INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION

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The Hon. Robert M. Califf, MD
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February 13, 2023

Re: Regulation of Respiratory Protective Devices ("Respirators") in U.S. Healthcare Workplaces

Dear Sec. Becerra, Dr. Califf, Assistant Secretary O'Connell, Dr. Walensky and Dr. Howard,

Given the President's decision to end the national COVID-19 emergency and public health emergency declarations, which will restructure the federal coronavirus response, the International Safety Equipment Association (ISEA) writes to express opposition to potential action by the Food

and Drug Administration (FDA) to expand its regulatory authority to include worker respiratory protection[1].

The FDA and NIOSH currently regulate surgical N95 respirators (also called SN95s) in healthcare workplaces. However, recent statements by FDA representatives suggest the agency's intention to expand its regulatory authority to include approval of other types of respiratory protection. ISEA believes such regulatory expansion would ***negatively impact the nation's access to respiratory protection.***

Since inception of the Occupational Safety and Health Act of 1970, the regulatory authority for workplace respiratory protection, including the healthcare workplace, rests with OSHA and NIOSH. This federal structure ***has been and continues to be effective*** in establishing and sustaining respiratory protection for workers in all workplaces.

The ISEA position is reinforced by the following:

- **Respirators used in healthcare are already safe for intended use**. There is no evidence of healthcare workers or patients being made unsafe or ill from use of standard (non-surgical) N95 respirators, reusable elastomeric respirators (RR), full-facepiece respirators and powered air purifying respirators (PAPRs) – in healthcare over many outbreaks (e.g. TB, H1N1, Ebola, SARS, COVID-19, etc.).

- **NIOSH-certified respirators are already acceptable for use in healthcare workplaces, per OSHA**.

[1] https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control;
Also, transcript of "FDA Webinar Series – Respirators and Other Personal Protective Equipment (PPE) for Health Care Personnel Use During the COVID-19 Pandemic:' Sept. 29, 2020; page 10:

> Q: "What would be the most prudent thing to pursue in preparation for the emergency period being lifted provided we would have NIOSH approval? A: (Cynthia Chang): Yes, I would recommend that you contact our Office of Surgical and Infection Control Devices for specifics about the marketing of [the] specific device."

- **Respirator manufacturers do not claim that respirators prevent specific diseases**. The guidance for respirator use during outbreaks comes from public health organizations such as the CDC, WHO, etc.[2]

- **FDA oversight would be an infeasible burden** on personal protective equipment (PPE) manufacturers:
    - Requires manufacturing under ISO 13485 Medical Device Quality Systems
    - Will add an unnecessary layer of oversight and certification in addition to NIOSH
    - FDA clearance may not accommodate system devices with interchangeable components (e.g. multiple hood options, multiple belts/harnesses, etc.)
    - Will increase prices of PPE
    - No product code for reusable respirators

For these reasons, *and more*, most respiratory protective device manufacturers will likely not pursue FDA clearance for a majority of respirator models. Therefore, FDA regulation of respirators would likely ***drastically limit healthcare organizations' access to this essential PPE***, particularly during outbreaks – the opposite of the stated goal of "improving supply chain resiliency." "Warm base manufacturing[3]" is a better solution than increasing regulation – it is more likely to achieve the intended outcome of making respirators more immediately available in needed quantities during a public health emergency.

FDA claims it should regulate "reprocessing" of respirators used in healthcare. However, evaluating the efficacy of agents against specific target infectious agents is EPA's role, and evaluating the impact of potential disinfection methods on respirators is the role of the manufacturer. In fact, we

[2] We recognize specific medical claims are approved by FDA

[3] Warm base is defined as the minimum sustainable level of testing to maintain preparedness for rapid response to a future PHE. The term "warm base" is derived from the Army, US Senate, and others who use warm base to reflect the minimum resources or capacity to maintain workload and manufacturing readiness for greater responsiveness. Warm base is traditionally referred to in the context of the manufacture of tests, components and consumables, and strategies for warm base testing services has not been well defined. (*from* Sam.gov). NOTE: PL 117-328, Sec. 2401 approves funding for Warm-Base manufacturing preparedness for public health readiness.

are not certain that all "reprocessing" methods included in the EUAs were safe for wearers and non-damaging to particular respirator models. FDA could help the response community as it evaluates potential health effects of the disinfectant agents used in proposed methods.

