



September 6, 2024

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers

Dear Sir or Madam,

On behalf of the Alliance for mRNA Medicines (mrnamedicines.org), we are pleased to submit comments on FDA's revised draft guidance on "Addressing Misinformation About Medical Devices and Prescription Drugs."¹ We agree with FDA that "Misinformation about or related to a firm's approved/cleared medical product can cause harm to both individuals and the public health in general." We appreciate FDA's recognition of the new challenges companies face in combatting misinformation and believe that revising this draft guidance is an important step forward.

About AMM:

The Alliance for mRNA Medicines (AMM) is an organization dedicated to advancing and advocating for mRNA and next-generation encoding RNA therapeutics and vaccines for the benefit of patients, public health, and society. Our mission is to propel the future of mRNA medicine, improve patients' lives, and advance scientific knowledge by convening and empowering mRNA industry leaders, innovators, scientists, and other key stakeholders.

AMM officially launched in November 2023 and has become the leading voice of the mRNA community, representing more than 60 members from North America, Europe, Asia, and Oceania. Our members demonstrate the diversity of the mRNA community, which includes biotechnology companies, pharmaceutical companies, academic institutions, service providers, contract development, and manufacturing organizations (CDMOs), all of whom are working to serve the patients who have and will benefit from mRNA vaccines and therapeutics.

The Promise of mRNA Technology:

We know that FDA is quite familiar with the role that mRNA played in the response to COVID-19, with millions of Americans having received at least one dose of a COVID-19 vaccine. While the first mRNA vaccines for COVID-19 were issued an Emergency Use Authorization in 2020, this was preceded by more than 25 years of research about how to use RNA.

The amazing story of mRNA's role in the COVID-19 response paved the way for mRNA to be used in other vaccines and treatments. We are only at the beginning of the benefit mRNA technologies will deliver to patients and public health through the revolution in vaccine development and future treatments for cancer, rare diseases, and other areas of unmet medical

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/addressing-misinformation-about-medical-devices-and-prescription-drugs-questions-and-answers>

needs. The technology's agility and flexibility make it well suited for many potential applications, but misinformation about how mRNA works and potential side effects represent a significant challenge to researchers and industry and a threat to patients and public health.

Why Misinformation is a threat:

A 2022 study published in *Scientific Reports* discovered that among their sample group of 500 American adults, 57.6 percent reported being exposed to conspiratorial misinformation such as COVID-19 vaccines are harmful and dangerous. This same study also found "exposure to misinformation and believing it as true could increase vaccine hesitancy and reduce behavioral intention to get vaccinated" using mRNA vaccines.²

In addition, AMM conducted its own qualitative review of news coverage of mRNA, which is attached as an appendix to this letter. Our review found that while the sentiment around mRNA is largely neutral (74 percent) or positive (12 percent), 14 percent is negative. Additionally, media coverage of mRNA is most often associated with the keyword "vaccine" but is also associated with terms that indicate the possibility of misinformation about mRNA, including "magnetic," "autism," "microchip," "infertile," "alter DNA," and "5G."³

Vaccines were the dominate factor in combating the COVID-19 pandemic and allowed our society to reach a level of normalcy that seemed distant in March 2020. AMM applauds FDA for updating this draft guidance on Combating Misinformation as our community needs to increase the public's awareness of the benefits of vaccines.

AMM is also concerned misinformation could negatively impact the future development of other mRNA therapies. Investors and innovators may be reluctant to invest as heavily in mRNA technology and products if they are concerned misinformation about the technology has become pervasive. Having language such as FDA provides in the Combating Misinformation draft guidance will be valuable to AMM member firms and the broader AMM community. FDA-approved methods to combat misinformation will greatly improve the ability of these firms to educate the broader public, and so AMM applauds FDA for including example language in the draft guidance.

