A Review of COVID-19-Related Food and Drug Administration Warning Letters

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BACKGROUND

- While the United States grapples with the COVID-19 pandemic, the Food and Drug Administration (FDA) continues to exercise its authority to protect the public health and well-being through a variety of COVID-19-related activities, including issuing guidance for vaccine development, creating the Coronavirus Treatment Acceleration Program, and monitoring for marketing information with fraudulent claims.
  - The FDA is particularly concerned with fraudulent products claiming to cure, treat, or prevent COVID-19 that have not been evaluated by the FDA for safety and efficacy; these claims may cause Americans to delay or stop appropriate medical treatment, leading to serious life-threatening harm.[1]
  - As the public spends more time online during quarantine and stay-at-home orders, the potential for exposure to these misleading or false claims has increased.
- To date, only 1 product has been approved by the FDA for the treatment of COVID-19.[2] However, many companies are advertising herbal products and dietary supplements as potential treatment options.
- The advertising of unapproved and misbranded products poses a significant threat to the public health and has led to a significant rise in FDA warning letters (WLs) issued in response to false and misleading claims for products intended to treat, prevent, or cure COVID-19.[3]
- There is a need to review and evaluate these WLs to understand the false information being advertised to and consumed by the public.

AIM

- This study evaluated the body of violations issued by the FDA and characterized the false and misleading claims that were made related to COVID-19.

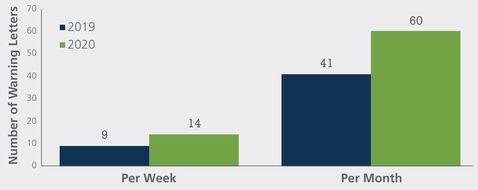
METHODS

- WLs from a 3-month time period early in the pandemic (ie, March 1, 2020 to June 1, 2020) were obtained from FDA.gov. Similarly, counts were also generated for the number of letters issued by the FDA over this same time period in 2019. These data are presented descriptively and only for context; no statistical comparisons were made.
- Letters from 2020 were extracted and analyzed to determine if they were COVID-19-related.
- Data extracted from each letter included date of issuance, product category, specific product advertised, number of claims flagged, and dissemination platforms.

RESULTS

- A total of 179 letters were issued by the FDA during the 3-month time frame. For context, in 2019, only 123 FDA WLs were issued during this same time frame.
- As depicted in **Figure 1**, on average, 14 WLs were issued per week and 60 WLs per month. The number of letters issued per week and per month increased substantially from the previous year (9 and 41, respectively).

Figure 1. Warning Letters Issued Over the Same 3-Month Period in 2019 and 2020



- On average, 6 claims were flagged per letter.
- Of the 179 total letters issued, 39% (N=70) were for false and misleading claims related to products for COVID-19; all of these were issued in relation to unapproved and misbranded products for COVID-19 (eg, products for sale intended to mitigate, prevent, treat, diagnose, or cure COVID-19).
- The Center for Drug Evaluation and Research issued 65 (93%) of the COVID-19-related letters during this time frame. The Center for Food Safety and Applied Nutrition and the Center for Biologic Evaluation and Research issued 4 (6%) and 1 (1%), respectively.
- Roughly 43% (6/14) of letters issued per week were COVID-19-related (**Figure 2**).
- The most cited products for violations were herbal products (30%), dietary supplements (29%), and CBD products and essential oils (11%, each) (**Figure 3**).
- Other products cited in the WLs included: soaps, vaccines, salt therapies, and antiseptics.