Moreover, respirators in preparedness stockpiles (standard N95s, reusable half-mask respirators, full facepiece respirators and PAPRs) are NIOSH approved. Healthcare systems have invested in standard N95s as effective, scalable respiratory protection solutions. If FDA were to declare those respirators inappropriate for use in healthcare, it would create ***significant procurement, logistical and deployment problems*** for healthcare workers and providers.

These statements are supported by more detailed information provided in the addendum.

Thank you for your time and attention to this matter. I can be reached at cmackey@safeytequipment.org or

Sincerely,

Cam Mackey
President & CEO
International Safety Equipment Association

cc:
The Hon. Douglas Parker, Assistant Secretary, OSHA
James Frederick, Deputy Assistant Secretary, OSHA
Amb. Susan Rice, Director, Domestic Policy Council
Dr. Ashish Jha, Coordinator, COVID-19 Response
Thomas Reilly, Dep. Associate Director, Health Div., OMB

Additional Information Supporting ISEA's Position on Optimal Regulation of Respirators

About the International Safety Equipment Association

The International Safety Equipment Association (ISEA) is the U.S. trade association for companies that design, test, manufacture and supply personal protective equipment (PPE), including respiratory protection. ISEA member companies also supply a wide range of products used by healthcare professionals.

ISEA's respiratory protection members are world leaders in designing, testing, manufacturing and supplying a wide range of respiratory protective devices (respirators), from filtering facepiece respirators to self-contained breathing apparatus.

Nationwide, the safety equipment industry supports 345,000 total jobs and generates economic activity of more than $71.6 billion. In addition, more than 111 million workers across the U.S. are protected by the safety equipment our members produce and ISEA represents.

Pre-COVID-19 respirator use in hospitals

For many years, NIOSH-approved respirators of all types have been used safely and effectively in healthcare workplaces to help keep healthcare workers safe from pathogenic airborne hazards, such as influenza and tuberculosis[4]. This guidance document, Protect Yourself Against Tuberculosis, published by the Department of Health and Human Services in 1995, states that not only filtering facepiece respirators but also RRs, PAPRs, and even supplied-air respirators are all acceptable

[4] . In response to respirator shortages during the 2009 influenza pandemic, the Strategic National Stockpile distributed more than 85.1 million disposable filtering facepiece respirators (sometimes referred to as N95s), which was in addition to the inventory that hospitals and other health care facilities already had in stock or had acquired through normal supply chains. Reusable respirators (specifically, reusable half-facepiece elastomeric respirators) are the standard respiratory protection device used in many industries, and they provide an option for use in health care that has to date not been fully explored. The durability and reusability of elastomeric respirators make them desirable for stockpiling for emergencies, where the need for large volumes of respirators can be anticipated.

options for use in healthcare workplaces. The document describes OSHA's regulatory requirements for selection and use of respirators, including the need for a written site-specific respiratory protection program. According to a 2015 Institute of Medicine publication, many hospitals routinely use N95 FFRs, and "many facilities with low incidence of [tuberculosis]...have opted for PAPR-only policies..."[5] Other health systems use elastomeric half-mask respirators[6].

Respirators of all types have been used successfully during other infectious disease outbreaks, such as H1N1, Ebola, and SARS. Many other references have been published to guide healthcare workplaces through the existing NIOSH-OSHA regulatory framework for hazard identification, exposure assessment, and – when needed – respirator selection and use. See Hospital Respiratory Protection Program Toolkit, 2015, DOL/DHHS

Surgical N95 is a category of respirator that is regulated by NIOSH under 42 CFR Part 84 and by the FDA, under 21 CFR 878.4040, as surgical masks.

