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COVID-19 Vaccine

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COMMENTS ON THE PRELIMINARY FRAMEWORK FOR EQUITABLE ALLOCATION OF COVID-19 VACCINE

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We appreciate this opportunity to comment on the Preliminary Framework. We offer the following remarks.

1. While the CDC currently reports over 6 million confirmed and probable cases of COVID-19, that number has been recognized as a likely underestimation of the actual case count (BMJ, Tanne, 2020). As such, targeting an estimated number of high-risk populations at large does not fully account for the likely on-the-ground effects of COVID-19. While we agree with the Committee that high-risk populations deserve priority consideration, we urge the Committee to balance the allocative model by incorporating additional factors. Given the probable underestimation of actual cases of COVID-19, it is possible that many individuals in high-risk categories will already have been infected with SARS-CoV-2. As such, we urge the Committee to consider pairing administration of the vaccine with the prior administration of a rapid antibody test, particularly in phases 3 and 4. In a situation of severe shortage of vaccine doses, it might even be advisable to consider conditioning phase 4 vaccination on antibody screening. These measures would reduce wasteful allocation and, subsidiarily, contribute to increase public trust in vaccines.

2. Racial minorities have and continue to bear a disproportionate burden of COVID-19. This disparity is deeply linked to the social determinants of health (SDOH) (Yearby et al. 2020). While the Committee has recognized the need for allocation criteria to account for health inequities arising from social inequities, we urge the Committee to give a higher priority to those made most vulnerable by the SDOH. In particular, we advise the Committee to move from phase 2 to phase 1 individuals who are in homeless shelters as well as those who are in jails, prisons or

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detention centers. Similarly, we urge the Committee to identify and prioritize geographic communities uniquely disadvantaged by the SDOH (for instance, geographic clusters – e.g. census block groups – with the highest percentage of households living below the federal poverty line). Critically, this recommendation presumes that any vaccine allocated under these Guidelines has been subject to standard approval, and not emergency use authorization, as noted below.

3. Relatedly, while the Preliminary Report notes the possibility of reserving a percentage of vaccine to be deployed in “hot spots” (1132-1138), it does not incorporate a geography-based approach in any of the four phases. We urge the Committee to explore insights from geographically focused measures of deprivation or risk zones, such as the area deprivation index and the index of concentration at the extremes.

4. The Preliminary Report relies on a timeline that projects vaccine delivery to occur in a limited setting by January 2021 (2256). Recent guidance from the Centers for Disease Control and Prevention points to an accelerated timeline starting as early as October 2020 (CDC, COVID-19 Vaccination Program Planning Assumptions for Jurisdictions; COVID-19 Vaccination Scenarios for Jurisdictional Planning Phase 1, Q4 2020; Early COVID-19 Vaccination Program Action Items for Jurisdictions). This guidance is consistent with statements made by some representatives of the current Administration. We urge the Committee to address the specific issue of possible changes to the allocative framework proposed in the Preliminary Report should one or more vaccines be authorized according to this earlier timeline.

5. Relatedly, the Preliminary Report is silent on possible distinctions between fully approved vaccines and vaccines made available under an emergency use authorization (EUA). Given the widely acknowledged unknowns and potentially detrimental effects of issuing an EUA for a vaccine, the Report should address the question of whether a vaccine made available under an EUA should be administered in all phases, if in any. We would disagree with the proposition that a vaccine authorized through an EUA should be administered in phase 4, for instance.

6. Relatedly, we note that the Preliminary Report is largely silent on the implications of technology heterogeneity among leading vaccine candidates selected by Operation Warp Speed. Although the development of mRNA vaccines may constitute an important scientific development, we are concerned that this new type of vaccine might be authorized through the EUA pathway. The EUA pathway lowers the review threshold from a demonstration of “substantial evidence” of effectiveness a vaccine to a “reasonable belief” that a vaccine “may be effective” (21 U.S.C. § 360bbb–3). This lowering of standards of review is especially concerning in the case of less-studied vaccines, as is the case with some of the leading candidates.

7. The Preliminary Report is also silent about possible adjustments to the allocative framework once additional data pertaining to multiple vaccines becomes available. The Committee should clarify how supply will be managed if a given vaccine proves more efficacious than others. Moreover, the Committee should clarify whether populations at higher risk will be able to receive a second vaccine, should the first authorized or approved vaccine prove less efficacious; and if not, which steps should be taken to prevent the administration of different vaccines to the same individual.

8. Finally, although the Preliminary Report addresses the problem of vaccine scarcity (e.g. 2428), it does not provide clear guidance on allocation of vaccine in the case of a surplus. We urge the Committee to specify whether unused doses of vaccine would automatically be allocated to next-level priority populations, and whether that would take place in the same geographical area.