

# Strategies to Address the Chronic Shortage of N95 Masks and Other Filtering Facepiece Respirators during the COVID-19 Pandemic

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**SUMMARY.** In March 2020, healthcare workers sounded the alarm on social media: #GetMePPE. As shortages of personal protective equipment (PPE) coincided with surges in hospital emergency department and intensive care unit capacity due to COVID-19, it became clear that a coordinated national strategy for PPE was needed. The Food and Drug Administration (FDA) released a series of guidance documents, accompanied by permissive emergency use authorizations (EUAs), to address the manufacture and use of PPE in health care settings. This article reviews actions taken by the FDA in response to the PPE shortage and the progress made in 2020 on procuring PPE for health care facilities. Given that N95 masks provide an essential barrier against droplet and aerosol transmission of SARS-CoV-2, this Chapter focuses on shortages of filtering facepiece respirators (FFRs). Finally, the Chapter offers solutions for federal and state policymakers, including the Biden administration, for the COVID-19 pandemic and beyond.

## Introduction

In the United States, the COVID-19 pandemic unmasked a fragmented and under-resourced public health system that failed to quell a lethal respiratory illness from rampant spread. As support for public health agencies has dwindled over the last few decades, so did preparedness for infectious disease epidemics. President Trump's decision to disband the National Security Council's pandemic office in 2018 is just one recent example. In fact, several government reports in the last 15 years highlighted the need for more and better PPE during outbreaks of emerging infectious diseases, calling for greater research and investment; those recommendations were largely ignored by federal authorities (Sinha et al., 2020).

In spite of these warnings, the United States has become increasingly reliant on foreign production of PPE, greatly limiting its ability to scale up domestic manufacturing during emergencies. A year into the COVID-19 pandemic, the situation has substantially worsened domestically, and PPE shortages persist. A recent study identified four major contributing factors to PPE shortages: (1) limited reserves in hospitals; (2) surge demand that could not match supply; (3) failure to adequately maintain the national stockpile; and (4) dependence on foreign manufacturing that is highly susceptible to supply chain disruptions (Cohen & Rodgers, 2020). In fact, more than 70% of medical grade face masks used in the United States were imported from China in 2019; China's

decision to nationalize its PPE supply in February 2020 caused significant disruption to PPE supplies in the United States (Congressional Research Service, 2020a). For more information on PPE and COVID-19, please see Chapter 20 in *Assessing Legal Responses to COVID-19: Volume I*.

## Federal Laws and Regulations Governing PPE FDA Regulation and NIOSH Certification of Medical Devices

Most medical grade PPE is regulated by the FDA as a medical device, pursuant to authority under the Federal Food, Drug, and Cosmetic Act. Oversight of medical devices is less rigorous than that of pharmaceuticals, requiring only a demonstration of substantial equivalence — comparable safety and efficacy — to one or more marketed devices. A 510(k) premarket notification, coupled with agency finding of substantial equivalence, clears the device for marketing and commercial distribution. For certain respiratory devices like filtering facepiece respirators (FFRs) and powered air purifying respirators (PAPRs), the National Institute of Occupational Safety and Health (NIOSH) must test and certify the product prior to filing a 510(k) premarket notification with the FDA.

## OSHA Regulation of Workplace Safety

The Occupational Safety and Health Administration (OSHA) regulates the safety and health of workplaces, including health care facilities. This includes the authority to require respiratory

protection programs and use of protective equipment approved by NIOSH, as well as to issue permanent and temporary standards that regulate exposures, including new sources of harm such as COVID-19 (Congressional Research Service, 2020b). OSHA has yet to issue new requirements for occupational COVID-19 exposure, but did issue an Updated Interim Enforcement Response Plan for COVID-19 in May (OSHA, 2020). On January 22, 2021, President Joe Biden issued an executive order directing OSHA to issue revised guidance on workplace safety within two weeks, with new emergency temporary standards, if necessary, by March 15, 2021.

Twenty-eight state workplace safety and health plans have been approved by OSHA under Section 18(b) of the OSH Act. State plans, which must be as protective as federal OSHA standards, give state officials full authority to regulate workplace safety within their borders, but OSHA can rescind the approval at any time. At least eight states (California, North Carolina, Michigan, Minnesota, Oregon, Utah, Virginia, and Washington) have unique PPE standards.

