

Quantitative Analysis of FDA Warning Letters Related to the Use of Social Media Sites in Misbranding Agents for COVID-19 Management



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Introduction

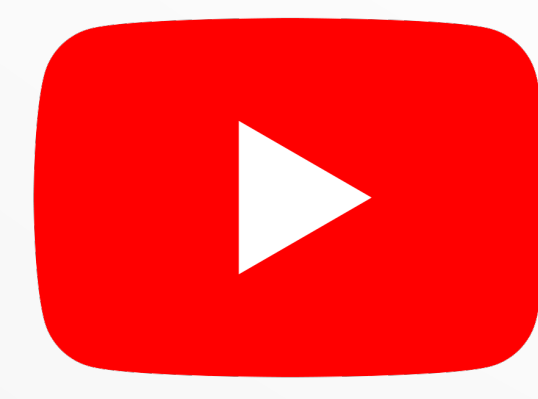
The dramatic growth of social media websites over the past two decades has created a platform for patients, providers, and pharmaceutical industry stakeholders to readily share information regarding healthcare and pharmacotherapy. In the context of Food and Drug Administration (FDA) approved agents, social media bridges the gap between patient and prescriber by educating the public on pharmacotherapeutic agents and increasing access to lifesaving medications. During the COVID-19 pandemic, the FDA noted a rise in the promotion and sale of misbranded products for the management of COVID-19 which held the potential to harm patients and challenged the integrity of the medical community. These products ranged from fake masks and harmful sanitizers to misbranded FDA approved agents such as ivermectin and chloroquine products.¹ This research focused on the misbranding of pharmaceutical agents for the management of COVID-19 on social media. The FDA typically sends warning letters to entities who violate the bounds of FDA regulations regarding manufacturing, advertising, adulteration, etc. and keeps a record of these letters in a public database on its website.² This study is an analysis of the amount of misinformation advertised on social media platforms related to therapeutic agents for the management of COVID-19, as represented by the quantity of warning letters related to various major social media sites. This research also seeks to examine the trends in warning letter issuance and COVID-19 cases among 18-29 year olds who encompass 84% of social media site users.²

Objectives

- Quantify warning letters issued to various entities regarding misbranding of products for the management of COVID-19 on social media sites and identify numerical trends.
- Compare the trends in warning letters involving social media to trends in COVID-19 cases among adults aged 18 to 29 years.

Methods

A full copy of the FDA database of warning letters was extracted on November 9, 2022. The entries ranged in date from January 2018 to November 2022 and were filtered to only include letters related to misbranding of pharmaceutical agents for COVID-19 on social media. The following terms were then searched for independently: "Facebook", "YouTube", "Twitter", and "Instagram". The results of each query was assessed and letters which fit defined exclusion criteria (related to illicit substances, medical devices, or not involving misbranding) were removed until only letters pertaining to products that are not approved for the management of COVID-19 remained for each social media website. The final list of entries was analyzed by date and social media site to ascertain which social media website contributed most to the spread of false/misleading information regarding agents for the management of COVID-19. We then graphed the rate of change of the issuance of included letters per quarter alongside COVID-19 case statistics for patients aged 18-29, from the second quarter of 2021 to the fourth quarter of 2022, to assess for the existence of a correlation between the two datasets.



Results

A total of 2798 Warning Letters were identified, of which 560 letters were written by the Center for Drug Evaluation and Research (CDER). Among the 560 CDER letters, 153 letters referenced COVID-19 in their subject. A total of 112 letters met all inclusion criteria. Twenty-five letters referenced multiple social media sites. The result of each respective social media search query, including overlaps, produced 53 letters related to Facebook, 18 letters related to Twitter, 24 letters related to YouTube, and 17 letters related to Instagram (See figure A). The number of letters issued related to each social media site was compared to the overall user base of each respective site to assess the relative abundance of COVID-19 misbranding between sites. Although Facebook had the most letters issued in the time period analyzed, Twitter had a larger proportion of letters relative to its user base.

