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Strategies for Improving Public Understanding of FDA-Regulated Products

Table of Contents

SECTION ONE

Overview 03

| | |
|------------------|----|
| Objective | 04 |
| Background | 05 |
| Topline Findings | 06 |
| Structure | 07 |

SECTION TWO

Observations, Potential Strategies, and Potential Tactics 08

| | |
|---------------|----|
| Observation 1 | 09 |
| Observation 2 | 12 |
| Observation 3 | 16 |
| Observation 4 | 19 |
| Observation 5 | 21 |

SECTION THREE

Conclusion 23

SECTION FOUR

Methodology 25

SECTION FIVE

References 27

SECTION SIX

Acknowledgments 32

SECTION ONE

Overview

- 04 Objective
- 05 Background
- 06 Topline Findings
- 07 Structure



Objective

This report, “Strategies for Improving Public Understanding of FDA-Regulated Products,” outlines opportunities for the U.S. Food and Drug Administration (FDA) to improve public understanding of the Agency and the products it regulates.

FDA Commissioner Dr. Robert Califf requested that the Reagan-Udall Foundation for the FDA (the Foundation) conduct research and consult with experts to better understand how consumers and other stakeholders find, consume, and perceive health information, especially as it pertains to FDA-regulated products.¹ This process included reviewing existing literature and engaging directly with consumers, health care professionals, regulated industry representatives, and other experts across multiple domains through listening sessions, roundtable conversations, individual interviews, and polling. This project was executed over nine months, from January 2023 through September 2023. Because the Foundation’s research focused on understanding and addressing consumers’ experiences with information related to FDA-regulated products, this project did not include a comprehensive evaluation of the FDA’s communications policies, tools, and practices.

Built from the Foundation’s research, this report provides a set of observations, potential strategies, and potential tactics for the FDA to consider.

This report is intended for the entire Agency, rather than a single team or division, as the challenges and opportunities discussed here are relevant across all centers and offices and at every level of the FDA. Successfully executing many of the strategies outlined in this report will require additional investment of resources and time by the Agency and its partners. Some of these strategies are already underway at the FDA; this report makes recommendations on where to invest or focus more.

1. The Reagan-Udall Foundation for the FDA is an independent 501(c)(3) organization created by Congress to advance the mission of the Agency.

Background

The digital health information environment and limited public trust in government institutions represent pressing challenges for the FDA. In particular, Commissioner Califf has highlighted that the growing problem of misinformation² undermines confidence in science and public institutions.³ While the spread of inaccurate health information is a long-standing challenge, the ways and speed with which it spreads have changed as the news ecosystem becomes increasingly digital, fragmented, and fast moving.

In the US, the spread of false information has accelerated in recent years, in part because more people than ever before are accessing information on the internet and via social media.⁴ Research shows that eight in 10 Americans seek health-related information at least once per year, and 73% of people who seek health information find this information online.⁵

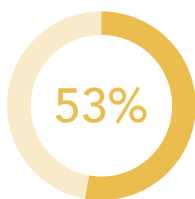
8 in 10

Americans seek health-related information each year

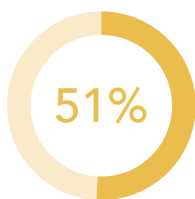
73%

Find this information on the internet and social media

When it comes to news on social media...



Of US adults said **one-sided news** is a very big problem.



Of US adults said **inaccurate news** is a very big problem.

Notably, US adults increasingly get their news from social media, even though more than half say that one-sided news (53%) and inaccurate news (51%) are very big problems with news on social media.⁶

This concern is, in part, because misleading information, which is often sensational or emotionally impactful, tends to garner more engagement than factual information.⁷ One group of researchers found that “falsehoods”—which they defined as a set of commonly posted claims that six independent fact-checking organizations have deemed false—are 70% more likely to be shared on Twitter (now X) than claims deemed truthful.⁸ They also found that false claims spread about six times faster than truthful claims on this platform.

70%

Falsehoods are 70% more likely to be retweeted on X than the truth.⁹

6x

False news has been found to travel about six times faster than the truth.¹⁰

Moreover, trust in government agencies like the FDA has declined in recent years, a trend exacerbated during the COVID-19 pandemic. Only 20% of Americans say they trust the broader federal government to do the right thing “always” or “most of the time.”¹¹

The strategies this report identifies are for the FDA’s consideration, within the boundaries of the Agency’s authority and responsibility. Because many of the challenges this report addresses are facing stakeholders across the entire health communications ecosystem (e.g. individuals, organizations, and groups that develop, communicate, or consume health information, including health care professionals, other government agencies, reporters, educators, and consumers themselves), several strategies recommend that the FDA partner with “stakeholders.” The strategies will better position the FDA to fulfill its mission statement with respect to “helping the public access the accurate, science-based information they need to use medical products and foods to maintain and improve their health.”

2. For purposes of this report, misinformation is defined as false, misleading, or inaccurate information that is shared unintentionally or intentionally.

3. Califf, Robert. “Remarks by Commissioner Robert Califf to the 2023 Food and Drug Law Institute (FDLI) Annual Conference.” U.S. Food and Drug Administration, 17 May 2023, www.fda.gov/news-events/speeches-fda-officials/remarks-commissioner-robert-califf-2023-food-and-drug-law-institute-fdli-annual-conference-05172023.

4. Romeo, John. “Disinformation Is a Growing Crisis. Governments, Business and Individuals Can Help Stem the Tide.” World Economic Forum, 11 Oct. 2022, www.weforum.org/agenda/2022/10/how-to-address-disinformation/.

