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A prescription for the US FDA for the regulation of health misinformation

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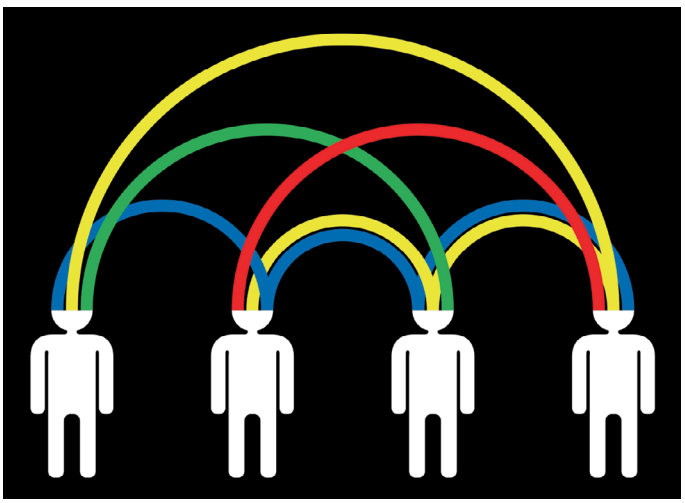
The US Food and Drug Administration should address health misinformation through existing and new regulatory approaches, including modernizing product labeling, investing in infodemic surveillance and addressing the roles of the internet and social media.



In 2022, US Food and Drug Administration (FDA) Commissioner Robert Califf announced that a core plank of the agency's agenda would be "countering misinformation about science and the FDA"[1]. Health misinformation, which Commissioner Califf characterized as the leading cause of death in the USA, has attracted substantial attention during the COVID-19 pandemic[2]. The US Surgeon General defines health misinformation as "information that is false, inaccurate, or misleading according to the best available evidence at the time," and issued a formal advisory calling attention to it as an "urgent threat"[3] (Box 1).

Although health misinformation was amplified during the COVID-19 pandemic, the regulation of health information has long been fundamental to the FDA's mission of consumer protection.

Consumer protection

Regulation of health and consumer goods was largely non-existent prior to the twentieth century, with food products frequently mislabeled and pill bottles often carrying claims of cures without any verification of their benefits, side effects or ingredients. The issue of health misinformation gained national prominence in 1905 after *Collier's* magazine published an 11-article series titled "The Great American Fraud" that exposed the deadly consequences of adulterated products with deceptive labels[4]. In response to this public health crisis, Congress passed the Food and Drugs Act in 1906 to provide the Department of Agriculture's Bureau of Chemistry (the predecessor agency to the modern FDA) with a mandate to improve safety and enable consumers to make informed choices when using health products[5].

As the task of regulating health information has evolved in scope and complexity, so too have the FDA's tools and authorities. Chief among these are the agency's gatekeeping powers, which prohibit manufacturers from selling new medical products without FDA approval, and the agency's labeling powers, which provide consumers with standard health information about regulated products at the point of purchase or use. The FDA also has some oversight across the advertising of medical products and the capabilities to pursue legal action when fraudulent products violate its standards, but such authorities are limited under federal law.

The past century of food and drug law offers examples that highlight the FDA's critical role in addressing health information but simultaneously expose the limits of the agency's abilities. For example, laetrile is an apricot seed extract that gained attention as a purported anticancer therapy and was banned by the FDA in 1977 after regulators found no evidence of benefit and received multiple reports of injuries and deaths[6]. Despite the agency's gatekeeping, misinformation about laetrile, which was seeded by reports of miracle cures from self-proclaimed health experts, bloomed, leading 27 states to legalize the drug in defiance of the FDA's plan. It ultimately took multiple congressional hearings and a clinical trial led by the National Cancer Institute for laetrile to fade from public prominence[7].

Similar challenges manifested during the COVID-19 pandemic, where fear of a new pathogen fomented misinformation regarding proven medical products (such as vaccines) and those that were unproven (such as hydroxychloroquine and ivermectin). The FDA followed its usual playbook, using its power to halt the sale of unapproved drugs and issue safety communications to address myths about unproven products[8,9]. Yet with COVID-19, as with laetrile, addressing core drivers of health misinformation, which include celebrity endorsements, political lobbying and media cycles, remained beyond the scope of the FDA's authorities.

Reducing health harms

These examples illustrate that the FDA has an important role in reducing the public health harm that results from health misinformation, despite it being inadequately equipped to protect consumers from this growing threat. Many of the agency's existing mechanisms are overdue for updates that could improve the regulation of health information. The labeling of medical products is one such mechanism. For example, labels for products used during the COVID-19 pandemic were difficult to understand for many consumers, lacked information on comparative effectiveness, and did not appropriately inform clinician

decision-making. Similarly, during the COVID-19 pandemic, the internet and social media have played a dominant role in public marketing and communication, yet the agency has issued limited guidance about how health information should be regulated on such platforms[10]. Although in some cases the FDA is constrained in its ability to reduce the spread of misinformation by the First Amendment's protections for speech, there is no question that there are steps available to the FDA that would better fulfill its mandate of consumer protection[11].

Although health misinformation has been an issue for decades, a convergence of factors, including the exigency of the pandemic, the speed of digital transmission and prioritization by the President and senior government officials, creates a unique policy window for action. Although addressing misinformation requires a coordinated response across federal agencies, the FDA's mandate for consumer protection uniquely positions the agency to address health misinformation as it relates to consumer and medical products (Table 1).