### PPE and the COVID-19 Pandemic Emergency Regulation of PPE

In his early February 2020 declaration of a public health emergency, Secretary of Health and Human Services (HHS) Alex Azar declared that the circumstances warranted emergency use of in vitro diagnostics and other medical devices for responding to COVID-19. Since that time, the FDA has issued several emergency use authorizations (EUAs) that allow non-FDA approved medical products to be used for the COVID-19 response – in the absence of adequate FDA-approved alternatives (U.S. Food and Drug Administration, 2020b). EUAs expire upon resolution of the public health emergency, as determined by the Secretary of HHS. The public health emergency and the EUAs are issued on a temporary basis, requiring routine reassessment and renewal if warranted. The FDA has also issued and frequently updated guidance documents for manufacturers seeking to produce novel medical devices for responding to COVID-19 PPE shortages. NIOSH guidance during COVID-19 included strategies for optimizing supply of PPE: extended use, reuse, and decontamination and use of N95s beyond their shelf-life (NIOSH, 2020). When continually renewed, the EUA process may not incentivize manufacturers to pursue full approval for their products, and may complicate post-market surveillance.

### Sourcing of PPE

The federal government has multiple levers by which it can compel production, acquisition, and distribution of PPE. The Defense Production Act (DPA) allows the president to commandeer the manufacturing of essential products during national emergencies (discussed in Chapter 24). The Trump administration declined to invoke the full authority of DPA, instead opting to enter into a variety of lucrative private contracts with entities that often had little or no prior experience in PPE manufacture or procurement. Many were unable to fulfill the obligations of those contracts; fraud and other criminal activity occurred as well. The Department of Justice has commenced 33 criminal and 11 civil cases involving COVID-19 related fraud, and U.S. Attorney General William Barr

established the COVID-19 Hoarding and Price Gouging Task Force to address illegal activity related to PPE (Congressional Research Service, 2020a).

The Office of the Assistant Secretary for Preparedness and Response (ASPR, within HHS), worked closely with the Federal Emergency Management Agency (FEMA) on acquisition and distribution of PPE from the Strategic National Stockpile (SNS). During the COVID-19 pandemic, the stockpile has often been unable to accommodate state needs for PPE and other critical medical supplies. The latest COVID-19 relief, part of the 2021 omnibus, allocates \$22.4 billion to the “Public Health and Social Services Emergency Fund,” which may be used to cover PPE. The law also requires a report “containing a whole-of-government plan for an effective response to subsequent major outbreaks of the COVID-19 pandemic and for other future global pandemic diseases,” which must include a section on PPE procurement and distribution (Title VI, Sec. 621(B)(2)(G)). In December 2020, the Congressional Research Service also made several recommendations for the new administration to consider in ensuring sufficient emergency PPE supply (Congressional Research Service, 2020a). The report recommends replenishing the SNS, expanding domestic manufacturing, supply chain control and distribution, and encouraging the use of the DPA. President Biden is already following these recommendations: in one of his first executive orders, he directed federal agencies to use the DPA to ramp up PPE production, though specifics are lacking.

### Filtering Facepiece Respirators

FFRs like N95 masks (**Not** resistant to oil, **95%** filter efficiency) are a critical component of infection control against contagious respiratory illnesses like COVID-19. N95 masks have three primary properties: (1) the ability to filter out small particles; (2) low inhalation resistance so that a user’s oxygen supply is not limited; and (3) a tight fit to the face so that inhaled and exhaled air is directed through the filter. Qualitative fit is evaluated through a process known as fit testing, which is routinely conducted in health care settings and ensures that the mask forms a tight seal with the user’s face. Quantitative testing evaluates filtration efficiency, confirming that the material filters particles effectively without posing harm to the user. Health care institutions are rarely able to measure filtration efficiency.

Shortages of masks, gloves, gowns, shields, and other PPE have resulted in health care-acquired infections and deaths. In a study of frontline health care workers in the United States and United Kingdom between March 24, 2020, and April 23, 2020, health care workers of color were more likely to be caring for patients with COVID-19, more likely to report inadequate or reused PPE, and nearly twice as likely as white colleagues to test positive for COVID-19 – five times more likely than the general public (Nguyen et al., 2020). Inadequate PPE correlated with a 30% greater chance of infection as compared to health care workers with adequate supplies.

**Imported and counterfeit face masks.** In addition to facilitating the manufacture of alternative PPE, the FDA issued EUAs in March

2020 permitting the importation and use of non-NIOSH approved masks that have met functionally equivalent international standards. N95 masks sold in the United States are regulated by the FDA and tested to standards set by NIOSH. Similar foreign standards and enforcement mechanisms exist, including in China (KN95, meeting Chinese standard GB2626-2006) and Europe (FFP2, meeting European standard EN 149-2001).

