

February 15, 2021

Mr. Jeffrey Zients  
Coordinator and Counselor to the President  
COVID-19 Pandemic Response  
The White House  
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Director, National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
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**Re: Immediate Action is Needed to Address SARS-CoV-2 Inhalation Exposure**

Dear Mr. Zients, Dr. Walensky and Dr. Fauci:

We write as physicians and scientists with expertise in aerosol science, occupational health and infectious disease to commend the Biden Administration's National Strategy for the COVID-19 Response and Pandemic Preparedness and to urge strong immediate action to strengthen measures to limit inhalation exposure to SARS-CoV-2 as a cornerstone of this plan.

The Biden Administration COVID-19 plan ramps up and expands the availability of life saving vaccines and calls for widespread use of masks, stronger measures to protect workers and updated and more protective guidelines for the public. Importantly, the plan highlights the disproportionate impacts of COVID-19 on Blacks, Latinos and other vulnerable high-risk groups and outlines actions to protect them.

There is a pressing and urgent need for action. COVID-19 infections and deaths recently reached record levels. The roll-out of vaccines that started out in December rocky and slow is now improving, but it will be months before most of the population is vaccinated. In the meantime, more transmissible variants are projected to become the dominant strains by March and may pose significant challenges to the efficacy of first-generation vaccines and monoclonal antibodies. While COVID-19 infections and deaths have started to decline in recent weeks, they remain at a very high level and, unless strengthened precautionary measures are implemented, the new variants will likely bring an explosion in new infections.

Stronger protective measures are needed immediately to limit exposure and transmission of the SARS-CoV-2 virus to control and end the COVID-19 pandemic. Action is needed to better protect workers and the public against inhalation exposure to the virus. Germany, Austria and France have all recently taken action by mandating respiratory protection equivalent to N95 filtering facepiece respirators (FFRs) and higher quality

masks for workers and members of the public and have recommended enhanced ventilation in indoor settings [1–3].

The United States should take similar strong actions to control the COVID-19 pandemic.

For many months it has been clear that transmission through inhalation of small aerosol particles is an important and significant mode of SARS-CoV-2 virus transmission. The gravity of this problem was emphasized this week by an editorial in the journal *Nature* [4]. Numerous studies have demonstrated that aerosols produced through breathing, talking, and singing are concentrated close to the infected person, can remain in air and viable for long periods of time and travel long distances within a room and sometimes farther [5–7]. Gatherings in indoor spaces without adequate ventilation place participants at particularly high risk, an important component of which is driven by asymptomatic and pre-symptomatic viral shedding of infected individuals [8].

In October, the CDC recognized inhalation as a route of exposure that should be controlled to protect against COVID-19 [9], but most CDC guidance and recommendations have not yet been updated or strengthened to address and limit inhalation exposure to small aerosol particles. CDC continues to use the outdated and confusing term “respiratory droplets” to describe both larger propelled droplet sprays and smaller inhalable aerosol particles. It also confuses matters with “airborne transmission” to indicate inhalation exposure exclusively at long distances and does not consider inhalation exposure via the same aerosols at short distances.

This artificial distinction needs to be replaced with up-to-date terminology [10], as advocated by the National Academies workshop on Airborne Transmission [11], focused on routes of exposure via a) touch, b) large droplets sprayed onto the body, and c) inhalation of small aerosol particles [12].

CDC guidance and recommendations do not include the control measures necessary for protecting the public and workers from inhalation exposure to SARS-CoV-2. Most recommendations from other agencies are also out of date.

For example, CDC continues to recommend surgical masks for most healthcare workers and limits the use of NIOSH-certified respirators only to direct patient care or aerosol generating procedures with COVID-19 patients. It is now well documented that healthcare workers in non-COVID-19 patient care and support positions are also at high risk of infection [13–17] and should be wearing respirators.

Similarly, for non-healthcare workers - even those at very high risk of exposure and infection such as in food processing, prisons and security - CDC and OSHA recommend only face coverings that do not protect against small particle aerosol inhalation. Even the most recent CDC guidelines on face coverings, issued February 11, 2021, focus on prevention of exposure to droplets and state unequivocally “CDC does not recommend the use of N95 respirators for protection against COVID-19 in non-healthcare settings” [18].

