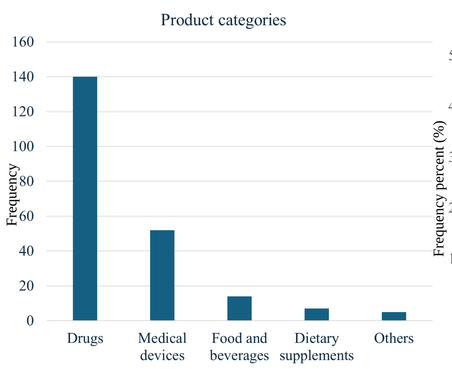

Figure 1. Product categories

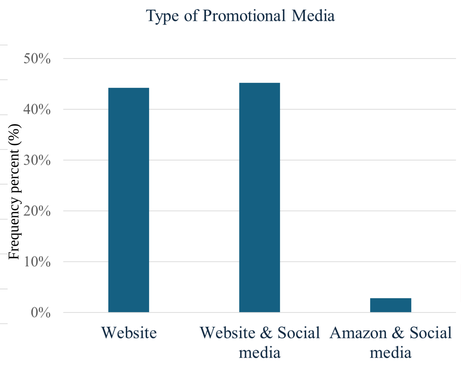

Figure 2. Type of promotional media

- Nearly, all products (n=211; 96.8%) targeted consumers, with four products (1.8%) targeting both consumers and health providers. (Table 1)

Table 1. Product categories

	Frequency	Percent (%)
Consumers	211	96.8
Consumers & Healthcare providers	4	1.8
Others	3	1.4
Total	218	100

- On average, each WL documented 5.0±3.5 violations (range: 0-21).

RESULTS (cont'd)

- Clinical outcome claims accounted for the majority (n=212; 97.2%) of the 218 fraudulent claims, followed by humanistic (n=34; 15.6%) and economic outcomes (n=20; 9.2%). Some claims fell under multiple outcome categories. (Figure 3)

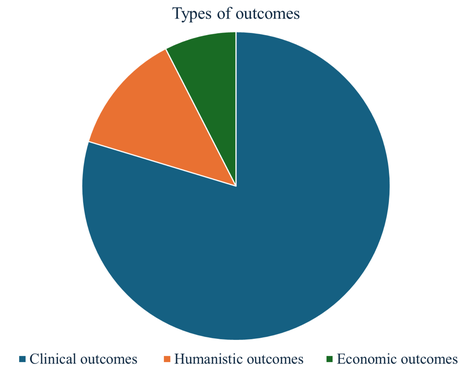

Figure 3. Types of outcomes reported

- The majority of manufacturers (62.8%) receiving WLs took corrective action.

DISCUSSION

- The most frequently reported outcomes were clinical outcomes followed by humanistic and economic outcomes.
- According to the FDA, of the companies who were issued a WL, more than half of those companies were found to have taken corrective action following the issuance of a WL. This shows a responsible behavior on the part of the drug manufacturers in protecting consumer health. Currently, n=130 (60%) products in the letters are sold without COVID-19 claims.

CONCLUSION

- This study revealed COVID-19 related fraudulent and unproven claims included in the warning letters issued by the FDA. Protecting consumers from products with such claims is crucial to promote consumer safety during the COVID-19 pandemic. Particular caution is needed, especially concerning clinical outcomes.