5. Pasquetto, Irene V, et al. Misinfo Rx, A Toolkit for Healthcare Providers, https://misinfoRx.com/wp-content/uploads/2021/11/hghi_Misinfo_Rx_NEW_v22-003.pdf. Accessed 26 Sept. 2023.

6. Shearer, Elisa, and Elizabeth Greico. “Americans Are Wary of the Role Social Media Sites

Play in Delivering the News.” Pew Research Center’s Journalism Project, 2 Oct. 2019, [pewrsr.ch/3HVw0Ao](https://www.pewresearch.org/3HVw0Ao).

7. Ecker, Ullrich K., et al. “The psychological drivers of misinformation belief and its resistance to correction.” *Nature Reviews Psychology*, vol. 1, no. 1, 2022, pp. 13–29, <https://doi.org/10.1038/s44159-021-00006-y>.

8. Vosoughi, Soroush, et al. “The spread of true and false news online.” *Science*, vol. 359, no. 6380, 2018, pp. 1146–1151, <https://doi.org/10.1126/science.aap9559>.

9. Ibid.

10. Ibid.

11. Nadeem, Reem. “Americans’ Views of Government: Decades of Distrust, Enduring Support for Its Role.” Pew Research Center - U.S. Politics & Policy, 6 June 2022, [pewrsr.ch/3xoMnR5](https://www.pewresearch.org/3xoMnR5).

Topline Findings

Efforts to “address” mis- and disinformation can, themselves, be misunderstood and interpreted as intending to silence discussion and are, at best, reactive versus proactive.



This report’s overarching finding is that clear, consistent communication, both directly to consumers and via media channels, is critical to the FDA’s mission to protect and promote public health.

Consumers won’t understand or trust policy—and the scientific evidence it is based on—if it is not well communicated to them or if they never hear about it at all. Strong communications reinforce sound policy and science; insufficient communications undermine it.

This finding underpins every observation and potential strategy outlined in this report. A strong and continuous communications approach should be viewed as a fundamental aspect of the Agency’s work and requires the early and active involvement of a range of FDA staff beyond those with “communications” in their title, including leaders, lawyers, and scientists. Prioritizing communications and being

accountable for communication efforts should permeate the Agency.

In short: sound science, sound policy, and sound communication are each fundamental to the Agency’s mission and should be resourced and approached with the same diligence.

A core component of this finding is that an effective way to address misinformation is to “prebunk” it. Prebunking is a strategy by which communicators “preemptively build resilience against anticipated exposure to misinformation.”¹² This includes both preempting anticipated health rumors and cultivating consumers’ capacity to detect the information manipulation tactics that often drive the spread of “disinformation,”¹³ defined as the “deliberate dissemination of false, misleading, or inaccurate information to discredit a person or organization.”¹⁴

12. Roozenbeek, Jon, et al. “Psychological inoculation improves resilience against misinformation on social media.” *Science Advances*, vol. 8, no. 34, 24 Aug. 2022, <https://doi.org/10.1126/sciadv.abo6254>.

13. Ibid.

14. “CSI Library: Misinformation and Disinformation: Thinking Critically about Information Sources: Definitions of Terms.” Definitions of Terms - Misinformation and Disinformation: Thinking Critically about Information Sources - CSI Library at CUNY College of Staten Island Library, <https://library.csi.cuny.edu/misinformation>.

Developing and executing clear, consistent communication will not be easy for the Agency. As a science-based regulatory agency, the FDA must navigate the inherently changing nature of science as concepts are explored and further understood, as well as the statutory and regulatory structures dictating process and boundaries for regulatory decision-making and the protection of commercial information. The Agency must frequently share decisions without the ability to disclose significant portions of underlying data or information. Legal proceedings further animate and adjust those boundaries, creating an uncertain, and thus inherently uncomfortable, environment. Despite—or perhaps particularly because of—these challenges, investment in communications throughout the Agency is necessary. Progress can be made.

The FDA has already taken important steps to strengthen its communications. The ideas in this report can help the Agency build on its progress and empower other health experts and communicators to strengthen their own communications.

Structure

The Foundation synthesized findings from its research into a set of five observations that identify challenges, opportunities, or other considerations for the FDA. Potential strategies and illustrative tactics are presented to address each observation.

This organizational approach aims to encompass a variety of ideas, ranging from communication fundamentals to more ambitious strategies. The report includes tactics the FDA already employs but could expand on or execute more often, as well as those the FDA has not yet adopted.

SECTION TWO

Observations, Potential Strategies, and Potential Tactics

- 09 Observation 1
- 12 Observation 2
- 16 Observation 3
- 19 Observation 4
- 21 Observation 5

Observation 1

There is a lack of understanding, particularly among consumers, about the FDA’s mission, responsibilities, and authority. Misconceptions abound about the FDA’s regulatory role and processes in the oversight of food, drugs and biologics, cosmetics, devices, veterinary products, and tobacco products. Most consumers only think about the FDA in the context of responding to a crisis, rather than ensuring the ongoing safety, efficacy, and security of products they use on a regular basis. There is a need for clear, simple communications explaining the FDA’s role for consumers, patients, and other audiences.

Strategy 1.1

Increase direct-to-consumer education, particularly with an emphasis on educating the public about the scientific rigor behind, and reasons for, the FDA’s regulatory and approval processes to dispel common misunderstandings.

