

745 Fifth Ave, Suite 500, New York, NY 10151
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

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VIA EMAIL AND FEDEX

Xavier Becerra
Secretary
U.S. Department of Health and Human
Services
200 Independence Avenue, S.W.
Washington, DC 20201
c/o Sean McCluskie
sean.mccluskie@hhs.gov

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Chiquita.Brooks-LaSure@cms.hhs.gov

Re: Request to Abrogate Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555, Nov. 5, 2021, The Interim Final Rule

Dear Secretary Becerra and Administrator Brooks-LaSure:

On behalf of our client, Informed Consent Action Network (“**ICAN**”), we write in support of the Section 553(e) Petition for Rulemaking submitted by the Attorneys General of 22 states.¹

The above-referenced Interim Final Rule (“**IFR**”) promulgated by the Centers for Medicare and Medicaid Services (“**CMS**”), which mandated COVID-19 vaccines for millions of health care workers, should be abrogated because there is no scientific justification for the IFR (*infra* § I) and it fails to account for natural immunity (*infra* § II).

I. THE DATA DEMANDS REPEAL OF THE IFR

The majority in *Biden v. Missouri*, 142 S. Ct. 647, 659 (2022), reasoned that CMS possessed the authority to issue the IFR in an effort to “significantly reduce COVID-19 infections, hospitalizations, and deaths” during the ensuing flu season. However, CMS promulgated the IFR during a period where the SARS-CoV-2 Delta variant predominated, and the biomedical literature, even at that time, argued against CMS’s justification. For example:

- An Israeli study released in September 2021 found “a high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals.”²

¹ Attorneys General, Section 553(e) Petition for Rulemaking (Nov. 17, 2022), https://content.govdelivery.com/attachments/MTAG/2022/11/17/file_attachments/2332228/11.17.22%20CMS%20petition%20for%20rulemaking.pdf.

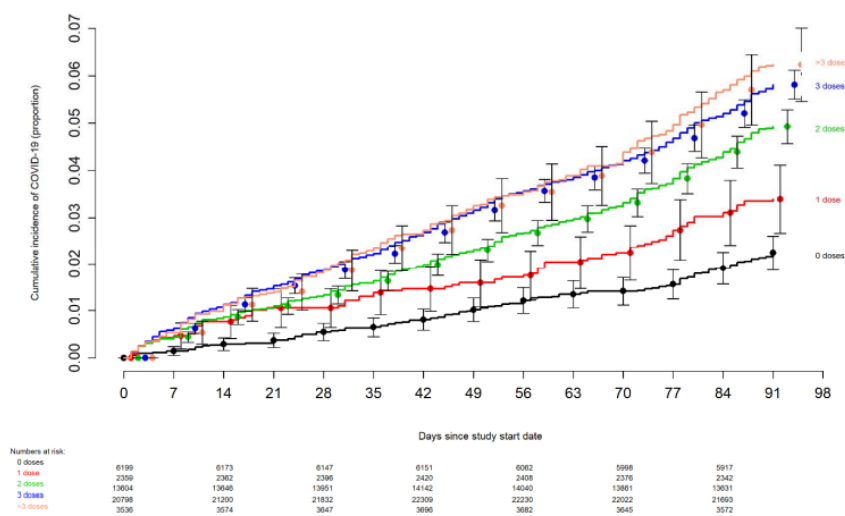
² Pnina Shitrit *et al.*, *Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021*, Eurosurveillance (Sept. 30, 2021), <https://pubmed.ncbi.nlm.nih.gov/34596015/>.

- A Wisconsin Health Department study released in August 2021 found a high viral load in 68% of fully vaccinated individuals versus just 63% of unvaccinated individuals.³
- A Harvard study released in February 2022 found a major Delta outbreak in Massachusetts was driven principally by vaccinated persons, who comprised 74% of the cases with “multiple transmissions of Delta from and between fully vaccinated individuals.”⁴

Accordingly, the justification for the IFR was highly tenuous at the outset.