NIOSH and FDA established a Memorandum of Understanding (MOU) in 2017 to outline the framework for coordination between the two agencies for regulation of these Surgical devices, also known as SN95s[7]. Under the MOU, SN95 applications are sent to NIOSH, which conducts a suite of tests. NIOSH reviews the applications to ensure the FDA requirements for flammability, biocompatibility, and liquid splash protection are met. This is a streamlined process for manufacturers. But, this process places a greater regulatory burden on NIOSH, which conducts much of the review, even though the final decision is from both agencies.

[5] Institute of Medicine 2015. The Use and Effectiveness of Powered Air Purifying Respirators in Health Care: Workshop Summary. Washington, DC: The National Academies Press. https://doi.org/10.17226/18990. page 19
[6] https://www.umms.org/ummc/pros/physician-briefs/ppe-use

[7] https://www.govinfo.gov/content/pkg/FR-2018-05-17/pdf/2018-10563.pdf

Respirator use in the medical workplace before and during COVID-19

On March 2, 2020, FDA published the first iteration of its Emergency Use Authorization (EUA) for NIOSH-certified Filtering Facepiece Respirator use in healthcare settings. The first version required manufacturers to file an intention to supply respirators for use against COVID-19. This was quickly followed by an update on March 27 and then on March 28 (and later updated on July 12, 2021). The stated purpose of the EUA was to allow all NIOSH certified respirators to be used in healthcare settings.

Hospital respiratory protection program administrators and procurement officials, along with manufacturers understood, even before the EUAs, all forms of NIOSH-approved respirators are safe and effective and do not need additional regulatory approval for use in healthcare workplaces. The EUAs caused confusion that still persists.

In addition, when the EUA was first written, it was justified by "respirator shortages" and a recognition that there were "not sufficient quantities of FFRs [filtering facepiece respirators] that are both NIOSH approved and meet FDA regulatory requirements to meet the needs of the U.S. healthcare system."

Not only did FDA's rationale fail to recognize the wide use of NIOSH-certified respirators in medical workplaces, but also the EUA has both allowed for and have shown how commonplace and essential these devices were, and have become, in medical workplaces.

NIOSH-certified respirators were welcomed into the medical workplace and saved medical professionals' lives. The nation saw non-surgical disposable and reusable respirators play a key role in keeping healthcare workers safe from COVID-19 exposures.

EUA necessary?

ISEA believes the difference between an SN95 and other types of respirators is not as stark as FDA characterized it. In its March 11, 2020, letter to CDC Director Robert Redfield, FDA said it was

permitting the emergency use and distribution of respirators "that had previously been intended for general use[8]." However, this is a false classification. As experience has shown, all NIOSH-certified respirators can be used effectively no matter where they are used – medical or non-medical workplaces – as long as there is a respiratory protection program in place. FDA did not need to issue an EUA to allow NIOSH-approved respirators to be used in hospitals.

No barriers for use

A reasonable person would view NIOSH-approved respirator use in medical workplaces as a success and would expect it to continue. In addition, those who work in healthcare workplaces but do not provide direct patient care, such as reception, security and maintenance may choose to wear a respirator. Moreover, this is also allowed under OSHA regulations at 29 CFR 1910.134, Appendix D (voluntary use), and is allowed in the new Mini-Respiratory protection program at 29 CFR 1910.504.

Current system of worker protection is effective

Fit-tested, NIOSH-certified respiratory protection, when used appropriately, is a known method to protect workers. The National Academies concluded this in 2009 when looking at how to protect workers from influenza[9]. The report recommended healthcare workers use a fit-tested N95 respirator. Similarly, during Ebola, there were no questions about the conformity assessment of NIOSH-certified PAPRs as they were used in hospitals to protect employees from potential Ebola exposures.

ISEA knows of no third-party experts calling on FDA to create a new regulatory system for respiratory protection for medical workplaces.

