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US social media promotion violation trends in a postguidance era

Lisa Cooper, PhD, RAC • Mahmoud Ajaj • Karen Kopicko, MS, RAC

Social media platforms have enabled prescription drug and biologic industry sponsors (market application holders) to engage more actively with a broader range of consumers and healthcare professionals and have become an integral part of an effective marketing campaign strategy. This article discusses compliance violations cited for social media direct-to-consumer advertisements (DTCAs) as listed in warning and notice of violation (NoV) letters issued by the US Food and Drug Administration (FDA) to sponsors of prescription drugs and biologics during 2017-2022.

Keywords – enforcement, notice of violation, promotion, social media, warning letter

Introduction

Estimates predict that the US pharmaceutical industry expenditure on social media prescription drug advertising will reach $15 billion in 2023. This figure reflects a two-fold increase from that of 2018, and a 12-fold increase from the $1.23 billion spent in 2013.[1] According to a 2019 survey of 100 pharmaceutical and bioscience companies, the anticipated expenditure will be 50% of the industry's allotted 2022 marketing budget.[2] The exponential growth of digital advertising expenditure is not surprising considering the increasing consumer use of social media platforms such as Facebook and YouTube to obtain health-related information and the potential for leveraging consumer and prescriber influence.[3-5] It is estimated that the number of social network users in the US will exceed 300 million in 2023, approximately 91% of the population, and will grow by another 20 million to reach 95% of the population by 2027.[6]

As with any DTCA, sponsors of social media promotional labeling pieces must adhere to FDA requirements for adequate and balanced presentation of benefit-risk information to avoid misbranding. Failure to do so may result

in an NoV, also known as an untitled letter, or a warning letter for more serious violations. Social media has made it easier for third parties to post information about drugs and devices. User-generated content can appear on a company's platform comment section, an interactive social media site, or on an entirely separate platform that is not under the control or influence of the sponsor. Twitter, Facebook, LinkedIn, live podcasts, and blogs allow for real-time and continuous communications with large audiences. The use of social media to promote pharmaceutical products has raised questions and concerns over whether existing regulations should be applied to product promotion and poses some unique issues related to platform limitations such as character space limitations, sponsor responsibility of real-time information posted on various social media platforms, and fulfillment of regulatory requirements for postmarket submissions of interactive social media.

FDA guidance on social media promotion

Since the FDA's first public hearing regarding the use of social media in 2009, the agency has issued four guidance documents on the subject. The first guidance, issued in 2011,[7] addresses how industry sponsors can respond to requests for off-label use of prescription drugs and medical devices including those that sponsors may encounter through emerging electronic media. According to the guidance, which remains in draft form, sponsors can answer both public and nonpublic requests using the same platform for response (e.g., Facebook post). However, they must follow several parameters. In both cases, the sponsor must provide accurate, truthful, and balanced information regarding a product's off-label use. The information must be based on scientific data, be nonpromotional in nature, and should answer only a specific request.[7]

In 2014, three additional draft guidances were released. The first guidance discusses the fulfillment of regulatory requirements for postmarket submissions of interactive social media for drugs and biologics and the factors determining a sponsor's responsibility for the real-time information posted on promotional media platforms.[8] According to the guidance, sponsors would be required to submit content of social media sites, blogs, and so on, under their control or influence to the FDA upon initial launch of the content as part of their postmarket surveillance, and then monthly thereafter for interactive components. It should be highlighted that the guidance specifically states that the sponsor is responsible for the posts their employees make when acting on behalf of the company.[8]

The second guidance provides recommendations to sponsors that voluntarily opt to correct misinformation related to a sponsor's own FDA-approved or -cleared products when that information is created or disseminated by independent third parties over which they have no influence.[9] In this case, the sponsor's response should be specific to the misinformation and provide a statement and date noting the correction. In addition, the sponsor should correct all misinformation in a given section of the forum, and not just the information that puts the product in a negative perspective.[9]

The third of the 2014 guidances discusses how to convey benefit-risk information on social media that have character limitations (e.g., Twitter).[10] Much of the guidance is dedicated to reiterating the truthful and fair balance requirements necessary to all DTCAs. Despite character limitation, if an efficacy claim is made, a similar representation of safety must also be present. In addition, a link or other mechanism should be provided so full safety information can be obtained. The guidance elaborates on several other scenarios, but concludes that if fair balance cannot be achieved, then sponsors should reconsider their use of the platform.[10]

