COVID-19 Clinical Advisory Task Force

September 24, 2021

Commissioner Howard A. Zucker, M.D., J.D.
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Commissioner Zucker,

The Clinical Advisory Task Force met via Webex at 5 PM on Thursday, September 23, 2021 to discuss what has become a burning question in the Covid-19 pandemic: What is the role for booster injections in individuals who have received the two-dose primary vaccination series (i.e., are fully vaccinated) with the Pfizer-BioNTech mRNA Covid vaccine? This issue was intensively addressed by two key federal agencies in the approval, regulatory, and public health recommendation pathways of Covid-19 vaccines. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), largely through the vehicles of their advisory committees – the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and Advisory Committee on Immunization Practices (ACIP), respectively – comprehensively reviewed the available data on the safety and effectiveness of the Pfizer-BioNTech mRNA vaccine. Discussion was restricted to this vaccine. The Task Force members monitored these proceedings and discussed them via conference call and email correspondence.

The Task Force commends the VRBPAC (FDA) and ACIP (CDC) for the quality of the presentations, the airing of varied viewpoints, and the thoughtful independence of their advisory committee members. Adaptation and revision of the recommendations during each proceeding highlighted a number of challenging issues to resolve, the need for more data in a number of areas, and the desire to reach consensus if possible. The intensity of the situation is highlighted by the fact that the FDA authorized the booster injection between days 1 and 2 of the ACIP Meeting. The regulatory authorization by FDA was needed for ACIP to consider making a recommendation.

On September 17, 2021, VRBPAC voted to amend the emergency use authorization (EUA) for the Pfizer-BioNTech Covid-19 vaccine to allow for a booster dose at least 6 months after completion of the primary series in:

- individuals 65 years of age and older;
- individuals 18 through 64 years of age at high risk of severe COVID-19; and

- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

On September 22, 2021, FDA amended the EUA as recommended by VRBPAC. ACIP met on September 22-23, 2021.

Overall, these committees expressed strong support for the use of boosters in persons fully vaccinated with Pfizer-BioNTech in whom waning immunity has been convincingly demonstrated and for whom the elevation of measures of immunogenicity has been associated with a reduction in severe disease, hospitalization, and death. In this regard, there was unanimity that the data were compelling for the age over 65 sub-population. There was comparable support for individuals aged 50-64 with underlying conditions who have completed their primary vaccination series >6 months previously. However, ACIP voted against the proposal to recommend booster injections for persons who are at increased risk for Covid-19 by virtue of occupational or institutional exposure. The lack of support was based on concern about whether there is an additional clinical benefit conferred to these already fully vaccinated persons and caution about the risk of rare events such as myocarditis in younger males. Despite the ACIP vote, this latter group was included in the guidance issued by the CDC. The CDC statement issued Friday, 9/24/2021 is as follows:

"CDC recommends:

- *people 65 years and older and residents in long-term care settings **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,*
- *people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series,*
- *people aged 18–49 years with underlying medical conditions **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks, and*
- *people aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting **may** receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks."*

The Task Force endorses this interim guidance from the CDC as it provides flexibility at the public health and individual care levels such that access will be available to all who would potentially benefit from a booster. Discussions are needed to adapt these recommendations to the NYS setting, especially the list of qualifying medical conditions (bullet point 3 above) and the occupational or institutional settings (bullet point 4 above). During its discussion, the Task Force endorsed the list of medical conditions that was used in early 2021 to determine eligibility for a primary series:

1. Cancer (current or in remission, including 9/11-related cancers)
2. Chronic kidney disease
3. Pulmonary Disease, including but not limited to, COPD (chronic obstructive pulmonary disease), asthma (moderate-to-severe), pulmonary fibrosis, cystic fibrosis, and 9/11 related pulmonary diseases
4. Intellectual and Developmental Disabilities including Down Syndrome
5. Heart conditions, including but not limited to heart failure, coronary artery disease, cardiomyopathies, or hypertension (high blood pressure)

6. Immunocompromised state (weakened immune system) including but not limited to solid organ transplant or from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medicines, or other causes
7. Severe Obesity (BMI 40 kg/m2), Obesity (body mass index [BMI] of 30 kg/m2 or higher but < 40 kg/m2)
8. Pregnancy
9. Sickle cell disease or Thalassemia
10. Type 1 or 2 diabetes mellitus
11. Cerebrovascular disease (affects blood vessels and blood supply to the brain)
12. Neurologic conditions including but not limited to Alzheimer's Disease or dementia
13. Liver disease.

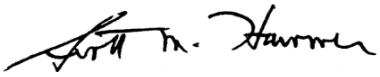
This list is similar to the list referred to by CDC above except for the following key differences:

- CDC includes Down Syndrome; New York included Down Syndrome and other intellectual and developmental disabilities;
- CDC lists HIV separately from immunocompromised states;
- CDC includes overweight (BMI > 25 kg/m2 but less than 30 kg/m2) in addition to obesity and severe obesity; New York included only obesity and severe obesity;
- CDC includes current or former smokers; New York did not;
- CDC includes substance use disorders; New York did not.

The proceedings and guidance described above put into relief a number of pressing and highly relevant issues that need to be addressed:

- Primary vaccination of the unvaccinated persons should remain the top priority. Boosting already vaccinated individuals is secondary to this over-riding objective.
- The discussion over this past week was complete with respect to Pfizer-BioNTech but there remains an urgent need to complete the evaluation and guidance for recipients of Moderna and J&J (Janssen) vaccines. This would also facilitate production and dissemination of homologous and heterologous boosting data and guidance.
- Pending pediatric reviews/approvals need to be completed as soon as possible.

Respectfully,



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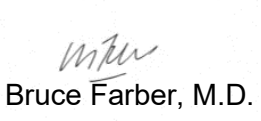

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