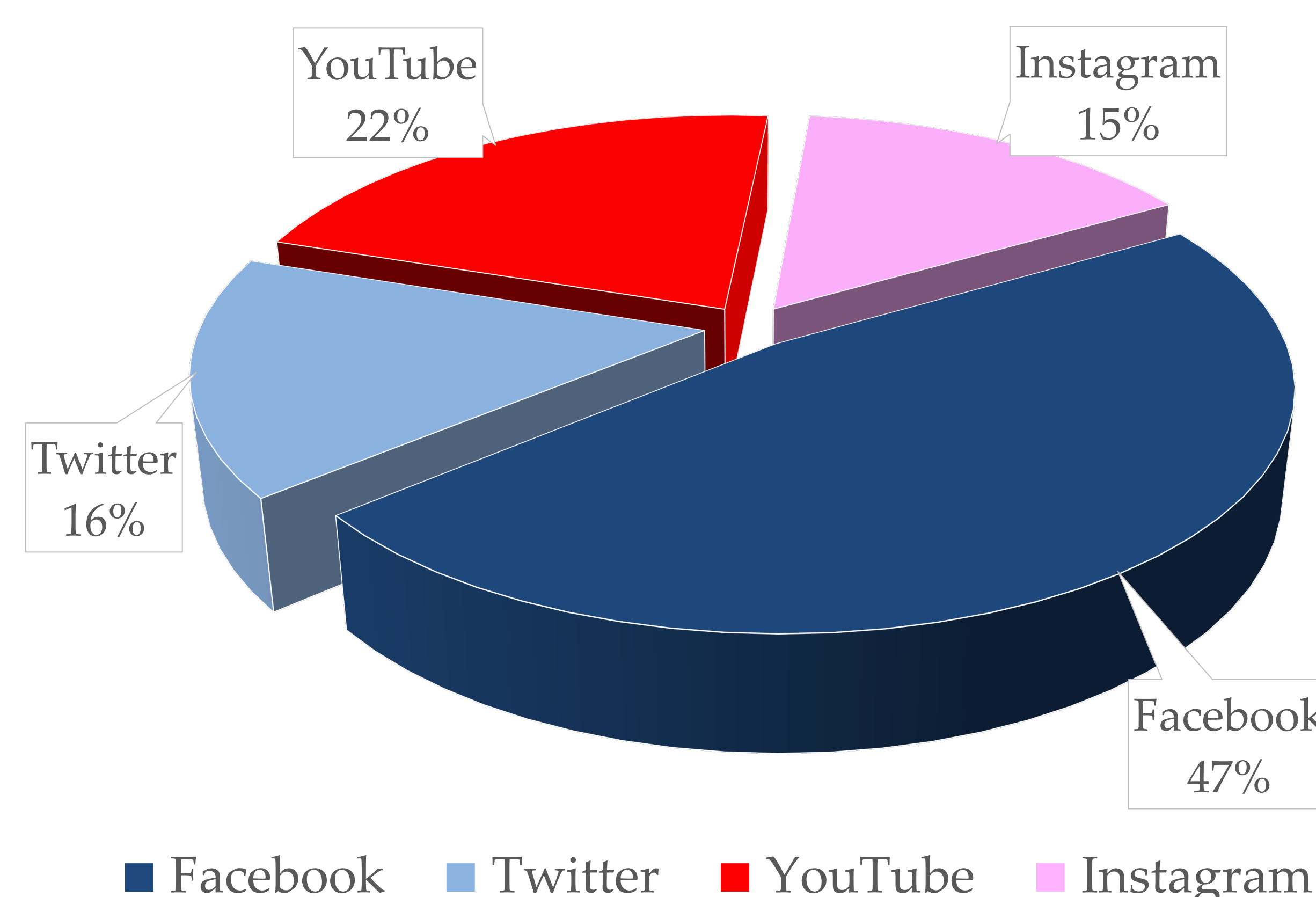


Figure A: COVID-19 Related FDA Warning Letters by Social Media Site

Figure B depicts the trend in COVID-19 cases among individuals between the ages of 18-29, per CDC databases⁴, in relation to the change in the rate of warning letters from the second quarter of 2021 to the third quarter of 2022.