Previous social media violation analyses

Since the release of the FDA's social media guidance documents, two comprehensive evaluations of pharmaceutical social media advertising violations were published. In 2015, Kim evaluated NoV and warning letters to understand the areas of violations noted by the FDA during 2005-2014.[4] In all, 179 violations were found in a total of 73 letters, which were then classified into six violation categories: risk, efficacy, indication, product label, material information issues, and approval issues. About half of the violations arose from product websites, 25% were from sponsored search engine and banner ad links, and 22% were from online videos (of which 12.5% were from independent websites, the remainder being embedded videos on sponsor or product websites). A small portion of the violative promotional material, 2.7%, originated from social media (notably Facebook). Social media violation categories included risk (n = 2), efficacy (n = 2), indication (n = 1), and material information issues (n = 2). While few social media violations were found, the author notes the increasing presence of social media advertising by top pharmaceutical companies. Consumer sharing and other uncontrollable elements were the principal concerns with this form of promotion.[4]

A second evaluation was conducted by Limbu and colleagues,[11] who evaluated NoV and warning letters during 2005-2016. During this 12-year period, 296 letters were issued citing 337 promotional platforms. Most of the platforms cited were derived from traditional materials (64.1%), such as promotional brochures, sales aids, print ads, direct mailers, and so on. Although there were 86 violations for internet media (25.5% of the total), only 8 were related to social media platforms (Facebook, YouTube, and Twitter) and included inadequate presentation of risk information and unsubstantiated and misleading efficacy information. The authors also noted an increase in online media violations over the review period compared with a general decline in traditional media violations. They argue that the lack of clear and final guidance from the FDA has created a public health concern though inaccurate online promotion and that it could be rectified through consumer advocacy group education.[11]

These analyses highlight the steadily increasing shift of the pharmaceutical industry's use of social media as a primary promotional campaign effort. Both, however, reflect analysis of letters issued during or immediately following the

release of the FDA's social media guidance documents. As with any guidance, time is needed for the industry to absorb and adhere to the recommendations. Therefore, additional analysis is necessary to truly understand the impact the guidance may have on compliance with social media promotion. The purpose of the present research study is to evaluate current trends in FDA enforcement of social media DTCA using NoV and warning letters issued to sponsors of prescription drugs and biologics.

Current social media violations

Social media letters issued 2017-2022

Between 1 January 2017 and 21 September 2022, the FDA issued a total of 3,252 warning letters. Using the FDA's warning letter database,[12] a search query was performed to narrow the scope of the warning letters issued in this time period using the terms "Facebook," "YouTube," "Twitter," "LinkedIn," and "Instagram." These social media platforms were identified as the most likely to have received NoV or warning letters. Other social media platforms were not evaluated. The query results were extracteds and a comprehensive data analysis was conducted, which involved manually reviewing the subject, issuing office, and recipient of each letter. The goal of the analysis was to identify letters issued for promotional violations of pharmaceutical products on major social media sites. Letters pertaining to adulteration, misbranding of tobacco products, or misbranding of nonapproved pharmaceutical agents were excluded from the dataset. A total of 223 social media–related letters were identified. **Figure 1** (p. 5) shows the breakdown of the platforms mentioned in the letters. Some letters contained violations from more than one platform.

Most warning letters for social media violations (81 of 223, 36.3%) were issued by the Center for Drug Evaluation and Research (CDER; **Figure 2,** p. 5) and typically included unapproved products such as herbal supplements. In addition, many of the violations were for promoting the treatment or prevention of COVID-19.

