

May 19, 2008

The Honorable Edwin G. Foulke, Jr.
Assistant Secretary of Labor
for Occupational Safety and Health
U.S. Department of Labor
Frances Perkins Building
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Leon R. Sequeira
Assistant Secretary of Labor for Policy
U.S. Department of Labor
Frances Perkins Building
200 Constitution Avenue, NW
Washington, DC 20210

Dear Assistant Secretaries Foulke and Sequeira:

I am writing on behalf of the International Safety Equipment Association (ISEA), the trade association in the United States for companies that manufacture safety equipment. The ISEA requests that the Occupational Health and Safety Administration (OSHA) address an issue of common and general concern to respirator manufacturers: whether ordinary principles of conflict preemption preclude state courts from finding that OSHA-required, National Institute for Occupational Safety and Health (NIOSH)-certified respirators can be found to be defective when their design, packaging, and labeling comply with all federal regulatory standards and conditions of certification.¹

As you are aware, the Occupational Safety and Health Act (“OSH Act”) provides NIOSH, the Mine Safety and Health Administration (MSHA), and OSHA with comprehensive authority to regulate respirator safety, including product specifications, instructions, labeling, and packaging, and the use of respiratory protective devices in the workplace.² OSHA regulations require employers to provide their employees with respirators “which are applicable and suitable for the purpose intended.”³ OSHA mandates use of NIOSH-certified respirators in the workplace⁴ and further mandates that employers provide their employees with specific types of NIOSH-certified

¹ On March 17, 2006, Heinz Ahlers, Acting Chief of the Technology Evaluation Branch of the National Personal Protective Technology Laboratory, issued a “Letter to All Respirator Manufacturers” on the “Meaning of NIOSH Approval.” That letter reaffirmed the Institute’s position that NIOSH approval does not allow a manufacturer to modify the respirator in ways that affect form fit or function or to make claims of NIOSH approval for features outside of those approved and certified by NIOSH. The letter, however, did not address the preemptive effect of NIOSH approval on state tort law claims when the theory of liability conflicts with a NIOSH standard or condition of approval.

² See 42 C.F.R. part 84.

³ 29 C.F.R. § 1910.134(a)(2).

⁴ 29 C.F.R. § 1910.134(d)(1)(ii).

respirators when they are exposed to certain contaminants.⁵ NIOSH, in its role as the expert federal agency charged by Congress with researching and developing occupational safety and health standards,⁶ has directed a respirator research program for over three decades. It provides a testing approval and certification program assuring commercial availability of safe personal protective devices and reliable industrial hazard measuring instruments. After a comprehensive review of each application, NIOSH specifically approves engineering specifications, drawings, test reports, quality assurance and control documents, respirator markings, instruction manuals, packaging, and labels.⁷ A manufacturer may not modify any of these elements without prior NIOSH approval.⁸

We believe that it is important that OSHA express its position on the impact of federal certification decisions and workplace requirements on state tort law claims. Courts are in need of guidance from the agencies Congress entrusted with regulating these areas on the preemptive effect of federal law.⁹ The ISEA is aware of at least one ruling in which a court applied these principles to find that the OSH Act preempts state tort law actions alleging defective design of a NIOSH-approved respirator,¹⁰ but thousands of such claims are still pending across the country. The judiciary would benefit from the perspective of OSHA on whether there is a conflict between federal regulation and state tort claims that would not allow a manufacturer to comply with both federal regulation and state law or whether tort lawsuits stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.¹¹

ISEA respirator manufacturer members report involvement in hundreds of thousands of state court tort claims and in recent years many have experienced a significant increase in silicosis claims.¹² In addition, more than 325,000 individual asbestos and silica claims have been filed against numerous respirator manufacturers for design and warning defects since 2000. During this same period, Centers for Disease Control data show a significant decline in silicosis deaths. One United States District Judge who reviewed over 10,000 of these claims ruled that many of these claims were “virtually impossible scientifically” and were “manufactured for money”.¹³ While respirator manufacturers can and have successfully defended against such claims, this comes at a steep price to the industry and, more importantly, to the public.

⁵ See, e.g., 29 C.F.R. § 1910.1001(g)(2) (requiring, with respect to asbestos, “[e]ach person entering a regulated area shall be supplied with and required to use a respirator,” selected in accordance with 1910.134, and that each device must be “tight-fitting, powered, air-purifying respirator”).

⁶ 29 U.S.C. § 671.

⁷ 42 C.F.R. §§ 84.31, 84.33, 84.42.

⁸ 42 C.F.R. § 84.35.

⁹ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 505-06 (1996) (Breyer, J. concurring) (In the absence of a clear congressional command as to preemption, courts may infer that the relevant administrative agency possesses a degree of leeway to determine which rules, regulations or other administrative actions will have pre-emptive effect. . . .”).

¹⁰ *King v. Custom Spraying and Reglazing Co.*, No. 121677, slip op. at 4 (N.Y. Sup. Ct., Mar. 31, 2005).

¹¹ See *Gade v. National Solid Wastes Management Ass’n*, 505 U.S. 88, 98 (1992); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869-74 (2000); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

¹² Certain manufacturers collectively, including MSA, Moldex, North and Sperian Protection, experienced a 5000% increase in silica related cases between 2002 and 2004.

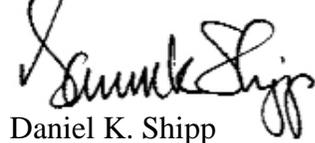
¹³ See *In re Silica Prods. Liab. Litig.*, 398 F. Supp.2d 563, 635 (S.D. Tex. 2005).

The total costs associated with defending these claims and lawsuits have cost the industry hundreds of millions of dollars,¹⁴ which diverts substantial capital otherwise earmarked for investments in research and development and expanding capacity. This comes at a time when the possibility of terrorist activity or an avian flu pandemic are at the forefront and providing NIOSH approved respirators for workers, first responders, health care providers and the general public is a critical component of our preparedness.

The ISEA submits the situation described above requires action to not only preserve manufacturers' ability to invest and produce the respiratory products needed in the future but to also realistically assess the impact on the public's and nation's welfare if not addressed. We believe that well-established principles of conflict preemption suggest that individual state courts should not reach conclusions about the design or the effectiveness of information disseminated on respirator packaging and labeling that are contrary to regulatory determinations made by OSHA or NIOSH based on their considerable institutional expertise and comprehensive statutory authority. Such claims would appear to compromise the agencies' ability to carry out their regulatory functions with respect to respiratory protective devices and unduly upset the need for uniformity in balancing the risks and benefits of respirator designs and instructions.

We appreciate the Department's consideration of this important issue and respectfully request that OSHA clarify the impact of its regulation of respiratory protective equipment on conflicting state tort claims.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel K. Shipp". The signature is written in a cursive, flowing style.

Daniel K. Shipp
President

¹⁴ For some manufacturers, as of 2006, 90 to 94 percent of their profits were being consumed for litigation efforts.