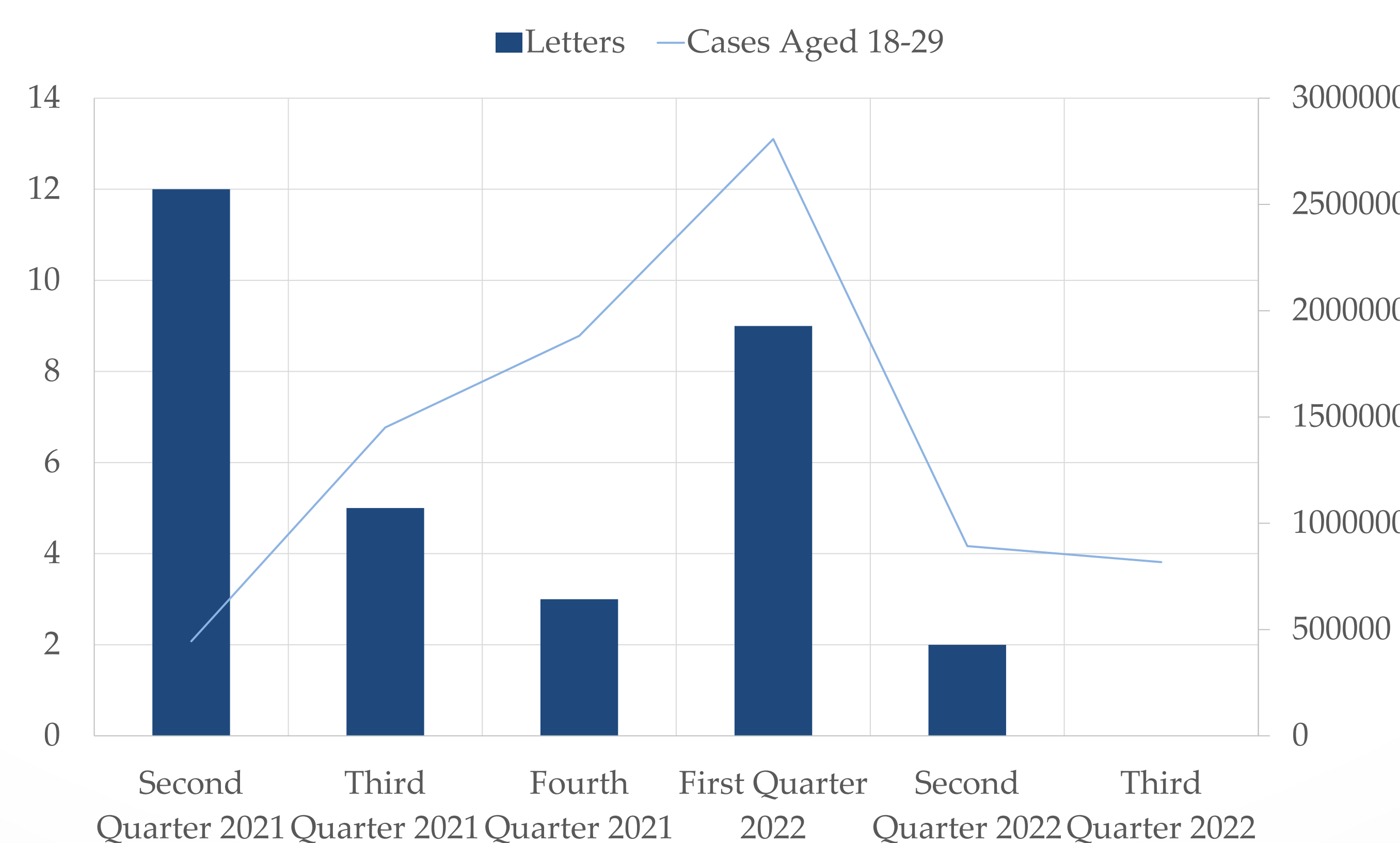


Figure B: Change in COVID-19 Cases amongst individuals between the ages of 18-29 in relation to the change in the number of included letters by quarter

Discussion

When depicted side by side the data reflects a few interesting trends: 1. the peak in letters issued by the FDA matches with a peak in the number of COVID-19 cases amongst the 18 to 29 year old population. 2. between the second quarter of 2021 and the fourth quarter of 2021 there was an inverse trend between the number of cases and the number of letters issued. As cases were increasing throughout that time period the number of letters was conversely decreasing. 3. In the third quarter of 2022 a sharp decrease in the number of COVID-19 cases among 18 to 29 year olds was also met with a sharp decrease in the number of letters issued by the FDA. The decline in letters could possibly be a reflection of sponsor self-policing, adequate FDA enforcement, shifting focus of FDA resources, social media site policy shifts, and improved content review, or other reasons. However, a major limiting factor to our ability to further evaluate the relationship between cases and warning letters in the earlier portions of the pandemic was the absence of age-specific COVID-19 case data prior to the second quarter of 2022. However, based on the trends seen with available data, one would expect to see a rise and fall of letters to, for the most part, parallel that of case load.

Conclusion

The data ultimately reflected that in light of widespread misinformation related to COVID-19 on social media, the FDA took an active approach in reducing the number of misbranded products being promoted on social media between January 2018 and November 2022. Although Facebook had the largest absolute number of related warning letters it also had the largest user base. Twitter was found to have the largest proportional number of related warning letters relative to its user base. This increase may be due to the limitations of Twitter including word count limitations. Future research can further elucidate the role of individual social media site policies and enforcement standards in impacting the amount of misinformation on a given platform. Although there are an abundance of factors which are related to the rise and fall of COVID-19 cases including vaccination rates, local policies and ordinances, mask use, comorbidities, etc., product misinformation posted on social media may play a role in COVID-19 case counts. Furthermore, the timing of posting product misinformation may also contribute to case counts, especially among 18-29 year olds who are the most common social media users. Additional research would be necessary to assess any relationship between social media product misbranding and COVID-19 case counts.

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