Tactic 1.1.1 Clearly describe the FDA’s role in regulating food, drugs, cosmetics, and other products in a prominent location on the FDA website, with additional Q&A for those interested. Currently, the “About FDA” page of the website does not feature this information prominently, and it takes several clicks and visits to multiple webpages to learn more.¹⁵



Government agencies can’t just parachute in when something is going wrong. They need to be engaged day to day on mundane issues citizens interact with all the time, so they understand your role and start to trust you.”¹⁶

Digital communications expert

Tactic 1.1.2 Invest in disseminating information on the FDA’s rigorous, science-driven regulatory processes via clear, concise, and easily shareable content. The Agency’s “Just a Minute” video series,¹⁷ as well as its “5 Things You Need to Know About the Drug Approval Process” video,¹⁸ are both easily understandable for visual learners and shareable on social media channels. The FDA should invest in producing and promoting more content in this style to explain to a broad audience how it ensures the safety and efficacy of products. It is important that any such content housed on the FDA website is updated on an ongoing basis.

15. Office of the Commissioner. “About FDA.” U.S. Food and Drug Administration, FDA, www.fda.gov/about-fda. Accessed 26 Sept. 2023.

16. Quote from interview with a digital communications expert.

17. U.S. Food and Drug Administration. “Isn’t the Pandemic over? – Just a Minute! With Dr. Peter Marks.” YouTube, YouTube, 10 May 2022, www.youtube.com/watch?v=P6G9rnQmEak.

18. U.S. Food and Drug Administration. “5 Things You Need to Know about the Drug Approval Process.” YouTube, YouTube, 5 Dec. 2016, <https://www.youtube.com/watch?v=JVNDgfCT1pg>.

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- Tactic 1.1.3** Develop a short, one- to two-sentence boilerplate on the FDA’s role in protecting public health through its regulatory processes and integrate it into all main communications products. This can help ensure that staff are more regularly reinforcing a consistent description of the Agency to the public. Given the breadth of Agency responsibility, the boilerplate can be tailored by center or product area.
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- Tactic 1.1.4** Develop a version of the boilerplate discussed above to use when communicating about topics on which FDA decisions may evolve. This version should include additional language acknowledging that the FDA’s decisions reflect current scientific evidence and may evolve as scientists’ understanding evolves.
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- Tactic 1.1.5** Review FDA content and messaging to identify more opportunities to share positive “everyday impact” stories via a variety of communication formats (video, infographic, etc.) and messengers. For example, having employees and leaders share how the Agency impacts consumers in their everyday lives can build credibility and enhance public understanding of the FDA.
-
- Tactic 1.1.6** Invest in training online health content creators to effectively and safely discuss health information related to FDA-regulated products in public channels, including social media.
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Strategy 1.2

Building on existing work to collect analytics on how consumers interact with the FDA website, formalize a process for ensuring that these analytics inform content creation and website publication decisions.

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- Tactic 1.2.1** Consistently audit the FDA website to further understand the most visited pages and search terms and leverage this analysis to determine how to make sought-after resources more prominent. For example, consider how to place the content discussed in Tactics 1.1.1 and 1.1.2 prominently.
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- Tactic 1.2.2** Invest in collecting web analytics and making content changes based on this data. Memorialize lessons learned regarding which types of content perform well and which do not.
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Strategy 1.3

Demonstrate the FDA's commitment to communication, consistent with the Agency's mission statement, by engaging more intentionally and frequently in public communications through media. American consumers—34 percent of whom say they do not trust the FDA's recommendations much or at all—may lose confidence in the FDA's decisions if they do not hear more from the Agency directly about its role and work.¹⁹

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- Tactic 1.3.1** Increase regular touchpoints between the FDA and the media, ensuring they are hearing from the Agency regularly and not just after large announcements. This includes encouraging the FDA's subject matter experts (SMEs), center directors, and other leadership, including the commissioner, to engage more readily with the media to increase public visibility for the health information the FDA needs to convey.
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- Tactic 1.3.2** Encourage, designate, and train more FDA SMEs to serve as resources to media on background (e.g., facilitating briefings or helping fact-check reporting). Background interviews are valuable forms of media engagement, as these conversations can provide information to help educate reporters on complex topics and enhance their understanding of the FDA's on-the-record statements. FDA leadership can set the expectation that communications is an important aspect of the agency's science and policy work, and therefore, every SME has a role in supporting a stronger approach.
-
- Tactic 1.3.3** Ensure that there is a step in the media response framework for quickly identifying the proper spokesperson to prioritize for each media inquiry. This step should consider not only the FDA processes but the likely audience and resonance of the individual, and their position, with that audience. For example, an SME who has worked closely on a given announcement may be the best spokesperson to respond to a technical media inquiry regarding the announcement. However, if the media inquiry focuses on broader policy issues, FDA leadership may be more appropriate. Communication-related responsibilities should be considered an essential element of the regulatory process and individual staff member responsibility.
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- Tactic 1.3.4** Continue and increase proactive engagement with reporters by regularly offering background briefings on timely topics and basic regulatory processes and concepts, including offering data points and figures they can use in reporting. These briefings do not necessarily need to be tied to an approval or regulatory announcement and should be consistent with Agency disclosure regulations and guidelines. While legal or regulatory considerations may limit the FDA's ability in this area, where possible and appropriate, the Agency should pursue more proactive media engagement. Regular interaction cultivates trust in the FDA as a helpful resource and increases understanding of complicated health information and processes.
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- Tactic 1.3.5** Conduct regular media mapping to ensure media contacts extend beyond traditional outlets and include a wide range of "non-traditional" sources (e.g., consumer-focused magazines, widely read blogs or online news sites, social media influencers, and publications serving non-English readers). The FDA engages with some of these outlets already, but it can do so more consistently and comprehensively.
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19. Lopes, Lunna, et al. "KFF Health Misinformation Tracking Poll Pilot." KFF, 22 Aug. 2023, www.kff.org/coronavirus-covid-19/poll-finding/kff-health-misinformation-tracking-poll-pilot/.