Product labeling

First, the FDA's signature tool against health misinformation — product labeling — is overdue for a revamp. Although the FDA recently concluded a decade-long process of updating food labeling to include facts about nutritional content, the agency's labeling practices for prescription medicines, over-the-counter drugs and medical devices are unproductive for many clinicians and uninterpretable for many consumers[12,13]. Although recent changes, including the addition of a drug highlights section and contact information to report side effects, are well intentioned, they do not address the core issue, which is that the current format is at odds with both the average consumer's health literacy level and preferred method of information consumption[14]. To prevent health misinformation, the agency needs to better equip consumers with health information. To this end, the FDA could consider initiating a national label redesign initiative for medical products for the first time since 2006. Redesigned labels should draw from best practices in the literature about using larger font sizes and a combination of graphics and text, which the FDA recently successfully trialed for over-the-counter naloxone[15,16]. The FDA could also consider bolder changes to adapt to the norms of a digital-first society. For example, the agency could support the development of interactive, multimedia and smartphone-compatible labels that could be accessed using quick response (QR) codes affixed to the outside of medication bottles.

Infodemic surveillance

The COVID-19 pandemic has illustrated how outbreaks of misinformation, in addition to being countered with more information, also require more agile and creative responses to minimize the harms to public health. To improve preparedness and response, the FDA needs dedicated resources for addressing misinformation. To this end, the agency could look to the US Census Bureau, which recruited communications experts in 2019 for the government's first Trust and Safety team — a unit tasked with monitoring media platforms and partnering with stakeholders to contain the spread of misinformation[17]. The FDA could consider adopting a similar model for infodemic surveillance by creating a dedicated Division of Health Misinformation within the agency's Office of Regulatory Affairs, which currently leads the FDA's cross-government work on health fraud. This division would be resourced to conduct active surveillance of health misinformation related to FDA-regulated products and to liaise with manufacturers, press outlets and public figures to deploy evidence-based responses when misinformation outbreaks arise. When responding to misinformation, FDA officials should focus on engaging consumers using a variety of communication techniques across different platforms. For example, in response to reports of ivermectin use for COVID-19, the FDA deviated from its traditionally slower, dry communications playbook and used speedy humor, tweeting: "You are not a horse. You are not a cow. Seriously y'all. Stop it."[18]. The tweet became the agency's most shared by an order of magnitude, helping to elevate public awareness about the issue. This example illustrates the sore need for more creative responses to public health communication to address health misinformation.

BOX 1

Key terms

Misinformation. Information that is false, inaccurate or misleading according to the best available evidence at the time.

Disinformation. Misinformation that is spread intentionally to serve a malicious purpose, such as to trick people into believing something for financial gain or political advantage.

Infodemic. An overabundance of information, both online and offline. It includes deliberate attempts to disseminate wrong information to undermine the public health response and advance alternative agendas of groups or individuals.

Source: US Surgeon General's Advisory on building a healthy information environment[3]; World Health Organization's joint statement on managing the COVID-19 infodemic[21].

Internet and social media

Containing health misinformation will require the FDA to address the roles of the internet and social media platforms in amplifying misinformation, with the Surgeon General's recent advisory specifically implicating the design of recommendation algorithms[3]. However, the FDA's draft guidance on this topic, which after eight years has yet to be finalized, is limited in scope (covering such topics as how companies should approach character space limitations) and focused on voluntary activities by manufacturers, with little to say about technology companies[19,20]. In the absence of clear directives from the FDA, the current paradigm of self-regulation by technology platforms, with little active monitoring or intervention by regulators, is inadequate amidst the current misinformation landscape. Although the FDA does not have jurisdiction over individual speech on such platforms, it does have the authority to intervene in online marketplaces, including those on social media platforms, regarding the sale of unapproved drugs. The agency could therefore consider investigating whether recommendation algorithms promoting the sale of such products constitute health misinformation, which would be subject to FDA oversight. Another approach would be for the FDA to consider opportunities for partnership. For example, the agency could develop digital black box warnings, similar to those already produced for the physical labeling of high-risk medications, that companies would incorporate into their recommendation algorithms to facilitate reporting of health misinformation. These labels could be appended to social media posts or

Table 1 | Approaches to tackle misinformation

Approach	Challenge	Example	Limitations
Product labeling	The health information presented on product labels is not easy for patients to understand or use	The FDA could move away from text-only labels, and incorporate graphics and digital media applications to improve the ease of interpretation	Labels provide health information at the point of care; label reforms should therefore go along with efforts to improve other aspects of the information environment, such as online news
Infodemic surveillance	The FDA currently lacks infrastructure for preparing and responding to episodes of health misinformation	The FDA could establish a dedicated team for monitoring and containing health misinformation, modeled off a similar structure at the US Census Bureau	The most effective surveillance program would involve more government entities than the FDA alone, necessitating cross-governmental coordination
Internet and social media	Health information and misinformation on social media and internet platforms is largely self-regulated	The FDA could work with technology companies to address how algorithm design may be promoting health misinformation	Certain elements of internet platforms may require oversight that is beyond the scope of the FDA's legal authorities

internet websites and include a short FDA warning about the risks of the product, as well as redirect links to official agency websites populated with answers to frequently asked questions and portals for reporting the sale of fraudulent products as relevant.

For more than a century, the FDA has regulated health misinformation to protect consumers from misbranded and adulterated products. As the agency navigates the infodemic of COVID-19, a return to the first principles of consumer protection can help to define policy priorities for the evolving landscape of health misinformation.

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Competing interests

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