May 31, 2018

The Honorable Greg Walden
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Susan W. Brooks
United States Representative
1030 Longworth House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
United States Representative
241 Cannon House Office Building
Washington, DC 20515

Dear Chairman Walden, Ranking Member Pallone, Representative Brooks, and Representative Eshoo,

As you craft the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), the 90-member companies of the International Safety Equipment Association (ISEA) – who are leaders in safety equipment manufacturing, testing, and application (see attached list) – ask that you make technical changes to the definitions of "covered countermeasure" and "qualified pandemic of epidemic product" to ensure all appropriate CDC-specified personal protective equipment (PPE) is covered by both the PAHPA and PREP Act. These improvements will ensure CDC-specified products are made available during the next pandemic without hesitation, even as it will facilitate improved coordination between HHS emergency planners and equipment manufacturers.

As you know, among the key provisions of PAHPA are sections that ensure appropriate forms of devices are acquired by the federal government and included in planning for public health emergencies, including pandemics and chemical, biological, radiological, or nuclear events. Unfortunately, due to a technical definitional issue, many of the forms of devices/PPE that are called upon by the Centers for Disease Control (CDC) to protect our nation's first responders during a public health emergency are not fully covered by PAHPA or the Public Readiness and Emergency Preparedness Act (PREP) Act.

Specifically, because the definitions used in these statutes for a 'covered countermeasure,' a 'security countermeasure,' or a 'qualified pandemic or epidemic product' only apply to drugs, biological products, and devices (which include PPE) that are cleared by the Food and Drug Administration (FDA), many of the devices/PPE the CDC expressly directs health care workers use during a public health emergency – such as chemical protective gloves, chemical protective garments, and many forms of respiratory protection, including Powered Air Purifying Respirators (PAPRs) that were widely deployed during the recent Ebola outbreak, or other forms of devices/PPE used for other chemical, biological, radiological, or nuclear events – are not covered by PAHPA or PREP Act.

To correct this oversight before the next national emergency hits – and with the Ebola threat again on the rise in the Democratic Republic of the Congo, including a case in a major city – a technical "fix" to the definition of a device in these statutes is needed to ensure the manufacturers of all appropriate drugs, biological products, and CDC-specified devices/PPE will receive the same narrow, time-limited, focused protection against liability when called upon in a national emergency.

Thank you for your consideration of this request, and we look forward to working with you to correct this oversight during the upcoming reauthorization of the Pandemic and All Hazards Preparedness Act.

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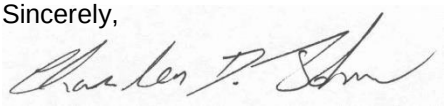
Thank you, again, for your ongoing efforts to improve public safety during the reauthorization of PAHPA – and we look forward to continuing to work with you on this issue in the coming weeks. Please contact me at 703-525-1695 or at cjohnson@safetyequipment.org for more information or with any questions about this issue.

Sincerely,



Charles D. “Chuck” Johnson, Jr.

Proposed legislative text is in bold red.

[NOTE:42 CFR 84 are the regulations for respiratory protective devices, which are tested and certified by the National Institute for Occupational Safety and Health (NIOSH). Subparts H – KK are the specific test methods for each type of respirator.]

42 U.S. Code § 247d–6d(i)

(i)(1) **COVERED COUNTERMEASURE**.—The term 'covered countermeasure' means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 319F–2(c)(1)(B)); or

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act***; or***

(D) a device that is:

(i) personal protective equipment certified under 42 CFR 84, Subpart H – Subpart KK; or

(ii) protective gloves and garments meeting the ASTM or other test standards designated by the Center for Disease Control and independently verified by a laboratory accredited by the Occupational Safety and Health Administration's Nationally Recognized Test Lab program; or

(iii) other personal protective devices designated by the CDC as necessary for worker protection.

(i)(7) **QUALIFIED PANDEMIC OR EPIDEMIC PRODUCT**.— The term 'qualified pandemic or epidemic product' means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 351(i) of this Act), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h) ***or in section (i)(1)(D) of this Act***) that is—

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—
(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or
(II) to limit the harm such pandemic or epidemic might otherwise cause; or

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act; or
(iii) authorized for emergency use in accordance with section 564 of the Federal Food, Drug, and Cosmetic Act.

INSERT IN THE APPROPRIATE SECTION:

> ***"When issuing a declaration or guidance on the personal protective equipment (PPE) that should be used in response to a public health emergency, the Centers for Disease Control and Prevention shall include the performance levels required for the appropriate PPE by citing appropriate standards, test methods, or materials."***

**This language would ensure the CDC provides specificity regarding the performance standards for PPE that healthcare workers should utilize in a particular emergency (for personal protection and acquisition purposes) and that HHS/ASPR can cite in any related PREP Act declaration.

Manufacturer Members

3M Company
5.11 Tactical Series
A-Med Supply (Oliver Landon International)
Accuform
Ansell
Avon Protection Systems, Inc.
Blauer Manufacturing Co.
Bollé Safety
Bradley Corporation
Buckingham Manufacturing Co., Inc.
Bullard
Bulwark
Carhartt
D3O
Delta Plus Group
Dräger Medical Systems, Inc.
DSM Dyneema
DuPont Personal Protection
Encon Safety Products
ERB Industries, Inc.
Ergodyne
Essilor of America
FallTech
Gateway Safety, Inc.
Gentex Corporation
Guardian Equipment
Guardian Fall Protection
Global Glove
Hammerhead Industries, Inc.
Haws Corporation
HexArmor
Honeywell Industrial Safety
Hughes Safety Showers (A Justrite Group Company)
International Enviroguard, Inc.
Ironwear
KASK America
Kimberly-Clark Professional
M.L. Kishigo Manufacturing Co.
Klein Tools, Inc.
Lakeland Industries, Inc.
Magid Glove & Safety Mfg. Co. LLC
Majestic Glove
Malta Dynamics
MCR Safety
Mechanix Wear, Inc.
Moldex-Metric, Inc.
MSA Safety Inc.
NASCO Industries, Inc.
National Safety Apparel
OccuNomix International, LLC
ORAFOL Americas Inc.
Pacific Safety Supply Inc.
PAFtec Australia Pty Ltd (CleanSpace)
Performance Textiles, div. of Brand & Oppenheimer Co.
Petzl
Prevor Inc.
Protective Industrial Products, Inc.
Pyramex Safety
Radians, Inc.
Rasco FR
Safe Reflections, Inc.
Safety Optical Service
Scott Safety
Superior Glove
SureWerx
Speakman Company
Tingley Rubber Corp.
Ty-Flot
Werner Co.
West Coast Corporation
World Fibers, Inc.