September 9, 2024

**VIA ELECTRONIC SUBMISSION**

Dockets Management Staff (HFA-305) Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

## Re: Draft Guidance for Industry: Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers (Docket No. FDA-2014-D-0447)

The Medical Information Working Group (“MIWG”) submits these comments to address the revised draft guidance for industry, *Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers* (the “Revised Draft”), which was recently issued by the U.S. Food and Drug Administration (“FDA” or “the Agency”).

# INTRODUCTION

MIWG is a coalition of firms engaged in innovative medical product research and development.[[1]](#footnote-1)  The group was formed to seek clarity in the FDA regulatory scheme regarding the dissemination of truthful, non-misleading information about prescription drugs, biological products, and medical devices, and to improve the regulatory and enforcement environment affecting communications regarding medical products.MIWG’s members are responsible, research-driven firms committed to advancing science and improving patient care. They are well-situated to support this goal through the dissemination of truthful and non-misleading scientific information regarding medical products.

The Revised Draft addresses a topic of significant importance to public and individual health. MIWG supports FDA’s concerted efforts—including the issuance of the Revised Draft—to combat medical misinformation, the proliferation of which is a serious and increasingly pervasive problem.

MIWG submitted comments on FDA’s prior draft guidance on this topic (the “2014 Draft Guidance”),[[2]](#footnote-2) and we appreciate FDA’s efforts to address the concerns raised therein through the Revised Draft. In particular, MIWG commends FDA for its recognition that firms are accountable only for product communications that they make or that are made on their behalf, a standard that more appropriately adheres to the scope of FDA’s statutory authority and regulations than the one proposed in the 2014 Draft Guidance.[[3]](#footnote-3) We also appreciate FDA’s acknowledgement in the Revised Draft that communications aimed at correcting misinformation need not necessarily be non-promotional in nature, tone and presentation, nor necessarily consistent with FDA-required labeling.

Despite these important clarifications, MIWG submits these comments to address concerns related to the scope of the Revised Draft and the overall approach to regulating manufacturer communications that it reflects.

1. **The enforcement policy outlined in the Revised Draft is overly narrow and incommensurate with the extent of misinformation that exists online.**

MIWG strongly believes that firms can play an invaluable role in combating and addressing third-party medical misinformation because, among other reasons, they generally have access to the highest quality and most up-to-date information about their own products. However, the enforcement policy for “tailored responsive communications” outlined in the Revised Draft does not effectively enable this. Instead, it is drawn narrowly and does not apply to anywhere near the full scope of misinformation that proliferates online.

As examples, the enforcement policy does not apply to communications that would address misinformation regarding products with an emergency use authorization (“EUA”),[[4]](#footnote-4) statements describing “opinions or value statements” about a medical product,[[5]](#footnote-5) or representations about an individual patient’s experience using a medical product.[[6]](#footnote-6)

These limitations make little sense, given that misinformation often comes in these forms and that misinformation related to EUA products for COVID-19, including when framed as opinion or patient experience, has apparently been a major impetus for FDA’s efforts.[[7]](#footnote-7) As a result, the categorical exclusion of these forms of misinformation significantly diminishes the potential value of the Revised Draft as a response to lessons learned from COVID-19. In practice, these limitations will likely hamstring the ability of firms to address a large amount of misinformation that exists on the internet and create an incentive for those intending to spread misinformation to avoid correction merely by framing their statements as opinion or personal experience.

1. **The Revised Draft continues an approach to regulating communications that is piecemeal and incomplete, does not align with FDA’s statutory authority, and stifles speech.**

MIWG has previously raised concerns with FDA’s piecemeal and incomplete approach to regulating communications by firms and has consistently advocated for the implementation of a clear and cohesive regulatory framework to govern such communications.[[8]](#footnote-8) Unfortunately, the Revised Draft is the continuation of a fragmented policymaking approach that is inconsistent with FDA’s legal authority and stifles speech.

First, the Revised Draft purports to summarize “existing avenues available to firms for communicating information about or related to their approved/cleared medical products” beyond what is covered by the enforcement policy outlined in the document. FDA’s attempt to summarize these existing avenues underscores the agency’s fragmented and disorganized approach to policymaking in this area. Notably, the summary does not provide a complete accounting of all relevant FDA policies, much less a comprehensive explanation of how they fit together. As one particularly important omission, the Revised Draft nowhere mentions the concept of scientific exchange, even though it is enshrined in a binding regulation[[9]](#footnote-9) and has long been recognized as a critical vehicle for addressing matters of public debate. In particular, FDA recognized decades ago that communications made “in defense of public challenges” are a form of scientific exchange that FDA does not limit.[[10]](#footnote-10) Responding to medical misinformation is such a defense that fully merits the same approach.

Second, this approach is inconsistent with the Federal Food, Drug, and Cosmetic Act (“FDCA”) because it suggests that firms may speak only if they conform to FDA policies explicitly describing specific “avenues” for communicating information regarding their products.[[11]](#footnote-11) To the contrary, FDA’s statutory authority as it relates to communications by firms only extends to “labeling”[[12]](#footnote-12) and, for prescription drugs and restricted devices, “advertising.”[[13]](#footnote-13) Firms may engage in any form of communication they like, as long as they comply with the general statutory requirements for these categories of communications or engage in communications that fall outside of them completely.