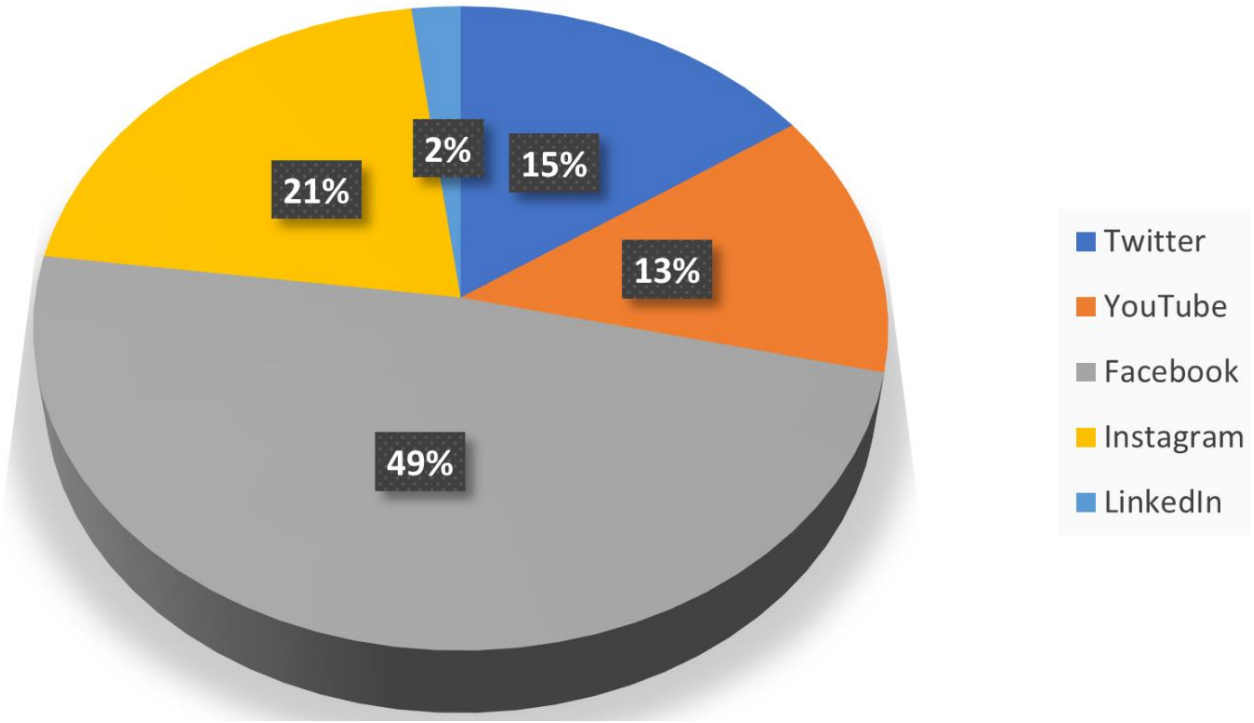
Only 3 of the 223 issued warning letters were deemed relevant for the purpose of evaluating social media promotional violations. These letters, issued by Office of Prescription Drug Promotion (OPDP), and two additional warning letters from OPDP regarding search engines are discussed below.

OPDP warning letters

Both Nephron SC[13] and CytoDyn[14] received warning letters noting promotional violations resulting from videos posted on YouTube. In the case of Nephron, the FDA became aware through the Bad Ad program of emails sent by a sales representative that contained links to a YouTube video that portrayed a physician discussing the use of budesonide for the treatment of COVID-19 patients, for which the marketed drug is not indicated. The FDA highlights in the letter that this claim is not supported by adequate directions for use in the label