[8] https://www.fda.gov/media/136023/download
[9] Institute of Medicine 2009. Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report. Washington, DC: The National Academies Press. https://doi.org/10.17226/12748.

No disease prevention claims on products

A claim about protection against a specific pathogen triggers FDA coverage. However, respirator manufacturers are not claiming their products prevent specific diseases. Respirator manufacturers only claim the products filter out airborne particles. The science, as ISEA understands it, holds that respirable pathogenic airborne particles behave in the same manner as other respirable airborne particles. The guidance for use during outbreaks comes from the CDC, NIOSH, FDA, WHO, etc…

Current products show effectives against airborne pathogenic particles

NIOSH-approved respirators are already safe for intended use. There is no evidence healthcare workers or patients are being made unsafe or ill from use of these respirators in healthcare over many outbreaks (TB, H1N1, Ebola, SARS, COVID-19, etc)[10].

Costly economic regulatory burden on manufacturers

FDA regulations for respirator use will create a high economic burden on manufacturers.

First, FDA regulation in this space would place manufacturers under the FDA Good Manufacturing Process (GMP), which respirator manufacturers are, by and large, not familiar with. There would be significant costs to ramp up to that level and to remain compliant with these regulations. The NIOSH certification program is appropriately thorough given what these products are asked to do. The empirical evidence of the success of NIOSH-certified respirator use in hospitals shows a new layer of regulatory compliance is not needed.

Such potential extra layer of regulatory cost and complexity would be added to the existing regulatory cost and burden of NIOSH certification, where, often, there already is a significant wait time from initial application to final decision. Another approval system would only lengthen the time

[10] https://www.osha.gov/news/newsreleases/trade/05142015-0, and https://www.osha.gov/sites/default/files/publications/OSHA3767.pdf

to market. Because of this, a majority of PPE manufacturers will most likely not pursue FDA clearance for a majority of respirator models. The result here would be fewer choices for hospitals, likely at an increased price.

In fact, FDA clearance may not accommodate system devices with interchangeable components (e.g. multiple hood options, multiple belts/harnesses, etc.). It does not seem reasonable for FDA to create a second respiratory protective device certification or approval process. Moreover, the association does not believe FDA should have a veto authority role in end-user access to respiratory protective devices.

Reprocessing (cleaning and decontaminating) reusable respirators

FDA argues it should regulate "reprocessing" (cleaning and disinfecting) of respirators used in healthcare. However, its strength, in this case, would be aiding the evaluation of disinfectants used in any proposed method or recommendations for potential health effects to the wearer. EPA's List N includes disinfectants known to kill SARS-CoV-2 (COVID-19)[11].

Public stockpiles include NIOSH-certified respirators

A majority of FFRs in stockpiles are standard N95 disposable respirators. In addition, the federal strategic national stockpile includes more than 100,000 elastomeric half mask respirators. As noted above, healthcare systems have invested in standard N95s and found them to be effective, scalable respiratory protection solutions: there is already a trained fit-testing workforce, respirators have been written into health and safety programs, and hospitals have included them into their supply chains. As noted above, some hospitals and hospital systems have been using elastomeric half-mask respirators for many years[12].

[11] https://www.epa.gov/coronavirus/frequent-questions-about-disinfectants-and-coronavirus-covid-19
[12] https://www.umms.org/ummc/pros/physician-briefs/ppe-use

Conclusion and summary

ISEA shares the federal government's interest in making sure our nation's healthcare workforce is fully protected from its workplace hazards as they provide care to the nation's populace. The association believes standard workplace safety and hygiene practices, where worker hazards are identified and addressed, will protect healthcare workers. This includes use of NIOSH-certified respirators which have been used successfully in healthcare settings for many years. Reusable respirators are routinely cleaned and disinfected. Disposable respirators are reused only in extreme situations and with federal oversight.

ISEA does not believe an additional health-related respiratory protection regulatory system is warranted. It would be redundant to NIOSH's respiratory protection certification system. In addition, it would be costly and a drag on innovation. We ask that no such program be created.