AMM Supports Empowering Firms to Combat Misinformation:

As mentioned above, AMM represents more than 60 members from North America, Europe, Asia, and Oceania in sectors such as biotech firms, academic institutions, and pharmaceutical companies. Unfortunately, misinformation about mRNA technologies in medicine is ubiquitous. As information is increasingly shared, discussed, and evaluated on social media at a lightning pace, the mRNA community has found themselves needing to focus resources on explaining their technology is beneficial, in addition to developing and improving their vaccines and therapies for patients. With so much misinformation swirling around on social media, our members and the broader mRNA community can sometimes feel overwhelmed. By updating this draft guidance with examples of how firms can push back on social media misinformation regarding their products and technologies, FDA is providing a valuable service to our members'

² Lee, S.K., Sun, J., Jang, S. *et al.* Misinformation of COVID-19 vaccines and vaccine hesitancy. *Sci Rep* 12, 13681 (2022). <https://doi.org/10.1038/s41598-022-17430-6>

³ AMM media analysis. Mar 1, 2020 to May 13, 2024.



efforts to improve patients' lives. Even our members outside of the U.S. applaud the examples and framework outlined in the guidance. While these firms are not bound by FDA regulations in their home countries, they eagerly look to FDA in matters like combating misinformation.

We appreciate FDA prioritizing updating this draft guidance and look forward to seeing it finalized. If you have any questions or would like to discuss this further, please contact Clay Alspach at Clay.Alspace@Leavittpartners.com or Sara Singleton at Sara.Singleton@Leavittpartners.com.

Sincerely,

Clay Alspach, Executive Director
Sara Singleton, Managing Director
Alliance for mRNA Medicines