Observation 2

Health rumors or misconceptions can spread rapidly in the absence of credible information. In addition to more deliberate initial communication, the FDA should be more proactive in listening for, spotting, and addressing misconceptions before they escalate.

Strategy 2.1

Invest in resources for prebunking efforts to shape the health information landscape before rumors spin out of control.

Tactic 2.1.1 Before releasing information related to FDA-regulated products, consider ways in which consumers might interpret the announcement or connect it to common misperceptions. In these cases, the FDA should prebunk predictable falsehoods by addressing them as announcements are made, whether via talking points, videos, the “rumor control” page, social media, or other educational pathways.²⁰ This could also entail pre-briefing, or at least concurrent briefing, of relevant partners and spokespeople with accurate information in advance of anticipated falsehoods or misunderstandings. Pre-briefing should account for limitations to protect confidential, commercial information; concurrent briefing (i.e., concurrent with a regulatory announcement) is a useful tool to prebunk misunderstanding.



You’re never going to be able to chase down every rumor, and it is a terrible waste of time. It is more important to get ahead of, and anticipate, rumors.”²¹

Public health communications expert

Tactic 2.1.2 Avoid using lengthy, technical names for titles (e.g., the titles of bodies overseen by the FDA, announcement headlines, etc.) to limit public confusion or misunderstanding. Carefully selecting names that do not require additional context to understand, or that clearly describe the takeaway being represented, can limit new misconceptions. For example, a study published by the Annenberg Public Policy Center at the University of Pennsylvania concluded that the name of the Vaccine Adverse Event Reporting System (VAERS) has contributed to public misconceptions around vaccination by implying a direct relationship between vaccines and reported adverse events, even though such a relationship does not necessarily exist for each adverse event.²² While changing the name of an existing project will not address broader lack of clarity about the content, new project names should consider potential misunderstandings.

20. Shared during interview with a public health communications expert.

21. Quote from interview with public health communications expert.

22. Hall, Kathleen, et al. Critica, “Minimizing public susceptibility to misconceptions about the effects of vaccination: Vaccine Adverse Event Reporting System (VAERS),” https://cdn.annenbergpublicpolicycenter.org/wp-content/uploads/2023/05/VAERS_APPC_May_2023.pdf.

Tactic 2.1.3 Invest in expanded social listening tools to monitor what topics, questions, or concerns are starting to emerge online but haven't yet become larger issues. These tools should be applied across all FDA communications, not just those affiliated with a specific topic or center. This can help inform where the FDA or its partners can prioritize sharing factual information early and often before rumors escalate.

Tactic 2.1.4 Quickly deploy factsheets, graphics, and videos to prebunk, and then debunk, expected or emerging health misconceptions or rumors. Use this content to build a repository of pre-approved materials that can be readily reused in the future to cut down on response times and improve public understanding before rumors spread. Research indicates that addressing misconceptions promptly and directly using sources on social media is effective in mitigating the spread of misperceptions.²³ Even if evidence does not change the views of internet users that are intent on spreading rumors, it can limit the spread of misleading information to neutral observers by providing countervailing facts.

Tactic 2.1.5 Invest further in monitoring web traffic data and analytics to identify the emerging issues or rumors related to FDA-regulated products. As part of this, consider investment in new technologies for social listening and monitoring.

Strategy 2.2

Collaborate with other agencies, such as the Centers for Disease Control and Prevention and National Institutes of Health or organizations working to improve consumers' health and media literacy, as part of a long-term strategy to empower consumers to recognize misleading information on their own. Several of the experts the Foundation interviewed pointed to health and media literacy among consumers as essential to increasing public understanding of FDA-regulated products.²⁴

Tactic 2.2.1 Help connect the public with educational content from health and media literacy organizations like the News Literacy Project, National Association for Media Literacy Education (NAMLE), MediaWise, or the Horowitz Center for Health Literacy at the University of Maryland. Use the FDA's channels to amplify tools, resources, and insights made by organizations like these, especially those that cultivate consumers' data literacy or help consumers recognize misleading information. A prominent study on prebunking indicates that exposing consumers to examples of misleading information and explaining its flaws can help "inoculate" consumers against misunderstandings.²⁵

23. Vraga, Emily K., and Leticia Bode. "I do not believe you: How providing a source corrects health misperceptions across social media platforms." *Information, Communication & Society*, vol. 21, no. 10, 19 Apr. 2017, pp. 1337–1353, <https://doi.org/10.1080/1369118x.2017.1313883>.

24. Four of the experts the Foundation interviewed discussed health and media literacy in this manner.

25. Roozenbeek, Jon, et al. "Psychological inoculation improves resilience against misinformation on social media." *Science Advances*, vol. 8, no. 34, 24 Aug. 2022, <https://doi.org/10.1126/sciadv.abe6254>.

