# Commentary

## The Respirator Access Assurance Act

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The Respirator Access Assurance Act of 2005 will help assure that Americans have access to affordable respiratory protection for use against hazardous materials in the workplace and at home, airborne diseases, and agents of bioterrorism. The legislation was introduced by Sen. John Cornyn (R-TX) as S. 1406 and by Rep. Bill Shuster (R-PA) as H.R. 2357.

Respirators have been used for years to reduce worker risk of injury, illness or death in millions of U.S. jobs in agriculture, manufacturing, storage of potentially hazardous materials, health care, construction, mining, and emergency rescue operations. They are required in many occupational health and safety programs. The Centers for Disease Control ("CDC"), the Occupational Safety and Health Administration ("OSHA"), and the World Health Organization ("WHO") have recognized that respirators provide the best and most practical protection against biological hazards such as SARS, tuberculosis, and Avian flu. Respirators have provided critical protection in responding to disasters in the United States and around the world, including in post-9/11 clean up operations, California forest fires, and post-tsunami activities in South Asia. Postal workers and other government and private sector workers relied heavily on the protections of respirators during the 2001 anthrax scare in Washington, D.C.

Action is needed now to protect the availability of respirators as a safety protection product. A rising tide of silica-related lawsuits naming respirator manufacturers and others as defendants has put many companies in jeopardy and is driving them out of the market. These lawsuits claim defective design or warnings as a cause of harm to claimants, even though manufacturers cannot affect how or when the respirators are used, and the federal government sets strict standards for respirator designs and approves all warnings. One major manufacturer of disposable respirators has already withdrawn from the industrial disposable respirator market, due in part to the onslaught of claims. A federal solution is needed to bring about a comprehensive, national solution to litigation claiming design and warning defects against respirator manufacturers and sellers.

The Respirator Access Assurance Act provides that solution. The Act integrates the respirator approval requirements developed through public comment and research by scientists and other experts at the National Institute of Occupational Safety and Health in the U.S. Department of Health and Human Services and its predecessor agencies ("NIOSH"). The Act provides that a manufacturer or seller of respiratory

protective equipment cannot be held liable when the respirator at issue has received approval from NIOSH and was manufactured in compliance with NIOSH-approved design and labeling. Compliance with NIOSH standards and NIOSH approval constitute the basis of the liability protection. The Act would not apply to a respirator that fails to comply with NIOSH standards. Under the Senate version of the Act, the Act also would not apply if fraud or misrepresentation or bribery were used to obtain NIOSH certification. House sponsors have agreed to this language. The Act would apply to any civil action in federal or state court asserted against either a manufacturer or a seller of the respirator. It would become effective upon enactment and apply to any case that has not gone to trial.

It is important to recognize that the Act would only eliminate claims of defective design and insufficient warnings. It does not affect claims for manufacturing flaws or any other violations of NIOSH standards.

NIOSH development of respirator standards involves comments from various participants from labor, the scientific community, government, and industry. Unlike some regulatory agencies that have been found to be overly influenced by the interests of companies they regulate, NIOSH has maintained a strict independence from its constituents. NIOSH enforcement of its standards is grounded on its own *independent* scientific research and testing. NIOSH does not rely on respirator manufacturers to provide this science or to test or evaluate their own products. For example, NIOSH conducts *independent* testing of each model of respirator to assure the design meets all criteria specified by the NIOSH standard. NIOSH also approves product labeling, including user information. NIOSH technicians conduct lab tests to develop guidelines for selecting and using NIOSH-approved respirators and test approved respirators in product audits and special investigations, both on their own initiative and at the request of others. NIOSH conducts product investigations to address problems associated with approved respirators or non-conformance. These investigations may result in field retrofits, requests to stop sale of a respirator as a NIOSH-approved device, or even revocation of approval. In sum, respirator manufacturers are subject to continuing NIOSH oversight to assure that NIOSH standards are met consistently.

The recent rise in silica-related claims against respirator companies reflects what one federal judge called a "phantom epidemic, unnoticed by everyone other than those enmeshed in the legal system." The vast majority of claimants are not sick. The CDC reports that from 1968 to 2002, the annual number of silicosis deaths decreased from 1,157 to 148, corresponding to a 93% decline in the overall mortality rate. Silicosis is the lowest cause of death of any of the pneumoconiosis diseases reported. In contrast, tens of thousands of new silicosis litigation claims were filed against respirator manufacturers from 2002 to 2004. Before 2002, one respirator manufacturer had about 200 silicosis claims filed against it each year. Between 2002 and 2004, ***29,000*** silicosis claims were filed. This is a ***5000%*** increase in claims filed.

In one telling example of the problems with such claims, this year the federal judge overseeing the silica multi-district litigation ("MDL") in Texas found "red flags of fraud" in approximately 10,000 claims generated by mobile screening operations under contract to plaintiffs' contingent fee law firms. Some of the small group of "diagnosing" doctors testified that they never authorized the inclusion of a diagnosis of silicosis in reports submitted in litigation and that they are not qualified to render such diagnoses. The MDL litigation also highlights apparent attempts by some to recycle plaintiffs who have already recovered in asbestos litigation by claiming they also have silicosis, a virtual medical impossibility. A grand jury in New York is investigating litigation screening practices and courts in Ohio and Florida have been asked to launch their own investigations of the legitimacy of some of the silica claims before them.

In other cases, respirator manufacturers and sellers are sued even though they cannot be on site to evaluate the specific contaminants or their concentration within each individual workplace. Respirator companies are not in the position to ensure that sufficient and/or appropriate respiratory protection is purchased, distributed and properly used in the workplace. The proper selection and use of respirators can only be carried out by employers. OSHA places the responsibility on employers to assure that workers are not exposed to harmful levels of airborne contaminants.

Silica-related lawsuits of dubious merit have cost the respirator companies millions of dollars in litigation defense costs and have forced companies into settling such nuisance suits for business reasons. The lead plaintiffs' lawyer in the silica MDL estimated in 2004 that defense litigation costs just for pretrial practice in federal court in Texas would collectively cost defendants over $1.5 billion, not including trial costs. Total litigation costs could actually exceed the total annual revenue for the industry — and the economic justification for making these respirators disappears once litigation costs approach the level of industry profits. Such an outcome would deprive U.S. emergency responders, health care and government workers, and the general public of this essential equipment.

A respirator manufacturer that designs and labels a respirator in compliance with NIOSH approval, and manufactures that respirator in compliance with the NIOSH-approved design and labeling, should not be liable for any claim based on that design or warning. This legislation is intended to serve the same purpose as the 1998 Biomaterials Access Assurance Act, signed by President Clinton, which also sought to assure the availability of materials needed to protect and enhance health and safety. ■