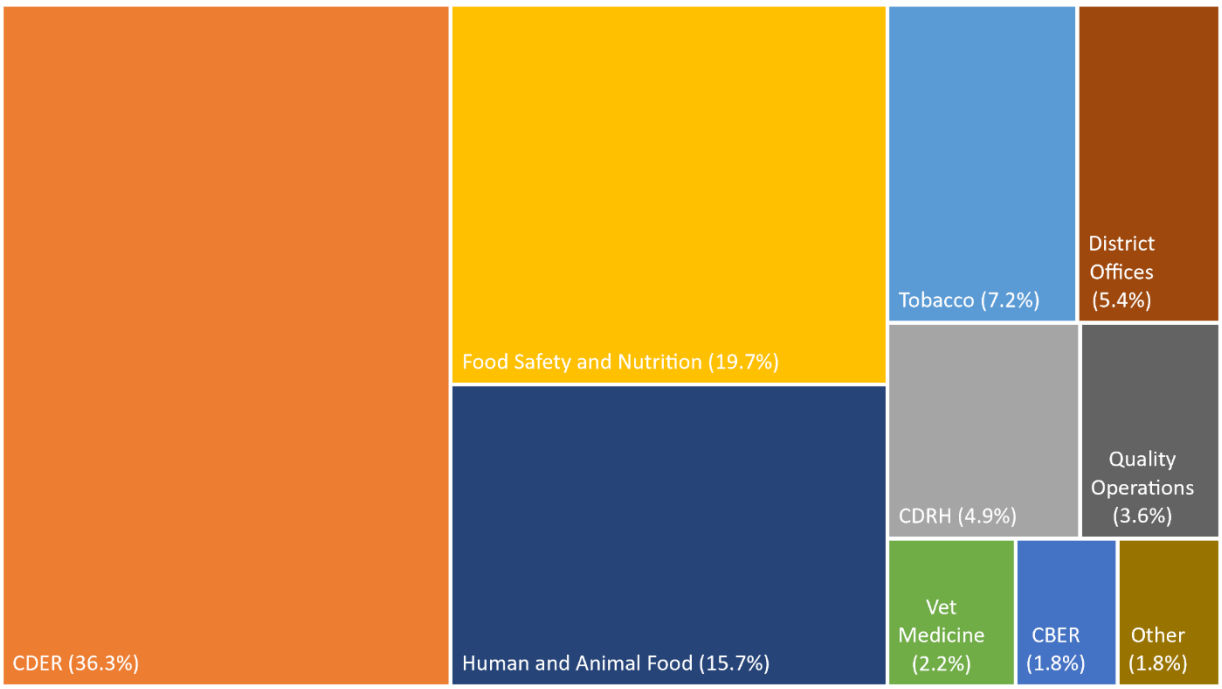
Continued on p. 6

Figure 1. Social media platforms noted in issued warning letters



Source: Cooper et al

Figure 2. Social media warning letters presented by issuing office



CBER, Center for Biologics Evaluation and Research; **CDER**, Center for Drug Evaluation and Research; **CDRH**, Center for Devices and Radiological Health

Source: Cooper et al

and no risk information is presented.[12] Similarly, CytoDyn's warning letter cites false claims surrounding use of a product for the treatment of ssCOVID-19. The agency notes that it became aware of the violative interview video through a link posted on the corporate website. In the video, claims are made for the safe and effective use of leronlimab, an investigational new drug, despite previous communication from the FDA explicitly stating that the sponsor's two clinical trials investigating the use of the drug for the treatment of COVID-19 did not demonstrate clinical benefit.[14]