Tactic 2.2.2 Pilot a media literacy education program in partnership with a third-party organization, such as NAMLE or the Media Education Lab, to build and test a curriculum educating youth about how to spot and vet trustworthy information sources. This partnership would fuse the FDA's extensive scientific knowledge with the organizational infrastructure of a specialized third party to maximize the impact of the pilot.

Tactic 2.2.3 Engage at the community level by participating in events held at local organizations, such as universities, schools, and non-profits, to improve health and media literacy. Consider leveraging FDA leaders or third-party health partners who can share practical tips for spotting and vetting credible health information. Additionally, participating FDA speakers should be trained to translate scientific information to non-scientific audiences through engaging and concise, TED Talk-style presentations.

Strategy 2.3

Strengthen the Agency's internal structure and process for monitoring emerging health rumors and developing an appropriate response strategy.

Tactic 2.3.1 Establish and invest in a dedicated team (with expertise from across the agency on the science, the policy, and the communications) with the role of monitoring for and addressing rumors and misunderstandings surrounding FDA-regulated products from science, policy, and communications perspectives.

2.3.1.A This team would establish a clear protocol for anticipating, responding to, and recovering from potentially harmful rumors.

2.3.1.B This team would also establish a clear process for media and social media monitoring, including how to structure keywords and alerts, and a clear process for escalating potential problems. To ensure a timely response to emerging health rumors, problems escalated by this dedicated team should be treated with priority throughout the Agency.

Strategy 2.4

Streamline and prioritize the review and approval process by which the FDA responds to media inquiries. An approval process with too many steps, or a process with participants who do not prioritize their participation, can delay the FDA's responses to the media and result in missed opportunities to provide substantive input and clarity that can be helpful to the public and other external audiences.

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- Tactic 2.4.1** Provide updated, regular, and collaborative training sessions and instructions to help FDA staff embrace communicating with the public. Training sessions can encourage best practices for translating technical health information to broad audiences. While the FDA provides media training to many employees each year, there is an opportunity to offer collaborative training across centers to ensure that all staff follow a consistent set of best practices.
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Strategy 2.5

When preparing to publish information, consider where the target audience will most likely look for health or nutrition guidance and consider publishing the information there prior to, or at the same time, as engaging with traditional news media.

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- Tactic 2.5.1** Offer FDA resources to third-party platforms (e.g., Healthline and WebMD) and patient advocacy groups to publish or share with readers.
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Strategy 2.6

Expand promotion and distribution efforts for existing FDA content so that it is delivered directly to consumers. Recognizing that many consumers may prefer communication from a source other than the federal government, the FDA can build on its strong foundation of direct-to-consumer (DTC) emails by leveraging different content, channels, and collaborators.

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- Tactic 2.6.1** Partner with third-party expert communications groups, such as the Ad Council, to conduct targeted digital advertising that links FDA resources to users. This advertising will educate audiences about the FDA or disseminate information about pressing topics like product safety.
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- Tactic 2.6.2** Share infographics or short excerpts containing information from the rumor control page on the most popular FDA channels. Then, to amplify reach, encourage external partners to share these resources with their own audiences as well.
-
- Tactic 2.6.3** Building on existing DTC communication efforts, regularly distribute rumor control content through targeted emails or professional organization channels (e.g., discussion boards, listservs, and blogs). This can help deliver timely information to consumers and help health professionals keep up with and respond to rumors the FDA sees emerging.
-

Observation 3

From consumers to clinicians to media, key audiences have identified a need for the FDA to communicate more clearly. Stakeholders saw an opportunity for every component of the Agency to align around a more understandable and consistent tone of voice. Addressing this challenge will help the FDA—and the media covering the Agency—to communicate more effectively about health topics.

Strategy 3.1

Prioritize a consistent, fact-based tone in communications to strengthen, and not undermine, the FDA’s scientific credibility.

Tactic 3.1.1 Establish an advisory committee (or other construct) of external experts to provide ongoing feedback, support, and input regarding the execution of strategies to improve public understanding of FDA-regulated products, including clarity of FDA communications. The insights shared by this committee could help inform areas where the Agency is succeeding and where it could improve its communications. Similar to the expert committee recommended on a related topic, this group could include communication experts, clinicians, manufacturers, social scientists, and others.²⁶



Information from the FDA is really hard to synthesize. It can feel like a black box.²⁷

Public health communications expert



The FDA website can be so dense to read. The videos, though, are great.²⁸

Online health information professional

Tactic 3.1.2 Use career staff as spokespeople to address rumors and false information. Using career staff may help underscore to the public that science, not politics, drives the FDA.

26. Pitts, Peter J., and Gregory A. Poland. “Trust and science: Public health’s home field advantage in addressing vaccine hesitancy and improving immunization rates.” *Vaccine*, vol. 41, no. 38, 2023, pp. 5483–5485, <https://doi.org/10.1016/j.vaccine.2023.08.003>.

27. Quote from interview with public health communications expert.

28. Shared during roundtable with digital destinations for health information.

Strategy 3.2

Scrutinize all communications to ensure they are concise, digestible, and written in plain language relatable to consumers without sacrificing accuracy.