As imported masks flooded the U.S. market, the CDC and FDA were unprepared to rapidly assess the quality of individual products. Health care systems, first responders, and others have received donations of unfamiliar mask models, many of them donated, and with unclear supply chain provenance. In an effort to clarify matters, the CDC released a list of authorized respirators under the EUA (Appendix A) on April 3, 2020 (U.S. Food and Drug Administration, 2020a). No performance testing data was required from respirator manufacturers to corroborate performance claims before inclusion on the list. In the ensuing weeks, the CDC noted a dramatic increase in counterfeit respirators that misrepresented NIOSH approval, and the CDC and other groups revealed that some respirators labeled as N95, KN95, or FFP2 fail to perform as expected for filtration and fit (Centers for Disease Control and Prevention, 2020). Appendix A has been revised several times since it was first published, creating uncertainty among state officials and hospital administrators as to which face masks are safe for use — particularly for masks labeled KN95. A recent study of donated FFRs of unknown provenance demonstrated variable performance, with no clear standards for identifying legitimate products (Plana et al., 2020).

**Reuse and sterilization.** As national PPE shortages emerged, methods were developed for sterilizing and reusing PPE. During the COVID-19 pandemic, the FDA issued EUAs for these methods. For instance, Battelle received an EUA on March 29, 2020, for its vaporized hydrogen peroxide sterilization system, on the same day President Donald Trump tweeted about the product at the behest of Ohio Governor Mike DeWine. The company was subsequently awarded a federal contract of \$400 million on April 13, 2020, to sterilize N95 masks. Battelle facilities that could sterilize up to 80,000 masks per day at full capacity were established across the country, but at a cost of \$3.25 per mask that did not include transportation to and from the facility. By comparison, the baseline pre-pandemic cost of an N95 mask was approximately \$1. The rollout did not go well: by June 2020, the company had billed the federal government \$78 million, which amounted to more than \$110 per sterilized mask. In October, the FDA sent a warning letter to Battelle regarding its inadequate procedures for identifying adverse events.

In contrast, a similar product, Steramist (using ionized hydrogen peroxide, or iHP), has been shown to sterilize masks as effectively as the Battelle system (Cramer et al., 2020). The Steramist environment chamber is more readily available in animal research facilities at academic medical centers, which allows institutions (like the Dana-Farber Cancer Institute in Boston) to decontaminate its own PPE. Quite unlike Battelle's quick path to an EUA, the manufacturer of Steramist, TOMI Environmental Solutions, applied for an EUA for Steramist in April 2020 but has yet to

receive authorization. Other companies have had more success in obtaining EUAs, but it is unclear how routinely these processes are being used given pushback from health care workers averse to wearing “dirty” PPE.

**Alternatives to N95 masks: Powered Air-Purifying Respirators.** Powered air-purifying respirators (PAPRs) are perhaps the most complex of all respiratory PPE. They supply filtered air to the user while preventing exposure to external air; no FFP is needed. PAPRs have historically been in short supply in hospitals: PAPRs are expensive, bulky, loud, and have short battery life, but in times of PPE shortage may be sustainable alternatives to N95s. Under NIOSH regulation, medical PAPRs are held to the same standards as PAPRs intended for other uses, which are that the device have a P100 rating (oil-Proof, 100% filter efficiency), a higher standard than N95 masks. No novel PAPRs have received an EUA to date, and it is not clear whether such devices could be made available through an EUA in the absence of NIOSH certification. 🦠

# Recommendations for Action

## Federal government:

- ASPR should immediately and substantially increase the Strategic National Stockpile of traditional and alternative PPE while developing an equitable national dissemination strategy for PPE dissemination to states.
- Congress should pass President Biden's \$1.9 trillion COVID-19 relief plan, which calls for an additional \$30 billion toward a Disaster Relief Fund, earmarked for supplies and PPE.
- Congress should fund research into more sustainable forms of PPE, including "biological N95 masks" designed for sterilization and reuse. Biomedical Advanced Research and Development Authority (BARDA) and Defense Advanced Research Projects Agency (DARPA) may be best suited to conduct such research, so long as any PPE-related innovation from these agencies is not held in confidence as a state secret.
- The FDA should require that manufacturers more comprehensively evaluate products or processes that have received EUAs and should revoke EUAs for which supplementary data fall short of appropriate regulatory standards. The FDA should update PPE-related guidance in the following areas: (1) a finalized "Appendix A" list of authorized respirators; (2) an amended EUA on imported face masks that penalizes identifiable manufacturers of counterfeit products under the agency's misbranding authority; and (3) guidance as to the role of FDA and NIOSH in testing newly fabricated PAPRs.

## State governments:

States should:

- establish permanent channels for sourcing traditional and alternative PPE in times of crisis, independent of federal authorities, and ensure those channels remain viable over time;
- and establish state PPE stockpiles or engage in long-term procurement contracts, while ensuring equitable distribution of PPE during public health crises, rather than a system based on prestige, financial resources, or political capital.



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