

July 3, 2008

US Department of Health and Human Services  
Attention: Pandemic Influenza Masks Comments  
Room 434E  
200 Independence Ave., SW  
Washington, DC 20201

**Comments of the International Safety Equipment Association  
On “Interim Guidance on the Use and Purchase of Facemasks and Respirators by  
Individuals and Families for Pandemic Influenza Preparedness”  
72 FR 31690**

The International Safety Equipment Association (ISEA) is the trade association for personal protective equipment (PPE), including respiratory protection, head, eye and face, hearing and fall protection; protective clothing and gloves; high visibility safety apparel; emergency eyewash and showers; first aid kits and gas detection instruments. Its member companies are world leaders in the design and manufacture of PPE for workers. ISEA is accredited by the American National Standards Institute (ANSI) as a standards developing organization, and is responsible for development and publication of numerous American National Standards for personal protective and safety equipment.

ISEA appreciates the opportunity to offer comments on the Interim Guidance. The association and its members work closely with NIOSH, OSHA, and other agencies to develop guidelines for the use of respiratory protection. ISEA has worked to educate the public about the use and limitations of respirators to help reduce exposure to pandemic influenza virus, and in February 2006, we released a statement on “What the General Public Should Know and Understand about Respirators and Avian Influenza.”

Throughout the interim guidance document, it is important that HHS consistently maintain the distinction between facemasks and respirators. Facemasks are primarily for protection of others from the user; respirators are for protection of the user. Facemasks should be worn by persons who are ill, to prevent the spread of infection to another person. While they may offer some barrier to inhalation of particulates, they are not intended for that purpose. Respirators are designed, tested and certified to reduce exposure to airborne contaminants. However, to provide protection, the respirator must be properly fitted and used to minimize inhalation of particles.

There are numerous places in the document where this distinction should be made more clear.

**Facemasks**

The statement in line 25 that “[a] facemask or respirator, if used correctly, may reduce the risk of acquiring or transmitting pandemic influenza illness in certain situations” should be clarified by adding language that notes that facemasks and respirators are designed for different purposes.

The sentence beginning in line 47 that refers to FDA-cleared facemasks should note the limitation that they “can trap germs from the wearer and resist fluids ...”

HHS suggests that facemasks may be worn for protection in environments where it is unknown whether there are others infected with influenza. This is embodied in the sentence beginning on line 28 ("If entry into a crowded setting..."), in key message #2, and the first bullet point on line 117. But these recommendations require users to make a determination that there is no risk – or minimal risk – and arm themselves with a mask that may at best offer a false sense of security. Facemasks may resist large aerosols from sneezes, for example, but it is possible that the particles that contain the pandemic flu virus could become airborne when the respired droplet that contains the virus evaporates. Then the virus is an airborne particle, for which a facemask is ineffective.

ISEA suggests a wording change on line 30: "a facemask or respirator should be used," with additional wording to clarify that a facemask will not protect the wearer against small particles in the air that may contain the influenza virus.

The document notes on line 121 that "it is prudent to wear a facemask because one may encounter people who are infectious but not yet ill," when in fact a facemask may not provide protection against inspiration of the virus.

Similarly, in the second bullet point (on line 124), HHS suggests that infected persons only need to wear facemasks when they are in close contact with others. But if the virus can become airborne, suspended in the air and settling on surfaces, infected persons could still pass the virus across greater distances.

## **Respirators**

The guidance document properly notes that only NIOSH-approved respirators should be used. HHS makes reference to N95 respirators, but acknowledges in footnote 1 that other classes of NIOSH-approved respirators (e.g. N99, R95 and P100) provide the same protection.

Although this document anticipates that individuals and families will probably use disposable, filtering facepiece respirators, it should also be noted that not all N95's are disposable. In the paragraph beginning on line 65, HHS should add the word "particulate" in describing a filtering facepiece N95 (i.e. "disposable particulate respirator that covers the nose and mouth."). In line 69, the word "disposable" should be deleted, making the sentence descriptive of all N95 respirators.

Later in that paragraph, the sentence at line 72 "Non-certified respirators are available but their effectiveness has not been tested by NIOSH" should be deleted, to avoid confusion that HHS may be endorsing the use of non-certified respirators.

It is important to stress that respirators must be worn properly, because a respirator is effective only when there is a good face seal. The paragraph beginning on line 82 explains the importance of properly fitting respirators, while acknowledging that most members of the public are not going to have the same rigorous fit testing that is required in the workplace.

ISEA suggests rewriting the sentence beginning on line 99 ("Because the material used ..."). Respirator breathing resistance is a factor of the efficiency of the filter media and the need for a tight fit, not just the density of the filter material. Similarly, the sentence beginning on line 106 about breathing resistance is misleading. Respirators become more difficult to breathe through when they are used in high dust concentrations. Most areas where respirators will be used to

protect against influenza are clean, non-industrial areas. There should not be a noticeable increase in breathing resistance over normal duration of use in these areas.

### **Stockpiling and Disposal**

ISEA urges HHS to take another look at recommendations on stockpiling of facemasks and respirators. The recommendation of 20 respirators per household, to be worn by people caring for ill family members, anticipates only one caregiver per household. This may be adequate for a small household, but not for a larger family. HHS should change its recommendation to a number of respirators per caregiver, not per household.

In addition, HHS should recognize that its recommendation of the number of facemasks and respirators to stockpile depends on people following its recommendations exactly. If a family chooses to use respirators instead of facemasks when going out in public during a pandemic, it should stockpile accordingly. The sentence beginning on line 152 referring to people commuting on public transit should be amended to read “may choose to purchase facemasks or additional respirators for use when going to and from work. An additional supply of facemasks or respirators also could be purchased ...”

ISEA recommends that HHS consider adding guidance on proper disposal of facemasks and respirators. In a pandemic, it is not hard to envision trash containers in public places filled with discarded, and potentially contaminated, facemasks and respirators. Also, families need to understand that contact with contaminated facemasks and respirators could spread the virus in the home.

For more information on ISEA respiratory protection programs, or questions regarding these comments, contact ISEA technical director Janice Comer Bradley, CSP.