-
- Tactic 3.2.1** Conduct message testing with intended audiences to improve the accessibility of the FDA's communications. Message testing will help the FDA gauge how information may be interpreted differently by scientific and non-scientific audiences. This can inform the development of messages related to the FDA's role, regulatory processes, and announcements. In particular, the FDA should use message testing to inform how and when to communicate using data. It is important to use data-driven messages judiciously, as varying levels of data literacy among the public can contribute to health misunderstandings.²⁹
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- Tactic 3.2.2** When developing communications materials for a broad audience, use digital tools to assess the grade level of the content and reduce it as necessary. Some public-facing health information websites have a policy of keeping their webpages to a 6-8th grade reading level, which the FDA can consider emulating when appropriate.
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- Tactic 3.2.3** Expand the use of storytelling and personal narratives where appropriate to relate to consumers and cut through technical information. A great example of this approach is the "Why Does The FDA Exist?" video on the FDA's YouTube channel, which uses historical storytelling to establish the purpose of the FDA.³⁰ The FDA has the opportunity to further invest in this approach.
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- Tactic 3.2.4** Ensure health information that is translated into multiple languages uses culturally appropriate translations. The FDA already publishes its rumor control page in both Spanish and English, and the Agency uses translation services for many other resources across its centers and offices. When possible, native speakers should review translated content to ensure that it uses appropriate names, terms, dialects, and cultural cues for the intended audience.³¹
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- Tactic 3.2.5** When communicating with the public, present information using channels and formats that meet the needs and preferences of the intended audience. For example, many consumers—particularly younger ones—are more likely to use mobile devices than a PC to access FDA information, so FDA communications meant for younger audiences should be mobile friendly. One approach would be to make information (such as recall announcements and medical product label information) accessible to third-party apps to make it easier for consumers to find.
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29. Karlin-Smith, Sarah. "US FDA Chief Scientist Thinks Increased Data Literacy Can Counter Misinformation." Pink Sheet, 7 Aug. 2023, pink.citeline.com/PS148644/US-FDA-Chief-Scientist-Thinks-Increased-Data-Literacy-Can-Counter-Misinformation.

30. U.S. Food and Drug Administration. "Why Does the FDA Exist?" YouTube, YouTube, 19 Jan. 2023, www.youtube.com/watch?v=DmYX23j5rnQ.

31. "Principle 3: Use Plain Language That Is Culturally Relevant." Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 8 Aug. 2022, www.cdc.gov/globalhealth/equity/guide/plain-language.html.

Strategy 3.3

Ensure that all communications convey a tone of humility and openness to questions or concerns. Avoid any word choice or tone that could make a consumer feel like they should not ask any questions or need additional explanation.

- Tactic 3.3.1** Add an “Ask the FDA” page for consumers to pose questions, allowing the FDA to track concerns and serve as an engaged resource for the public. Consider featuring select questions and answers on social media channels for greater amplification.

Strategy 3.4

Create a clear framework for identifying external communicators who can clarify or speak about the health topics underlying FDA-regulated products or FDA announcements. FDA leaders and SMEs can speak to policy and scientific matters, but on many other topics, a third party will likely be a more trusted voice.

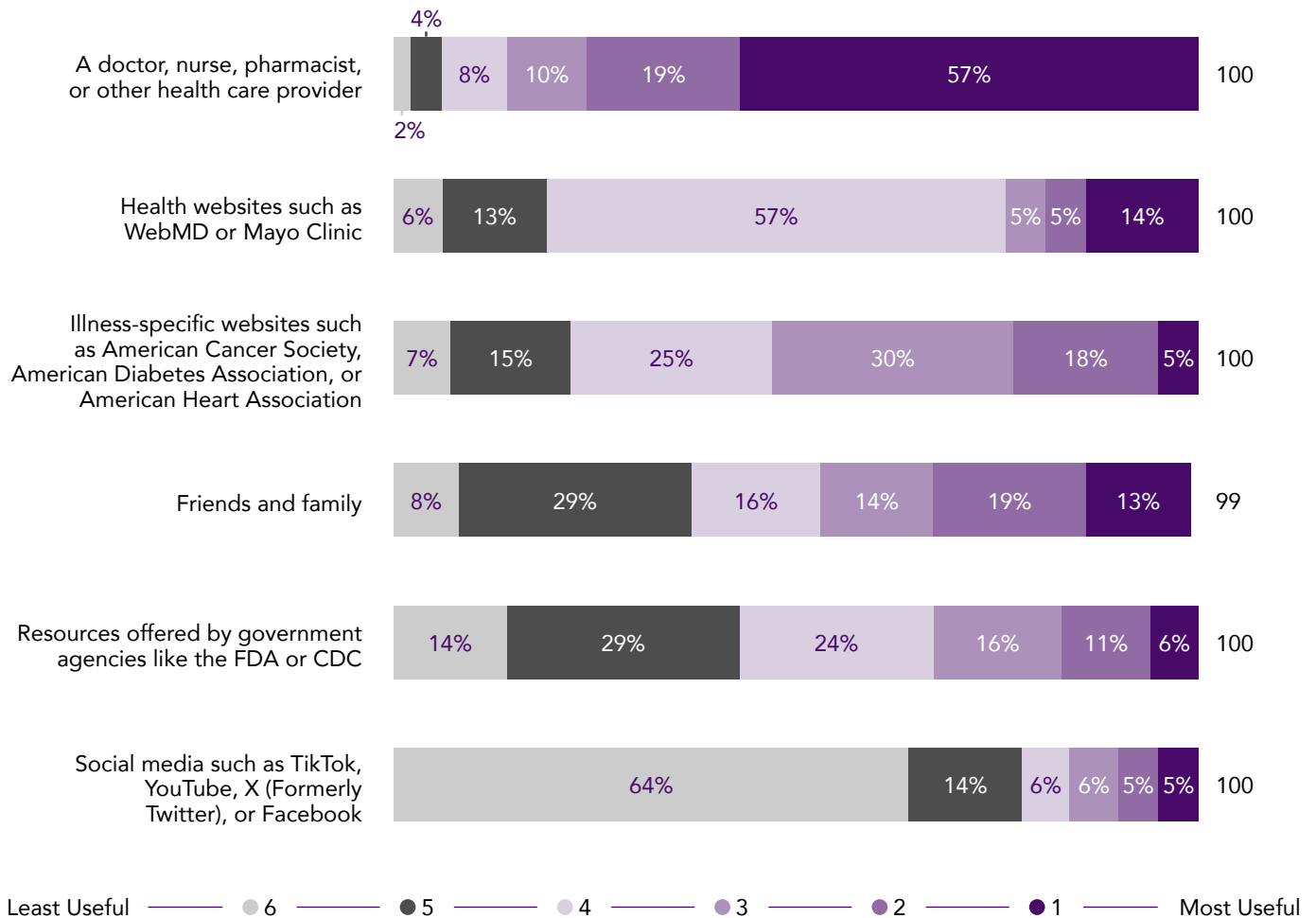
- Tactic 3.4.1** Develop an accessible, “go-to” list of media-trained external sources, such as doctors, academics, or local community health leaders to whom the FDA can refer reporters for comment on broader health topics. Equip these sources with up-to-date collateral, such as fact sheets and talking points, to use in media engagements. These sources would not speak on behalf of the FDA regarding its decisions or process, nor would the FDA control what they say, but they could speak credibly on the health topics related to FDA-regulated products.