Justification for the IFR is now at its end. The less virulent Omicron variant is currently predominating in the United States⁵ and the data clearly shows that that vaccinated COVID-19 health care workers are now more likely to have COVID-19 than unvaccinated workers. In fact, the data shows that, the more doses of vaccine, the higher the risk of COVID-19.

A large recent study of approximately 50,000 workers in the Cleveland Clinic health care system shows, very clearly, that with each dose of COVID-19 vaccine, one’s risk of contracting SARS-CoV-2 increases steadily, as the figure below depicts.⁶ Note that the black line (0 doses) is lower than the red (1 dose), green (2 dose) lines, etc. This data makes clear that **the receipt of each additional booster dose (starting with 1 dose) actually increases the risk of COVID-19.**



³ Riemersma, Kasen *et al.*, *Shedding of Infectious SARS-CoV-2 Despite Vaccination*, MedRxiv (Aug. 24, 2021), <https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf>.

⁴ Katherine J. Siddle *et al.*, *Transmission from vaccinated individuals in a large SARS-CoV-2 Delta variant outbreak*, *Cell* (Feb. 3, 2022), <https://www.sciencedirect.com/science/article/pii/S0092867421014902>.

⁵ Centers for Disease Control and Prevention, *COVID Data Tracker – Variant Proportions*, <https://covid.cdc.gov/covid-data-tracker/#variant-proportions> (last accessed Oct. 26, 2022); Blas J. Larrauri, *et al.*, *Omicron and vaccines: An analysis on the decline in COVID-19 mortality*, MedRxiv (May 23, 2022), <https://www.medrxiv.org/content/10.1101/2022.05.20.22275396v1>.

⁶ Nabin K. Shrestha, *et al.*, *Effectiveness of the Coronavirus Disease 2019 (COVID-19) Bivalent Vaccine*, Medrxiv (Dec. 19, 2022), https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full.pdf?utm_source=substack&utm_medium=email.

As such, the IFR is mandating a medical product that is in fact increasing, not decreasing, the risk of COVID-19. This undercuts any justification for continuing this irrational policy.

II. THE IFR FAILS TO ACCOUNT FOR NATURAL IMMUNITY

Even if the IFR's premise were scientifically sound (which it is not), CMS makes no attempt to tailor the requirement to account for natural immunity despite the fact that the data are clear that natural immunity is equal to or more robust than vaccine induced immunity.⁷ This further reflects that something other than health is driving CMS's one-size-fits-all scientifically bereft policy.

There are numerous other issues with and resulting from the IFR, but the foregoing is sufficient to repeal it forthwith. We hope that CMS will rise above politics and dogma and repeal the IFR which has needlessly increased costs and reduced access to health care by causing staff shortages. Justice Alito has already admonished CMS for acting on motives that clearly are not driven by health considerations.⁸ Prove him wrong.

Accordingly, we respectfully request that the Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555, Nov. 5, 2021 be abrogated forthwith.

Very truly yours,



Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Catherine Cline, Esq.
Thomas Stavola, Esq.

⁷ Sivan Gazit *et al.*, *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, MedRxiv (Aug. 25, 2021), <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full-text>; Paul Elias Alexander, Ph.D., *160 Plus Research Studies Affirm Naturally Acquired Immunity to COVID-19: Documented, Linked, and Quoted*, (Oct. 17, 2021), available at <https://brownstone.org/articles/research-studies-affirm-naturally-acquired-immunity/>.

⁸ The questionable nature of CMS's motive in adopting the IFR did not escape the notice of Justice Alito in his *Biden v. Missouri* dissent: "Although CMS argues that an emergency justifies swift action, both District Courts below held that CMS fatally undercut that justification with its own repeated delays. The vaccines that CMS now claims are vital had been widely available 10 months before CMS's mandate, and millions of healthcare workers had already been vaccinated before the agency took action." *Biden*, 142 S. Ct. at 660.