Figure 2. All and COVID-19-Related FDA Letters Issued During Study Period

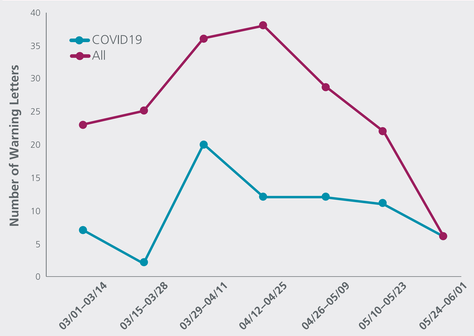
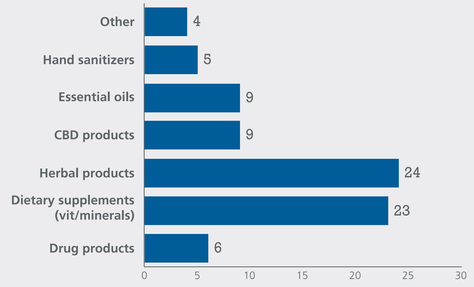


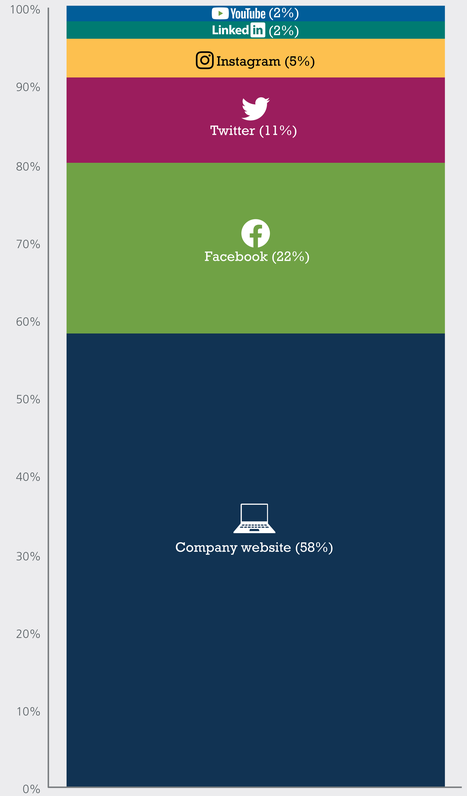
Figure 3. Categories of Products Cited in FDA Warning Letters



Letters: N=70
Products: N=74
Note: Some letters flagged >1 product/letter.

- A total of 120 dissemination platforms were cited for false or misleading claims across the 70 FDA letters.
- Each WL was issued to a different company. In total, 34 of the 70 companies identified in the WLs were cited for false or misleading claims on ≥2 sites and/or platforms.
- The most commonly cited dissemination platforms for the claims were company websites (58%), Facebook pages (22%), and Twitter accounts (11%) (**Figure 4**).

Figure 4. Dissemination Platforms Cited in FDA Letters



LIMITATIONS

- *Date of Issuance and Date Posted:* The total number of letters collected during the time frame of the study may not be all-inclusive. The letters issued by the FDA are not posted in chronological order and the agency updates their website daily; the results reflect all letters posted from March 1, 2020 to June 1, 2020. If any letters were issued during this time period but posted to the FDA website after June 1, 2020, they were not captured in this review.
- *Claims Cited in Letters:* Although the FDA cited specific claims made by the companies in each letter, the agency also included a disclaimer that this was not an all-inclusive list of claims that may have been made in relation to their products. As such, the results reported here are likely an underestimate of COVID-19-related false claims.
- Caution should be exercised in comparing the 2019 and 2020 data presented, as the results reported were only descriptive in nature; no formal statistical methods were employed to allow for more direct comparison.

CONCLUSIONS

- False and misleading claims related to COVID-19 can pose a considerable threat to public health.
- The uptick in COVID-19-related violations in the early part of 2020 underscores the need for and importance of robust and accurate medical information.
- As products are approved for the diagnosis and treatment of COVID-19, it is reasonable to anticipate that manufacturers of these products should expect high levels of vigilance and scrutiny of these claims.
- Future research on this topic could compare violations over the length of the pandemic to previous years to provide a more robust assessment of FDA enforcement activity specific to COVID-19.

REFERENCES

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3. FDA. Warning letters. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters. Accessed September 25, 2020.

Sponsorship: None.