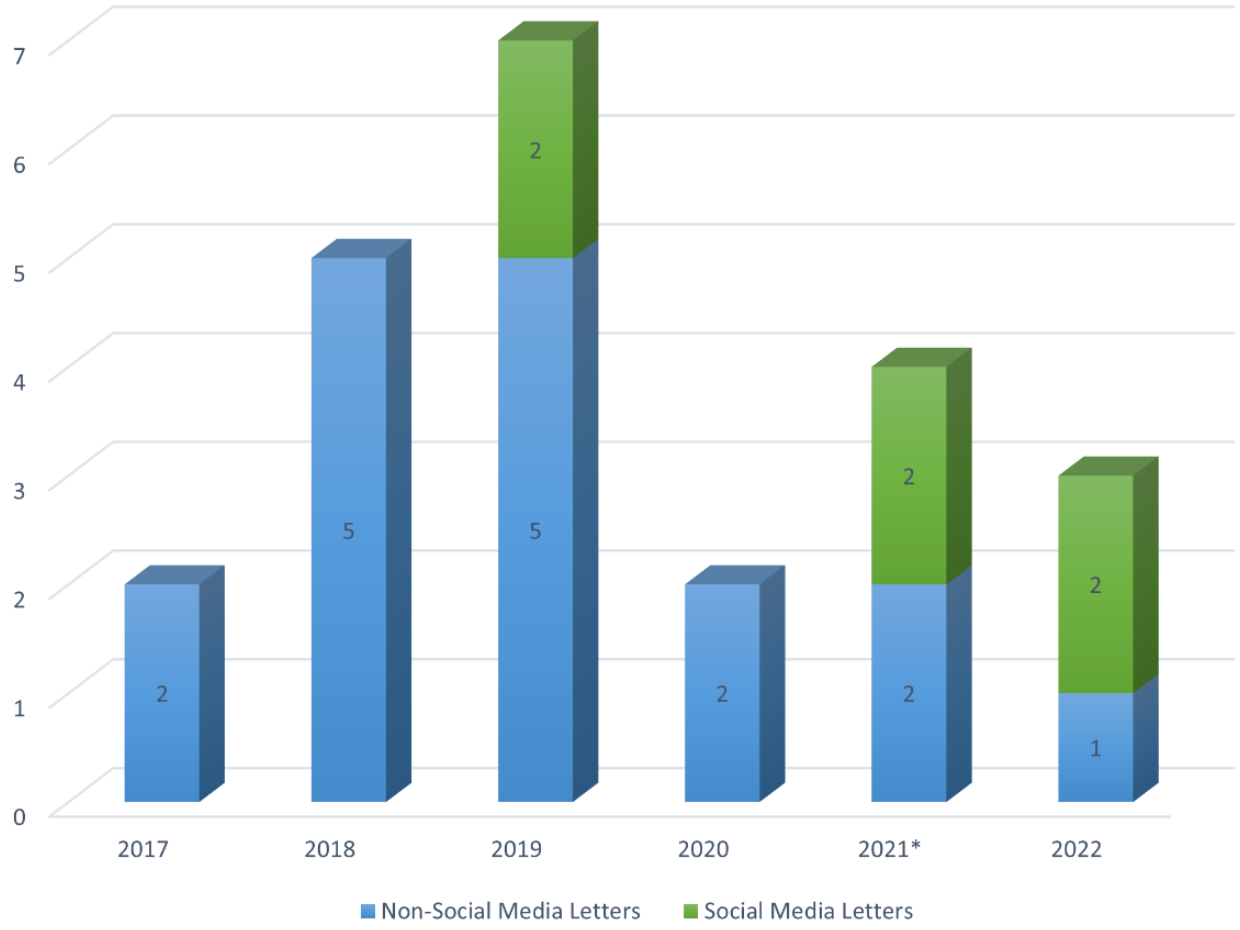
In 2018, the FDA issued a warning letter to MannKind,[15] citing misleading presentation of risks on a Facebook page for Afrezza, a human insulin, again discovered through the Bad Ad program. The product labeling contains limitations of use, a boxed warning, and several serious and potentially life-threatening risks that are not noted in the advertisement.[15]

Two warning letters were issued in 2020 to sponsors for promotional violations through links on Google. The internet search engine is not considered a social media platform, but these letters, to Outlook Pharmaceuticals and Nalpropion Pharmaceuticals, respectively, provide examples of challenges in presenting complete product information on platforms with limited character space. In the letter issued to Outlook, the agency states that complaints were received through the Bad Ad program regarding links to ProCentra, indicated for attention deficit disorder with hyperactivity. In addition to not providing any safety information, the links did not include the established name of the drug.[16] Similarly, Google links for Contrave, indicated for chronic weight management and sponsored by Nalpropion, also did not contain any safety information. The link also failed to fully disclose the complete indication and limitations for use of the product and misrepresented efficacy information. The misbranding is of particular concern because the product is associated with significant safety concerns such as a boxed warning and several other warnings and precautions in addition to previous communications from the agency regarding promotional violations including omission of important risk information.[17]

OPDP notice of violation letters

All NoV letters posted to the OPDP's warning letter and NoV webpage[18] during 2017-2022 were reviewed for violations pertaining to social media platforms. Of a total of 23 NoV letters, 6 (26%) were relevant to promotion through social media (n = 5) or search engine (n = 1; **Figure 3,** p. 7). Violation letters were issued to Aclaris Therapeutics, Eton Pharmaceuticals, Bausch Health Companies, Biohaven Pharmaceuticals, Eli Lilly, and Kowa Pharmaceuticals. The drug indications of these products include, but are not limited to, antiseptics, migraine treatment, adrenal insufficiency, psoriasis, hyperlipidemia, and diabetes. The FDA was primarily made aware of violative content through FDA Form 2253, although two violations were identified through the Bad Ad program. In general, the FDA took issue with each respective advertisement's

Figure 3. **Notice of violation letters by year and reference to social media**



*An NoV letter for Google is included in social media letters in 2021.