CDC has cited shortages of N95 FFRs as a key reason for limiting their use outside of healthcare, but in recent months the supply and availability of these and other NIOSH-approved respirators has increased as new manufacturers enter the market. Millions of NIOSH-approved N95 FFRs are now available and sitting in warehouses, with many employers reluctant to buy from new producers or believing there is no need for their use [19]. Without clear guidance and direction on the need for enhanced protection, there is no demand for these N95 FFRs and some of these new manufacturers may go out of business.

CDC and OSHA must recommend and require the use of respiratory protection, such as N95 FFRs, to protect all workers at high risk of exposure and infection.

CDC and OSHA guidelines fail to follow or recommend an objective risk assessment approach built on well-understood principles, such as exposure being a function of aerosol concentration and contact time or a control hierarchy that emphasizes source and pathway interventions over receptor controls (personal protective equipment). A risk-based control-banding model developed and published by CDC and NIOSH investigators designed specifically for conserving personal protective equipment resources during an aerosol-transmissible infectious disease pandemic [20], updated specifically for COVID-19 [21,22] was not employed and represents a major missed opportunity that could have saved lives.

The failure to address inhalation exposure to SARS-CoV-2 continues to put workers and the public at serious risk of infection. People of color, many of whom work on the front lines in essential jobs, have suffered – and continue to suffer -- the greatest impacts of the COVID-19 pandemic [23,24].

In assuming the directorship of CDC, Dr. Walensky recognized that many of the agency's recommendations did not reflect the latest science and she committed the agency to reviewing and updating them. On January 20, 2021, Dr. Walensky issued the following statement:

CDC's Principal Deputy Director Anne Schuchat will begin leading a comprehensive review of all existing guidance related to COVID-19. Wherever needed, this guidance will be updated so that people can make decisions and take action based upon the best available evidence [25].

We applaud this much-needed focus on science to inform public health guidance and encourage the Administration and its agencies to focus on aerosol inhalation.

To address and limit transmission via inhalation exposure and prevent COVID infections and deaths, we urge the Biden administration to take the following immediate actions:

- Update and strengthen CDC guidelines to fully address transmission via inhalation exposure to small inhalable particles from infectious sources at close, mid and longer range. Updated guidelines should be informed by a risk assessment model that focuses on source and pathway (ventilation) controls first, followed by respiratory protection. Workers in the highest risk categories, including all healthcare workers and other workers with prolonged, close contact with infectious people, must also be provided respiratory protection.
- A year into the pandemic with a re-established supply chain that includes increased US production, CDC must direct healthcare organizations to stop all contingency and crisis practices (e.g. decontamination of N95 FFRs and use of non-respirator facepieces such as surgical masks in place of respiratory protection), and expand its recommendations for respiratory protection to include all workers in healthcare and related sectors, not just those with direct care of COVID-19 patients.
- Issue an OSHA emergency standard on COVID-19 that recognizes the importance of aerosol inhalation, includes requirements to assess risks of exposure, and requires implementation of control measures following a hierarchy of controls. The standard should address requirements for effective respiratory protection for all healthcare and other workers at high risk of exposure to COVID-19. Workers at lower

exposure risks should be offered high-performing barrier face coverings tested to the ASTM F3502-21 Standard Specification for Barrier Face Coverings with at least 80% filter efficiency, no more than 15 mm H<sub>2</sub>O air flow resistance and total inward leakage of no more than 5% on a panel of at least 10 subjects.

- Update CDC recommendations and adopt standards for barrier face coverings for the public with high levels of filter efficiency, low breathing resistance and low inward and outward leakage to ensure both source control and personal protection from small particle inhalation, following the test methods described in ASTM F3502-21 Standard Specification for Barrier Face Coverings [26].
- Coordinate a national effort to enhance and distribute the supply of NIOSH-certified respirators and ASTM barrier face coverings for worker protection. Immediately identify existing supplies and help distribute them where they are most needed. Existing supplies of respirators need to be made available and used now, not allowed to sit in warehouses and in supply rooms.
- Use the Defense Production Act to ramp up production of N95 FFRs (particularly models already certified and in wide use), elastomeric respirators, powered air purifying respirators and high-quality barrier face coverings. Provide funding and enter contracts with manufacturers to increase supplies. Coordinate the supply chain and require the purchase of US-manufactured respirators.

As we have emphasized, immediate action is needed to address inhalation exposure risks in order to bring the COVID-19 pandemic under control. We stand ready to assist the administration in these efforts.

We thank you, President Biden, and the entire administration for your strong leadership and efforts to protect the American public and workers from this deadly virus.

Sincerely,

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