

ge²p² global foundation

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GE2P2 Global Foundation – Center for Vaccine Ethics and Policy

Public Comment Offered at ACIP Meeting of 12 December 2020 Considering Recommendation for Pfizer-BioNTech COVID-19 Vaccine with FDA Emergency Use Authorization

I am David Curry, President of the GE2P2 Global Foundation and head of its Center for Vaccine Ethics and Policy. I am also Affiliate Faculty at the Division of Medical Ethics at NYU's School of Medicine.

By way of disclosure, our Foundation receives support from a range of individuals and organizations, including Pfizer and the Gates Foundation, to support a free weekly digest reviewing peer-reviewed literature and global strategic developments in immunization and public health.

Our comment focuses on a key element supporting responsible and ethically sound deployment of the Pfizer-BioNTech COVID-19 Vaccine – and others likely to follow very soon.

This key element involves the information to be presented to recipients and caregivers as they are offered or seek vaccination. We argue that this information must:

- Be clear,
- Be appropriately written and presented for limited literacy and reading levels,
- Be broadly translated for the diverse populations that will need to be vaccinated,
- present alternative vaccine options as they become available, and
- be otherwise supportive of recipients in making a well informed decision to accept the vaccine.

We recognize that FDA Emergency Use Authorization does not require formal informed consent and that the minimum information to be provided is via a [Fact Sheet for Recipients and Caregivers](#).

But in examining the EUA Fact Sheet now posted we note that it is presented

- in text only, with no graphical information to assist recipient comprehension, even though the Fact Sheet for providers does include graphical information,
- is presented at a reading level that does not appear to align with lower reading and literacy levels, and is
- limited to a document in English with no translations posted or any indication that translations will be posted.

We are enthusiastic that Dr. Cohn – at the ACIP meeting of December 1– reported that additional supporting information was in development to enable informed consent for individuals offered vaccine in long term care facilities.

The CDC toolkit content now posted – apart from that focused to health care workers – appears to generic to all recipients and include an FAQ and limited additional webpages. Apart from the limited depth of the content itself, these web resources seem to be available only in English.

We are concerned that, especially with the mention of “assent” today, the posted content will not be robust enough to effectively respond to either the information needs of long term care individuals and caregivers, or to the serious levels of vaccine hesitancy operative across many vulnerable and hard-to-reach communities and populations.

We energetically urge – and are confident that CDC will – extend its best efforts to develop additional, graphically-rich, translated supporting content for these populations and assure that it is effectively available.

We also urge that ACIP continue to closely assess this supplementary information as it emerges to ensure that it adequately supports the intent of its recommendations.

Thank you.