Source: Cooper et al

emphasis on the benefits of their products and failure to highlight important risk considerations such as side effects, limitations of use, and misrepresentation of efficacy data.

The NoV letter addressed to Biohaven Pharmaceutical is for the migraine treatment Nurtec ODT.[19] Biohaven published an advertisement on ABC's The View, which featured reality television star Khloe Kardashian. This advertisement was also available on The View's YouTube page. The FDA perceived the advertisement as violative because it contained content that contradicted efficacy parameters stated in the package insert. The spokesperson in the interview claimed that she experiences migraine relief with Nurtec within 15-30 minutes of administration, whereas primary endpoints shown in the package insert show relief beginning at 2 hours. The spokesperson also stated that Nurtec consistently treated her symptoms, whereas other products were

not as effective in providing relief. The FDA perceived these statements as suggesting clinical superiority to other over-the-counter migraine products and hence deemed the advertisement misleading.[19]

Similarly, Aclaris Therapeutics was cited for violations stemming from an advertisement that ran on ABC's The View broadcast in September 2018, which was also available on the company's Facebook and LinkedIn pages. Upon review of the script, submitted to OPDP under Form FDA 2253, the safety of Eskata (hydrogen peroxide) topical solution indicated for seborrheic keratoses was inadequately presented and its efficacy overstated. Both violations had been communicated to the company approximately one year before.[20]

In a similar situation, Kowa Pharmaceuticals sought to promote Livalo (pitavastatin) for the treatment of hyperlipidemia in a DTCA available on YouTube, which was submitted to the FDA under Form FDA 2253.[21] In the video, a patient testimonial was used to discuss their experience with the product. The patient made statements regarding improvements in cholesterol and statin-related myopathy when they switched to Livalo. The FDA perceived these statements to be suggestive of clinical superiority.[21]

The most recent social media–related NoV letter posted by the FDA is also for a video posted to YouTube. Bausch Health Companies submitted a DTCA video to the FDA under Form FDA 2253 for Duobrii (halobetasol propionate and tazarotene) lotion indicated for the topical treatment of plaque psoriasis.[22] The video fails to include information on the product's warning and precaution for embryofetal risk. This was concerning as the "patient" speaking in the video appears to be of childbearing age. Other risk information is also not present. As with Kowa, such concerns had previously been communicated to the company two years before.[22]

Eli Lilly received a letter from the FDA regarding Trulicity, a medication used for the management of diabetes.[23] In its ad, which was posted on Instagram, Eli Lilly presented the risks of using Trulicity. However, these risks were presented in a small window, competing for the consumer's attention. The ad also failed to note several important side effects. These violations were noted during review of the advertisement under Form FDA 2253, as well as through complaints submitted to the Bad Ad program.[23]

Finally, the violations noted for Eton Pharmaceuticals stem from a Google search engine link for Alkindi Sprinkle (hydrocortisone), which did not provide any risk information.[24] Again, while search engines are not the focus of this article, they do provide relevant examples of online forums with limited character space.

Evaluation of violation trends

Among the NoV and warning letters analyzed, the most common form of misbranding (violations) was false or misleading risk presentation, followed by false or misleading claims about efficacy. Each of the violations noted within the five warning and six NoV letters that were analyzed (including those regarding Google) is summarized in the **Table**. Some letters contained more than one violation.

The violations shown in the table were often due to a failure to present product benefits in a balanced fashion with relation to risk. In practice, this meant that companies were neglecting material information regarding risks, limitations of use, side effects, and applicable black box warnings. These failures were manifested in the form of either blunt omission of pertinent risk information or obfuscation of material facts due to either poor wording or poor placement. Pharmaceutical companies participating in the development of social media advertising with the intent of advertising directly to consumers should take heed to ensure that their content is balanced in its approach to presenting risks, benefits, and efficacy data. This would mean ensuring that risk information is provided consistently throughout advertising materials and is available in a readable and readily accessible form to all audiences. The violations pertaining to failure to submit under Form FDA2253, failure to use required established name, and lacking adequate directions of use, although significant, occur infrequently and do not reflect any significant industry-wide trend.