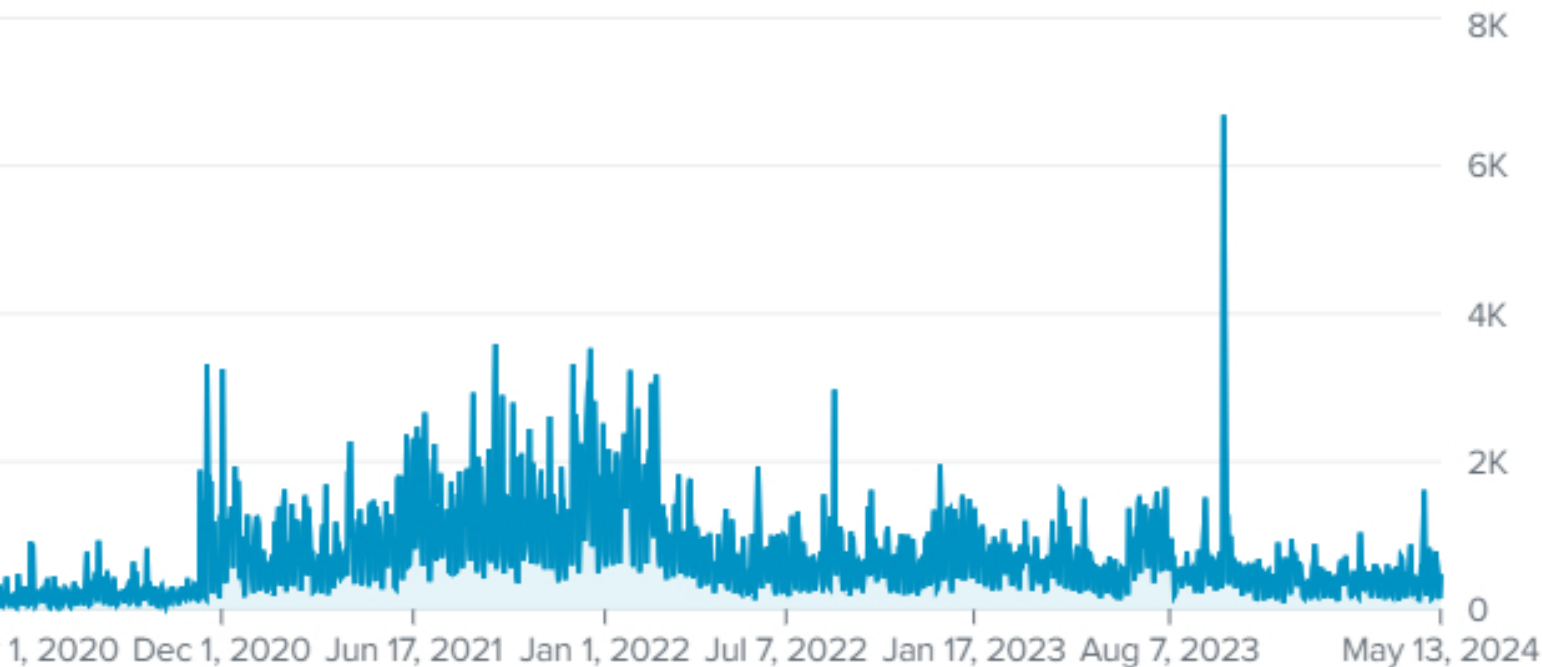
Total Mentions Over Time

Search: mRNA 720

D W M

1,123,872

TOTAL MENTIONS



Mar 1, 2020 to May 13, 2024

Ad Equivalency

Search: mRNA 720



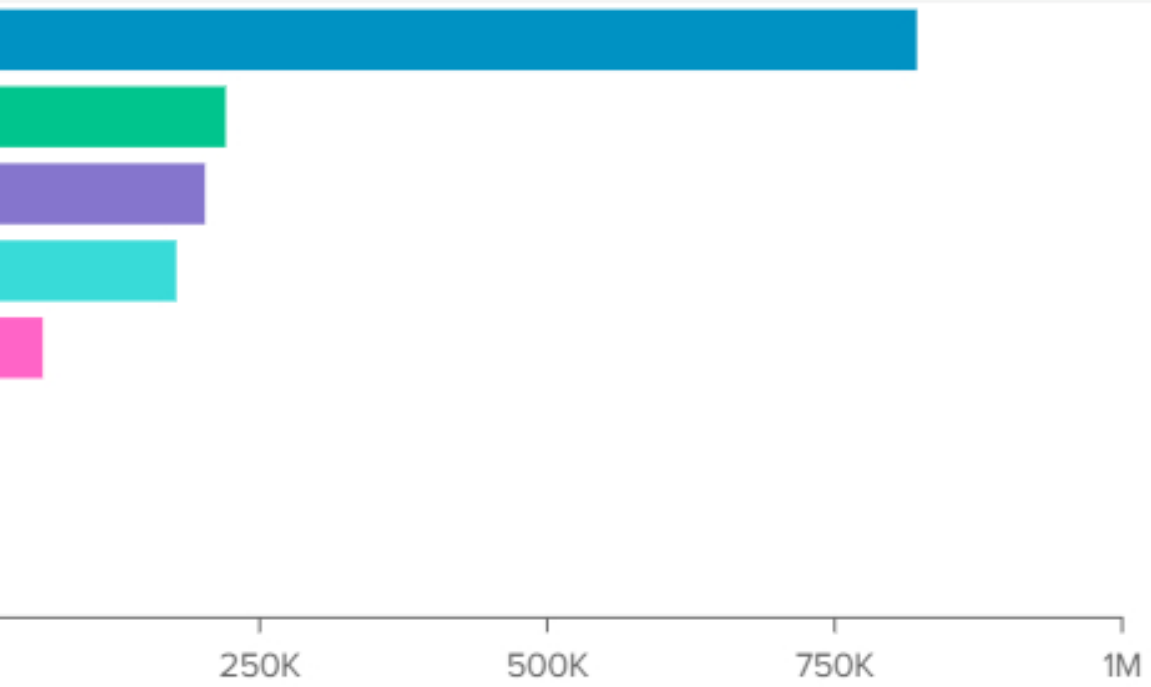
MEDIA TYPE	AD EQUIVALENCY
Total	\$10.61B
● Online News and Licensed Content	\$10.56B
● Blogs	\$50.12M

