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VIA EMAIL

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Re: *February 4, 2022 ACIP Meeting on the Recommendation of Moderna's COVID-19 Vaccine, Spikevax, for Individuals 18 Years of Age and Older*

Dear ACIP Members:

We write to you on behalf of our client, Informed Consent Action Network ("**ICAN**"), in advance of your upcoming Advisory Committee on Immunization Practices ("**ACIP**") meeting where you will be voting on whether or not to recommend Moderna's COVID-19 mRNA vaccine, Spikevax, for individuals aged 18 and older.

Setting aside the fact that Moderna's COVID-19 mRNA vaccine will not prevent infection or transmission, is associated with serious adverse events, and vaccine-derived immunity wanes rapidly, the primary reason why the ACIP committee should not recommend Moderna's Spikevax COVID-19 vaccine is *because its clinical trial measured vaccine effectiveness against a SARS-CoV-2 variant that no longer exists.* The FDA's January 31, 2022 announcement of its approval of Spikevax describes the "FDA Evaluation of Effectiveness Data for Approval for Individuals 18 Years of Age and Older." In its explanation of the efficacy analysis, the FDA admits: "**The data used for the analyses were accrued before the Omicron variant emerged.**"[1] Omicron is currently the dominant variant in the United States.[2] Any analyses not taking this variant into account are therefore irrelevant and outdated.

The COVID-19 mRNA vaccines were genetically engineered over two years ago using sequencing data collected from a patient in Wuhan China on December 26, 2019 (Wuhan-Hu-1)[3] However, the current SARS-CoV-2 variant in the United States, the Omicron variant, has

[1] https://content.govdelivery.com/accounts/USFDA/bulletins/308641a (emphasis added).
[2] *See https://covid.cdc.gov/covid-data-tracker/#variant-proportions.*
[3] Jackson, L. et al., An mRNA Vaccine against SARS-CoV-2 – Preliminary Report. N Engl J Med. November 12, 2020. https://www.nejm.org/doi/10.1056/NEJMoa2022483?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

accumulated 30 non-silent mutations, three deletions, and one insertion in the spike protein, significantly altering the primary structure.[4] Fifteen of the non-silent mutations are located in the domain accessible to antibodies, the receptor binding domain ("**RBD**"), of the S1 protein.[5] This alone suggests the affinity of vaccine-derived antibodies against the Omicron S protein will be significantly lower than the S protein from the parental strain. The data agrees. Over 13 pre-print studies reveal that Spikevax is significantly less effective at neutralizing the Omicron variant compared to the Delta variant. These studies find between a 20- and 127-fold reduction in the ability for vaccine-derived antibodies to neutralize the Omicron variant.[6]

Epidemiological evidence is consistent with the aforementioned *in vitro* data. A Canadian study, led by Public Health Ontario, discovered the median vaccine effectiveness against the Omicron variant to be <10% between 7 and 59 days after receipt of the second dose of a COVID-19 mRNA vaccine series.[7] In fact, the study found a negative vaccine efficacy after 2 months post-vaccination and through more than 8 months post-vaccination indicating that Omicron-infected individuals are more commonly vaccinated, not unvaccinated.[8] Even the most recent MMWR publication released on February 1, 2022 suggests same. This study revealed that Omicron caused 45.8%, 64%, and 89.8% of symptomatic COVID-19 cases[9] among the unvaccinated, fully vaccinated, and fully vaccinated with a booster dose respectively, between November 7, 2021 and January 8, 2022.[10] This suggests the vaccine is less effective at protecting against infection caused by the Omicron variant (compared to the Delta variant).

According to the FDA guidelines on the development and licensure of vaccines to prevent COVID-19, "the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial

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[4] Garcia-Beltran, W., *et al.,* mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron Variant. *MedRxiv*. December 14, 2021. https://pubmed.ncbi.nlm.nih.gov/34931201/.

[5] *Id.*

[6] Schmidt, *et al.*, "Plasma neutralization of the SARS-CoV-2 Omicron variant" *medRxiv* December 13, 2021. https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:3622e942-dfc0-48e5-b3df-c0e93646ec5d. *see also* Aggarwal *et al.,* "SARS-CoV-2 Omicron: evasion of potent humoral responses and resistance to clinical immunotheraputics relative to viral variants of concern" *medRxiv* December 15, 2021. https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:eb17a360-c011-4579-a0e3-09627419c204. *See also*, Roessler, A. *et al.,* SARS-CoV-2 B.1.1.529 variant (Omicron) evades neutralization by sera from vaccinated and convalescent individuals. *MedRxiv.* December 11, 2021. https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1. *See also* Wilhelm, *et al.*, Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera and monoclonal antibodies *medRxiv* December 8th, 2021. https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v2. *See also,* Garcia-Beltran, W., *et al.,* mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron Variant. *MedRxiv.* December 14, 2021. https://pubmed.ncbi.nlm.nih.gov/34931201/.

[7] Buchan, S., *et al.,* Effectiveness of COVID-19 vaccines against Omicron or Delta infection. *MedRxiv.* January 1st, 2022. https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v1.full.pdf.

[8] *Id.*

[9] The remaining cases were caused by the Delta variant among each group.

[10] Danza, P. et al., SARS-CoV-2 Infection and Hospitalization Among Adults Aged >18 Years, by Vaccination Status, Before and During SARS-CoV-2 B.1.1.529 (Omicron Variant Predominance – Los Angeles County, California, November 7, 2021 – January 8, 2022. MMWR. February 1, 2022. https://www.cdc.gov/mmwr/volumes/71/wr/mm7105e1.htm?s_cid=mm7105e1_x.

should be at least 50%".[11] Moderna's trial did not measure efficacy against the current dominant variant of the virus. Real world data evidences that Moderna's Spikevax does not meet that threshold. Therefore, any recommendation for this vaccine is one that ignores the FDA's own guidelines.

Spikevax was FDA-approved based on clinical trial data that is now outdated. Numerous studies demonstrate that vaccine efficacy against Omicron has plummeted. Therefore, recommending this vaccine to millions of Americans is not supported by data. We hope you will consider this in the upcoming ACIP meeting.

Sincerely,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Matthew Menendez, Ph.D.

[11] *See* https://www.fda.gov/media/139638/download.