Observation 4

Health care professionals are important messengers, because consumers are more likely to trust them³² and rate them as useful sources of information than they are other health messengers, including government agencies.³³ Likewise, local health officials and organizations can be effective health messengers.³⁴ Yet these messengers report not having easy access to necessary information and resources from the FDA to play this role well.

Among those surveyed, 57% ranked health care providers as the most useful source of health information, far more than any other source.



N= 1,007 Voters in the 2024 Likely Electorate nationwide, fielded March 27-29, 2023
 Source: Echelon Insights March 2023 Omnibus Poll. See "Methodology" for details.

32. American Board of International Medical Foundation, 2021, Surveys of Trust in the U.S. Health Care System, https://www.norc.org/content/dam/norc-org/pdfs/20210520_NORC_ABIM_Foundation_Trust%20in%20Healthcare_Part%201.pdf.
 33. Echelon Insights March 2023 Omnibus Poll. See "Methodology" for details.
 34. United States, Department of Health and Human Services, Office of the Surgeon General, 2021, www.hhs.gov/sites/default/files/surgeon-general-misinformation-advisory.pdf.



Trust is the end-all be-all. A trusted messenger is more important than the message.”³⁵

Digital communications expert



My doctor retired after 20 years with me. I’ll never have a relationship like that one. It made me want to take better care of my health.”³⁶

Consumer

Strategy 4.1

Increase regular lines of communication between the FDA and a wide group of health stakeholders who are closer to, and trusted by, patients and consumers. Establishing routine Agency outreach can equip key health stakeholders with the tools needed to be a helpful resource for patients year-round, not only after FDA announcements.

-
- Tactic 4.1.1** Conduct regularly scheduled briefings and webinars with health care professionals, local public health organizations, and national organizations such as the National Association of County and City Health Officials (NACCHO), the Academy of Nutrition and Dietetics, and the American Pharmacists Association, on timely health topics related to FDA-regulated products. Use these sessions to answer providers’ questions and further establish the FDA as a helpful resource.
-
- Tactic 4.1.2** Similar to Tactic 3.4.1 above for media engagement, build an expansive distribution list of local messengers (e.g., networks of doctors, pharmacists, nurses, local health nonprofits, local clinics, local community leaders, large local employers, county extension agents, etc.) and create toolkits that can be regularly updated and disseminated (e.g., fact sheets and posters for their offices, talking points to use in speaking engagements, infographics to share in-office or on social media, etc.).
-
- Tactic 4.1.3** In addition to the framework for identifying external communicators recommended in Tactic 3.4.1, engage in purposeful decision-making about which collaborators and stakeholders should be prioritized for the FDA to engage through local, routine interactions before and after announcements. All announcements can begin with engaging fact-checking organizations to disseminate accurate information and prepare organizations to respond to any misconceptions that arise. From there, enhance stakeholder engagement for each announcement based on the intended audiences. For example, if the FDA will be making an announcement likely to spur questions from dermatology patients, the announcement plan should include a specific effort to coordinate with relevant health professional groups to prepare them with communications materials for the patients of those professionals.
-

35. Quote from interview with digital communications expert.

36. Quote from consumer listening session.

Observation 5

Consumers have an easier time trusting and understanding health information if they hear it consistently from multiple sources. The FDA can do more to support consistent messaging across stakeholder groups.

Strategy 5.1

Place greater emphasis on collaborating with other regulatory agencies and organizations in regulated industries to support clear and consistent messaging. As appropriate, and depending on the regulatory circumstances, this could include giving other agencies or organizations advance notice of certain announcements or publications.



If I hear a bunch of different people saying the same thing or give the same advice about my health, that's a really good sign that it's good advice."³⁷

Consumer

Tactic 5.1.1 Provide Representational State Transfer for Application Programming Interface (REST APIs) to allow external information providers to securely access data outputs. This will allow digital destinations to present accurate FDA data in various formats for different end users.