3B 6B 9B 12B

Mar 1, 2020 to May 13, 2024

Key Messages 1

Search: mRNA 720

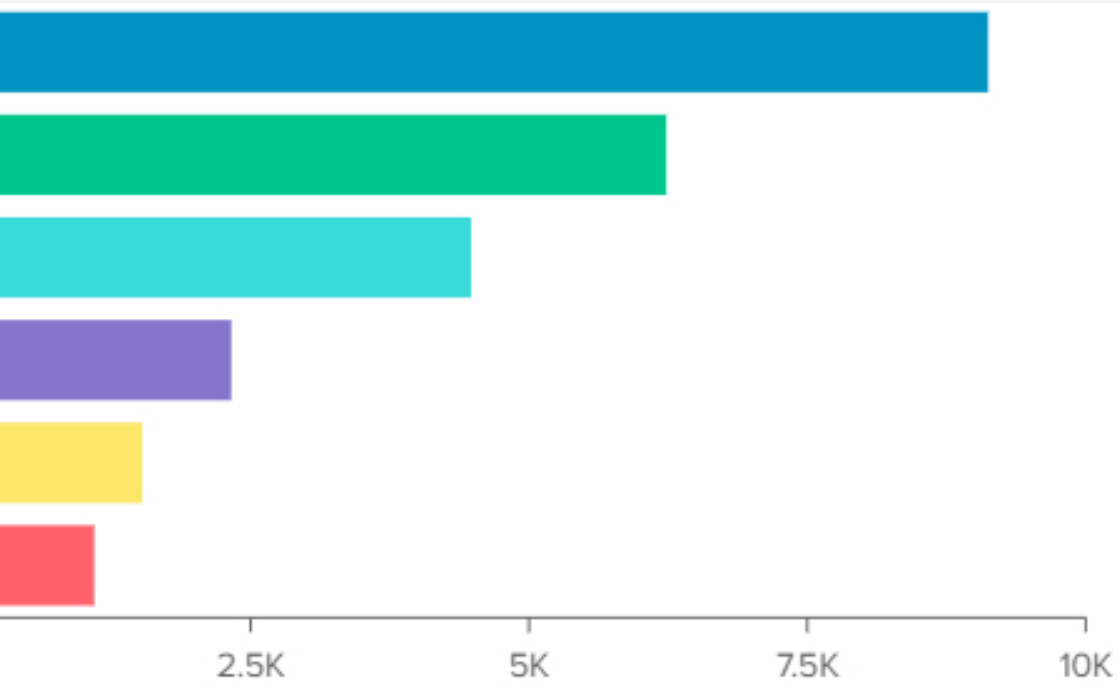


KEY MESSAGE	TOTAL MENTIONS
● vaccine	821K
● death	220K
● food	202K
● cancer	177K
● Myocarditis	61.32K
● heart attack	21.69K
● fertility	13.49K

Mar 1, 2020 to May 13, 2024

Key Messages 2

Search: mRNA 720

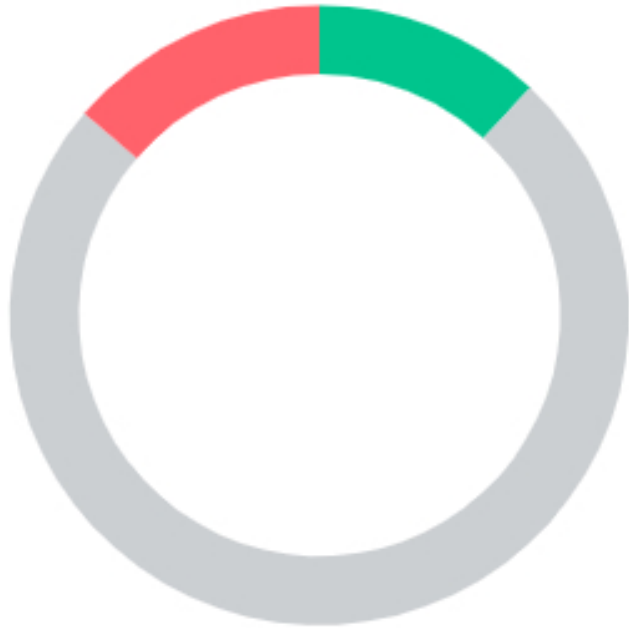


KEY MESSAGE	TOTAL MENTIONS
● 5G	9.1K
● autism	6.2K
● Microchip	4.5K
● alter DNA	2.3K
● infertile	1.5K
● biological weapon	1.1K

