

200 Park Avenue, 17th Floor, New York, NY 10166
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July 22, 2022

VIA EMAIL AND FED EX

Rochelle Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30329
Aux7@cdc.gov

Re: *Inaccurate Information Presented in a Press Briefing on June 23, 2022*

Dear Director Walensky:

On behalf of the Informed Consent Action Network (“ICAN”), we write regarding an incorrect statistic you provided during a June 23, 2022 White House press briefing. Without providing a source, you stated, “[D]uring March 2020 through April 2022, COVID-19 was among the top five leading causes of death in every age group of children under the age of 19 and the number one infectious cause of death in children.”¹

According to CDC data, and contrary to what you states, COVID-19 ranks only 8th out of the top ten leading causes of death in individuals 0-19 years of age.² And even this statistic overstates the impact of COVID-19 on this age group for reasons explained in our petitions to the FDA of May 24, 2022,³ and June 30, 2022.⁴ It is, in any event, patently incorrect to state that COVID-19 was among the top five leading causes of death for this age group.

We note that CDC Medical Officer Katherine Fleming-Dutra, MD likewise cited this incorrect “top five” leading cause of death statistic in her June 14, 2022 VRBPAC⁵ and July 17, 2022 ACIP⁶ presentations days before your briefing. The source Dr. Fleming-Dutra cited was a pre-publication British study that distorted the data it interpreted in numerous ways, including by

¹ <https://www.whitehouse.gov/briefing-room/press-briefings/2022/06/23/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-86/>.

² <https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v3>.

³ <https://www.regulations.gov/document/FDA-2022-P-0872-0001>.

⁴ <https://www.regulations.gov/document/FDA-2022-P-1399-0001>.

⁵ <https://www.fda.gov/media/159222/download> at 30.

⁶ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-Fleming-Dutra-508.pdf> at 26.

comparing COVID-19 deaths during a 26-month period to annualized deaths of other causes, as well as by including deaths where COVID-19 was not an underlying cause of death (and therefore, overcounting COVID-19 deaths).⁷ Fortunately, on June 19, 2022, four days *before* you made the incorrect statement, the study's lead author announced that after receiving "some feedback and criticism," the study would be updated and, on June 28, 2022, the updated version was published with more accurate data.⁸ Our office has sent a letter to Dr. Fleming-Dutra requesting she issue a correction to VRBPAC and ACIP immediately, as both of her presentations relied on incorrect data.⁹

Likewise, ICAN requests that you promptly issue a correction acknowledging that the "top five cause of death" statistic you provided during the White House press briefing was incorrect.

ICAN looks forward to your prompt response.

Very truly yours,

A handwritten signature in black ink, appearing to read "E A Brehm".

Elizabeth A. Brehm, Esq.
Catherine Cline, Esq.

⁷ Flaxman, Seth, *et al.*, *Covid-19 is a leading cause of death in children and young people ages 0-19 in the United States*, MedRxiv (May 25, 2022), <https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v1>

⁸ https://twitter.com/flaxter/status/1538533537355288577?s=20&t=J0WQWP_3FnQob8ePqv8siA.

⁹ See Exhibit 1 attached hereto for a copy of this letter.

Exhibit 1

200 Park Avenue, 17th Floor, New York, NY 10166
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July 22, 2022

VIA EMAIL AND FED EX

Katherine Fleming-Dutra, MD
Medical Officer
COVID-19 Vaccine Policy Unit
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Room 6105, Duty Station GA 30333
1600 Clifton Rd. NE
Atlanta, GA 30333
Ftu2@cdc.gov

Re: *Inaccurate Data in Your Presentations at the June 14, 2022 VRBPAC and June 17, 2022 ACIP Meetings*

Dear Dr. Fleming-Dutra:

On behalf of Informed Consent Action Network (“ICAN”), we write regarding your presentations at the June 14, 2022 VRBPAC and June 17, 2022 ACIP meetings titled *COVID-19 Epidemiology and Disease Burden in Infants, Children and Adolescents*, wherein you presented inaccurate data indicating that COVID-19 ranks in the top five leading causes of death among children ages 0-19 years-old.¹ Your slides presenting this information cite a British pre-publication study from May 25, 2022, titled *Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States*.²

As we hope you are now aware, the study you cited falsely claimed that COVID-19 is one of the top five leading causes of death in children and young people ages 0-19 years in the United States.³ The study erred by, *inter alia*, (i) comparing COVID-19 deaths during a 26-month period with deaths from other causes during 12-month periods, and (ii) including in the analysis deaths where COVID-19 was not an underlying cause of death (and therefore, overcounting COVID-19 deaths). Fortunately, on June 19, 2022, the study’s lead author announced that after receiving

¹ <https://www.fda.gov/media/159222/download> at 30; <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-Fleming-Dutra-508.pdf> at 26.

² Flaxman, Seth, *et al.*, *Covid-19 is a leading cause of death in children and young people ages 0-19 in the United States*, MedRxiv (May 25, 2022), <https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v1>.

³ See <https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v3.article-info> (Revision Summary).

“some feedback and criticism” the study would be updated.⁴ Ultimately, on June 28, 2022, the updated version was published. When the more accurate source of COVID-19 deaths was used (CDC WONDER) and an equivalent time period was assessed to recreate the rankings, instead of coming in at 4th or 5th, depending on the age range, COVID-19 ranks 8th among the top ten leading causes of death for this age group overall (0-19-year-olds). Even these more accurate results overstate the impact of COVID-19 as it constitutes less than 5% of the deaths from the top ten causes in each age group.⁵ Regardless, COVID-19 is not a “top five” cause of death for the age range at issue as you stated in your presentations.

It is deeply concerning that, as a presenter, you did not vet and confirm the pre-print study you cited before asserting it as fact to individuals tasked with weighing the risks and benefits of a novel vaccine for babies and children. It is equally troubling that no one on VRBPAC or ACIP questioned the data. Because both VRBPAC and ACIP likely relied on your presentation, and the inaccurate data it contained when making their recommendations, ICAN requests that you immediately issue a correction to your VRBPAC and ACIP presentations and indicate to the committees and to the public that the data relied upon in your presentation has since been corrected.

ICAN looks forward to your prompt response.

Very truly yours,



Elizabeth A. Brehm, Esq.
Catherine Cline, Esq.

cc: Members,
Advisory Committee on Immunization
Practices
acip@cdc.gov

Members,
Vaccines and Related Biological Products
Advisory Committee
vrbpac@fda.hhs.gov

⁴ https://twitter.com/flaxter/status/1538533537355288577?s=20&t=J0WQWP_3FnQob8ePqv8siA.

⁵ <https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v3>. A side-by-side comparison of the two versions can be found here: <https://draftable.com/compare/JUMoilBlbfKR>.