Third, this approach generally stifles speech because, in all the ways already stated, it does not acknowledge the full range of communications that may permissibly address misinformation, and therefore raises unnecessary questions about whether firms should engage in communications that are not explicitly described in FDA policy. In addition, the Revised Draft stifles speech by carrying forward certain problematic concepts from other draft guidance documents, including the concept that FDA does not intend to use communications consistent with the recommendations in the guidance “standing alone” as evidence of a new intended use.[[14]](#footnote-14) We have previously raised concerns about how this leaves firms in a position where even perfect adherence to FDA’s stated policies would not protect them from enforcement action, and with significant ambiguity when seeking to understand what communications are and are not permitted, in FDA’s view.[[15]](#footnote-15) This uncertainty will undoubtedly chill firms from engaging in the very scientific communications that the Revised Draft purports to allow and that are so vital to ensuring that misinformation does not persist.

Lastly, we believe that FDA’s own statements in the *Federal Register* notice accompanying the Revised Draft show how FDA’s approach results in all stakeholders playing a constant game of “catch up” when highly detailed policies or guidance documents inevitably, and quickly, become obsolete. The statements describe how various changes in internet-based communications have occurred since the issuance of the 2014 Draft Guidance, which necessitated the issuance of the Revised Draft.[[16]](#footnote-16) Misinformation about COVID-19 vaccines and therapeutics and other life-saving medical products proliferated quickly in recent years, yet firms lacked up‑to-date guidance from FDA regarding how they could appropriately address such misinformation. That FDA is only now issuing updated guidance for addressing medical misinformation—more than four years after the start of the pandemic and more than a year after the declared end of the public health emergency—illustrates a fundamental defect in FDA’s piecemeal policymaking approach.

All of this shows how FDA’s attempt to regulate communications through highly prescriptive “enforcement policies” tailored to specific communication types, rather than an articulation of broad, cohesive principles that apply to all forms of communication, leaves firms seeking to align their practices with the applicable legal requirements without the clarity they need, at the time they need it.

# CONCLUSION

MIWG strongly supports efforts to combat misinformation regarding medical products to promote the appropriate and safe and effective use of medical products and to improve patient care. While we commend FDA for its focus on addressing medical misinformation, we believe that the proliferation of misinformation requires a more robust, comprehensive, and flexible response than the Revised Draft provides. We respectfully request that FDA refrain from issuing any further policy that exacerbates the lack of a cohesive framework, and we implore FDA to redouble its efforts to establish a clear regulatory framework for manufacturer communications based on broad, cohesive principles that adhere to constitutional and statutory mandates.

Respectfully submitted,

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1. The members of the MIWG are: Amgen, Inc.; Bayer Healthcare Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; Eli Lilly and Company; GlaxoSmithKline, LLC; Johnson & Johnson; Novartis Pharmaceuticals Corp.; Pfizer Inc.; and Regeneron Pharmaceuticals, Inc. [↑](#footnote-ref-1)
2. MIWG Comments, Draft Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, Docket No. FDA-2014-D-0447-0009 (Sept. 16, 2014) [hereinafter *MIWG Comments on 2014 Draft Guidance*]. MIWG’s prior submissions, including the MIWG Comments on 2014 Draft Guidance, are available at [www.miwg.org](http://www.miwg.org). [↑](#footnote-ref-2)
3. *See* *MIWG Comments on 2014 Draft Guidance* at 3. [↑](#footnote-ref-3)
4. *See* Revised Draft at 1 n.4. [↑](#footnote-ref-4)
5. *See* *id*. at 9-10, 11 (example 5), 12 (example 9), 13 (example 13). [↑](#footnote-ref-5)
6. *See id.* [↑](#footnote-ref-6)
7. *See e.g.*, FDA, Letter to Florida Surgeon General Joseph Ladapo (Dec. 14, 2023) (stating that “[t]he challenge we continue to face is the ongoing proliferation of misinformation and disinformation about [COVID-19] vaccines which results in vaccine hesitancy that lowers vaccine uptake”). [↑](#footnote-ref-7)
8. *See, e.g.,* MIWG Comments, Revised Draft Guidance for Industry: Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products, Docket No. FDA-2008-D-0053-0176 (Jan. 5, 2024) [hereinafter *MIWG Comments on SIUU Draft Guidance*], at 19-20. [↑](#footnote-ref-8)
9. 21 C.F.R. § 312.7(a). [↑](#footnote-ref-9)
10. *See, e.g.*, 52 Fed. Reg. 19466, 19475 (May 22, 1987) (“FDA’s understanding of commercial promotion does not place limits on the free exchange of scientific information (e.g., publishing results of scientific studies, *letters to the editor in defense of public challenges*, investigator conferences).”) (emphasis added). [↑](#footnote-ref-10)
11. We acknowledge that the Revised Draft, when final, would only represent the current thinking of FDA and that firms are free to use any alternative approach that satisfies the requirements of the applicable statutes and regulations, as FDA acknowledges in its good guidance practice regulations. *See* 21 C.F.R. § 10.115(d)(2). Nonetheless, issuing exceedingly narrow policies on complex topics fails to expressly authorize the full range of permissible speech and has a chilling effect. [↑](#footnote-ref-11)
12. 21 U.S.C. §§ 352(a). [↑](#footnote-ref-12)
13. 21 U.S.C. §§ 352(n), (q), (r). [↑](#footnote-ref-13)
14. *See* Revised Draft at 3, 4 n.11, 20. [↑](#footnote-ref-14)
15. *See, e.g., MIWG Comments on SIUU Draft Guidance* at 17. [↑](#footnote-ref-15)
16. 89 Fed. Reg. 56387, 56388 (July 9, 2024). [↑](#footnote-ref-16)