Tactic 5.1.2 Engage with companies that produce or sell FDA-regulated products to coordinate, when appropriate, a clear and consistent system for product- or commodity-specific announcements. For example, consistency in how the FDA designates approved products and how companies that produce FDA-regulated products refer to the Agency's approval can help prevent confusion for customers and the public, as well as help build trust in the FDA-regulation process. Coordinated communication regarding the end of an outbreak of foodborne illness can, similarly, help consumers keep up with the newest recommendations.

Tactic 5.1.3 Conduct a review to determine whether FDA regulation may unnecessarily limit an industry or organization's ability to respond to health misconceptions and effectively improve public understanding of relevant information.

37. Quote from consumer listening session.

Strategy 5.2

Approach communications holistically across FDA teams and build accountability throughout the organization.

-
- Tactic 5.2.1** Leverage communications expertise across the FDA, including communications professionals within and outside the Office of External Affairs and center-level communications offices, to promote collaboration across teams.
-
- Tactic 5.2.2** Encourage all FDA communications staff to share knowledge and learnings across related centers and teams.
-
- Tactic 5.2.3** Ensure that announcements are made only after all relevant components of the FDA are prepared to respond to questions from the media and the public. Communications vehicles (e.g., press releases, factsheets, etc.) and the underlying source documents for a given action (e.g., review memos) that help the public dive deeper into the announcement must be available at the time announcements are made.
-



SECTION THREE

Conclusion

It is important for the American public to trust the FDA, its regulatory process, and its decisions. If they do not, the public cannot be expected to take the appropriate steps based on the FDA’s work to protect and enhance their own health, the health of their families, and the health of the nation. Improving understanding of FDA-regulated products first requires trust.

In his public statements and his request for this report, Commissioner Califf has recognized that the Agency is in an asymmetrical information-generation situation. There are many fronts and many players, and they are all important. The FDA must deploy strategies and tactics by choosing the venue best suited to its public health aims and strengths. The FDA can inform consumer understanding by using the Agency’s “home field advantage”—science.³⁸

The communication reality is that the best way to address misinformation is to pre-empt it with relatable, science-based information on a consistent basis through multiple channels. Pre-emption requires thoughtful and creative action. The FDA must accelerate its response to the evolving needs of consumers and the ways in which they seek, trust, and use information. The observations and strategies presented in this report focus on delivering clear, consistent, and timely messages with a focus on pre-bunking potential misinformation.

To further improve public understanding of the FDA and the products it regulates, the FDA—throughout its centers and offices—must choose to lead and embrace its role not just as a regulator, but as a communicator.



38. Pitts, Peter J., and Gregory A. Poland. “Trust and science: Public health’s home field advantage in addressing vaccine hesitancy and improving immunization rates.” *Vaccine*, vol. 41, no. 38, 2023, pp. 5483–5485, <https://doi.org/10.1016/j.vaccine.2023.08.003>.

SECTION FOUR

Methodology

To produce the observations, strategies, and tactics listed in this report, the Foundation engaged Penta Group, LLC, to support conducting research and consulting with experts, health care professionals, and consumers to better understand the information environment surrounding FDA-regulated products. This approach included the following components:



Listening sessions with consumers and health care providers

Echelon Insights, a research and polling company, was engaged to recruit participants for, and moderate, three listening sessions, including two sessions with consumers and one with health care professionals. The Foundation developed guiding questions for the moderators of these sessions, asking participants to share how they consume health information, which sources they do or do not consult for health information, how much they trust these sources, and related questions. Each session lasted roughly two hours and included six to 12 participants. The Foundation observed these sessions and identified common response themes to inform further research and support the observations listed in this report.



National omnibus polling

In March, the Foundation added several questions related to health information to Echelon Insights' monthly national omnibus survey. Questions asked respondents about which sources they find the most useful when seeking health information, which types of online communications they find most compelling, and other topics. Echelon distributed this survey online from March 27-29, 2023, to a sample of 1,007 voters in the likely electorate nationwide. The margin of sampling error was +/- 3.8 percentage points. The sample was weighted using population benchmarks for registered voters and the 2024 likely electorate based on gender, age, race/ethnicity, education, region, party, past primary participation, 2022 US House vote, and 2020 presidential vote adjusted for 2024 turnout probability. The survey results further informed the recommendations in this report.



Research summary and opportunity analysis

The Foundation reviewed and analyzed the literature on health information and communications and summarized its findings in a "Research summary and opportunity analysis." This research identified opportunities for enhanced health communications and rumor response that helped inform the recommendations in this report and the topics examined in the other components of the research process described in the "Methodology" section. Relevant literature included peer-reviewed research, survey results, government reports, news media, and other content. All sources consulted in the literature review are listed on the "References" page.



Expert roundtables

The Foundation convened four two-hour, virtual roundtables, each with a group of seven to nine participants representing a relevant field or industry:

1. Representatives from FDA-regulated companies
2. Senior staff from online health information organizations
3. Academic experts in communications
4. Health professionals and health professional communicators

The Foundation team recruited participants for these roundtables, and Foundation CEO Susan C. Winckler moderated the discussions, gathering participant feedback on the FDA's current communications and perspectives on how to increase public trust in credible health information.



In-depth interviews

The Foundation recruited more than 25 experts from relevant fields, such as public health, communications, technology policy, media, and government for 60-minute interviews. The team asked interviewees to share insight into successful strategies they have encountered or employed to address misleading health information, best practices for health communication, potential partners for the FDA to engage, and other resources to consult.

SECTION FIVE

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SECTION SIX

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