Mar 1, 2020 to May 13, 2024

Sentiment

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SEARCH NAME	TOTAL MENTIONS
● Positive	121K (12%)
● Neutral	754K (74%)
● Negative	139K (14%)

Mar 1, 2020 to May 13, 2024

Highest Readership


Search: mRNA 720

 **Jadakiss to Voice COVID-19 Safety** 517M
Feb 4 • Yahoo!

 **The CDC Just Quietly Gave You Pe** 517M
Jan 22 • Yahoo!

  **China pushes conspiracy theories** 517M
Jan 25 • Yahoo!

4  **Johnson & Johnson's COVID-19 Vaccine** 517M
Jan 29 • Yahoo!

5  **'I'm a Breastfeeding Mom And An** 517M
Jan 29 • Yahoo!

6 **We Broke Down the Differences Betwe** 517M
Jan 29 • Yahoo!

Mar 1, 2020 to May 13, 2024

Aggregate Readership

Search: mRNA 720



MEDIA TYPE	TOTAL READERSHIP
Total	54.19B
● Online News and Licensed Content	53.17B
● Blogs	1B

15B 30B 45B 60B

Apr 14, 2024 to May 14, 2024

Domain Authority

Search: mRNA 720



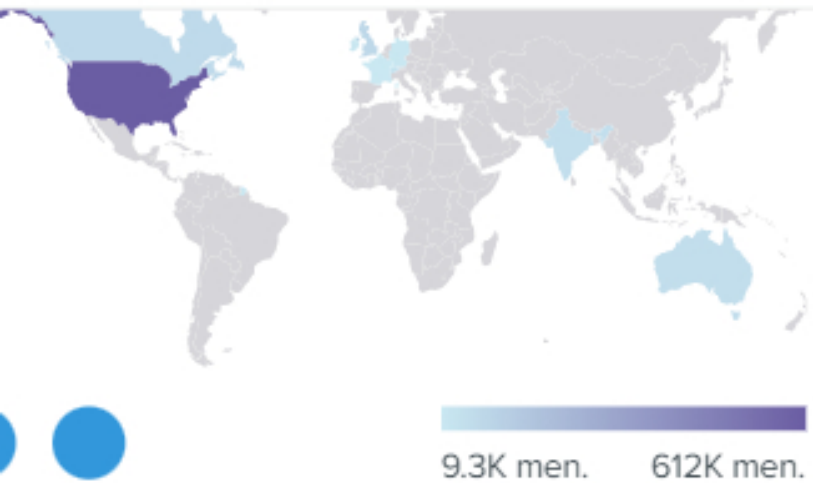
DOMAIN AUTHORITY TOTAL MENTIONS

● 40-59	3K (26%)
● 81-100	3K (25%)
● 20-39	2.6K (22%)
● 60-80	2.5K (22%)
● 1-19	624 (5%)

Apr 14, 2024 to May 14, 2024

International

Search: mRNA 720



COUNTRY	TOTAL MENTIONS
United States	612K (64%)
United Kingdom	77.06K (8%)
Canada	71.74K (8%)
Australia	51.83K (5%)
India	46.39K (5%)
Switzerland	33.29K (3%)
Korea, Republic of	24.37K (3%)

Apr 1, 2020 to May 14, 2024

Word Cloud

Search: mRNA 720

genetic material initial evidence emergency use authorization
human cells spike protein mRNA-based vaccines emergency use
effective vaccine biotech company Moderna mRNA vaccines
vaccinated people coronavirus vaccine infectious diseases
safety concerns mRNA vaccines weakened forms
Moderna vaccines immune system actual virus clinical study
Conventional vaccines enough doses vaccine candidate
adverse events immune response interim analysis
immune responses age groups genetic code rapid solution
fully vaccinated 19 vaccine candidate Moderna vaccine
prior evidence severe disease coronavirus vaccines pharmaceutical giant
single dose biotechnology company enough shots

Aug 1, 2020 to Aug 1, 2021