Table. Violations contained within warning and notice of violation letters

Type of violation	Violations in untitled letters	Violations in warning letters	Total violations
False or misleading risk presentation	6	4	10
False or misleading claims about efficacy	3	1	4
Failure to submit under form FDA-2253	1	–	1
False or misleading benefit presentation	1	–	1
Misbranding of an investigational drug	–	1	1
Lack of adequate directions for use	–	1	1
Failure to use required established name	–	1	1
Total	*11*	*8*	*19*

The higher number of violations for risk and efficacy claim is not unique to social media platforms, as they are the dominant violations cited for all promotional materials. The current trends continue to align with the findings of both Kim[4] and Limbu,[11] which also noted these as primary violations.

Conclusions

Despite the widespread use of social media as a primary marketing strategy for the promotion of prescription drug and biologic products, there remains a low number of NoV and warning letters issued by the OPDP. The small number of letters are likely due to a few factors:

- The low number of overall NoV and warning letters issued by OPDP in general, which is aligned with their risk-based approach to enforcement and sponsor self-policing philosophy;
- Focus of other divisions within the FDA around social media promotion, especially regarding unapproved COVID-19 treatments in recent years;
- Sufficient guidance; and
- Lessons learned from previous violation letters. The number of NoV and warning letters and has remained consistently low for the past 15 years.

The FDA's risk-based approach focuses on new products, products that have significant safety risks, those with past violations, and promotional campaigns that extend beyond industry standard. The violation trends assessed in this report reflect these focus areas. The COVID-19 epidemic brought an onslaught of false advertisements from companies and individuals seeking to capitalize on consumer fears, and a high volume of letters was issued for social media promotion of a variety of products claiming to prevent, treat, or diagnose the disease. While most of these letters were issued by CDER, OPDP resides within the division, and it is clear that resources were allocated to the most pressing public safety concerns.

The 2014 guidance documents stress that sponsors are responsible for promotional communications and other content on internet-based platforms that they own, control, create, influence, or operate or are operated on their behalf. A sponsor may also be responsible if it has any control over, or influence on, content posted on third-party platforms. Together, these guidance documents, along with those for DTCA in general, and past violation letters serving as unacceptable promotional practice examples, build a foundation for sponsors to assess the content of their social media promotional campaigns. As these documents remain in draft eight years later, it would be prudent for the agency to finalize the guidance documents, solidifying their recommendations to the industry. Overall, the industry appears to have created a successful standard for using the most prominent social media platforms. As social media platforms change and adapt to new consumer demands, additional guidance may be required, and new standards set.

Abbreviations

CDER, Center for Drug Evaluation and Research; **DTCA**, direct-to-consumer advertisement; **FDA**, [US] Food and Drug Administration; **NoV**, notice of violation; **OPDP**, Office of Prescription Drug Promotion.

About the authors

Lisa Cooper, PhD, RAC, is an assistant professor at the School of Health Professions, a division of Rutgers, The State University of New Jersey, teaching within the clinical research management master's program. She has more than 20 years of pharmaceutical industry regulatory affairs experience, several of which include leading advertising and promotion review. She has been Regulatory Affairs Certified since 2005. Cooper earned her doctorate in leadership from Alvernia University in 2015. She can be reached at lisa.cooper@rutgers.edu

Mahmoud Ajaj is a PharmD candidate at the Rutgers Ernest Mario School of Pharmacy, with an anticipated graduation in May of 2024. He is interested in pursuing a career in regulatory affairs upon graduation. Ajaj has served in various leadership and pharmacy practice roles throughout his time in pharmacy school, including student government, residence life, retail pharmacy, specialty retail pharmacy, and hospital pharmacy. He looks forward to applying his diverse skillset to an engaging career within the pharmaceutical industry. He can be reached at mahmoud.ajaj@rutgers.edu

Karen Kopicko, MS, RAC, is an adjunct assistant professor at the School of Health Professions, a division of Rutgers, The State University of New Jersey, where she teaches within the clinical research management master's program. She has 17 years of pharmaceutical industry regulatory affairs and quality assurance experience. She has been Regulatory Affairs Certified since 2009. Kopicko earned her master's degree in regulatory affairs drugs, biologics, and medical devices from Northeastern University in 2011. She can be reached at karen.kopicko@rutgers.edu

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