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### PREEMPTION

#### PRODUCT LIABILITY

## Preemption: Department of Labor Reversal and Ruling By Washington Supreme Court Could Impact Respirator Availability



BY VICTOR E. SCHWARTZ AND CARY SILVERMAN

**M**anufacturers took surprised notice when the U.S. Department of Labor (DOL) recently issued an interpretive letter,<sup>1</sup> followed by an eleventh-hour rule change,<sup>2</sup> declaring that a regulation intended to standardize labeling on chemicals does not preempt state tort claims. Less noticed, but strikingly similar in

<sup>1</sup> Letter from M. Patricia Smith, Solicitor of Labor to Steven H. Wodka, Esq., Oct. 18, 2011.

<sup>2</sup> See "Hazard Communication," 77 Fed. Reg. 17574, 17605, 17786 (Mar. 26, 2012) (altering the language of 29 C.F.R. § 1910.1200(a)(2) from referring to state "legal requirements" to "legislative or regulatory enactments" to reflect the agency's view that its standards do not preempt common law claims). OSHA's authority for this action is facing a challenge in court. See *American Tort Reform Association v. Occupational Safety & Health Administration*, No. 12-1229 (D.C. Cir.).

*Victor E. Schwartz is chairman of the Public Policy Group in the Washington, D.C., office of Shook, Hardy & Bacon LLP. Cary Silverman is an attorney in the group. They can be reached at [vschwartz@shb.com](mailto:vschwartz@shb.com) and [csilverman@shb.com](mailto:csilverman@shb.com), respectively.*

its liability-expanding impact, was the DOL's stark reversal of its position that federal law preempts tort claims that challenge the federally-approved design of, or warnings used on, respirators that protect workers from contaminants.<sup>3</sup>

In both instances, the sudden, unanticipated change in public policy can be directly traced to the urging of the plaintiffs' bar: a New Jersey trial lawyer and the plaintiff lawyer trade association, the American Association for Justice (AAJ), respectively.

This article explores DOL's policy about-face with respect to government-approved respirators and whether it came about as a result of sound policy or plaintiff lawyer-driven politics. The issue has become more urgent since the Washington Supreme Court ruled in August that respirator makers are subject to liability for failing to warn of the dangers of harmful substances that they did not make or sell, and for which their products provide protection.

### Reliance on Respirators

To reduce or prevent injury from exposure to virtually any hazardous airborne substance or agents, workers rely on, and often are required by workplace regulations to use, respirators. Respirators are used throughout the industrial workplace, particularly in the manufacturing, mining, construction and chemical industries. They are also regularly used by the general public in household activities, by first responders, and in disaster relief or containment efforts.

The most commonly used and widely available equipment to protect wearers from contaminants in the air is

<sup>3</sup> Letter from Deborah Greenfield, acting deputy solicitor to Les Weisbrod, president, American Association for Justice, Feb. 3, 2010.

the N-95 respirator.<sup>4</sup> N-95 respirators are mandatory protective equipment in many occupations. They are commonly used at construction sites and hospitals, and also recommended by health officials for use as protection against airborne transmission of infectious agents, such as measles, swine flu, and Severe Acute Respiratory Syndrome (SARS).

## Federal Certification and Regulation of Respirators

Three federal agencies share responsibility for respirator safety: the National Institute for Occupational Safety and Health (NIOSH), the Mine Safety and Health Administration (MSHA), and the Occupational Safety and Health Administration (OSHA).

NIOSH, a research-centered agency that is part of the Centers for Disease Control and Prevention, develops recommendations on workplace safety practices<sup>5</sup> and manages a comprehensive respirator certification program. MSHA sets mandatory, science-based and clinically-supported safety standards specifically to protect the health of miners. OSHA regulates workplace safety through regulations that are binding on employers. Both MSHA and OSHA fall within DOL. The complementary efforts of these agencies establish a rigorous regulatory system for respirators that provides an optimal level of workplace safety for those exposed to various dangerous contaminants.

All applications for respirator approval are jointly reviewed and the certifications issued by both NIOSH and the MSHA.<sup>6</sup> The certification program closely considers and specifically approves nearly every aspect of a respirator's design specifications, performance, inspection and testing results, respirator samples, and proposed user instructions, including manuals, packaging, and labeling.

NIOSH regulations are highly specific with respect to the information and warnings imparted to potential users through the product's labeling. The NIOSH certification application includes specific language regarding the cautions and limitations on use that must be included on the label or in a package insert.<sup>8</sup> In addition to manufacturer identification information and the NIOSH and HHS emblems, the label must contain, "where appropriate, restrictions or limitations placed upon the use of the respirator by the Institute."<sup>9</sup> In fact, the certificate of approval is accompanied by a repro-

duction of the mandated label design.<sup>10</sup> NIOSH maintains responsibility for notifying the manufacturer "when additional labels, markings, or instructions will be required."<sup>11</sup> Federal regulations explicitly provide that a manufacturer may not modify the design or labeling of a respirator without prior NIOSH approval.<sup>12</sup> A respirator manufacturer that deviates from conditions of certification may be subject to rescission of its NIOSH certificates.<sup>13</sup>

The Occupational Safety & Health Act of 1970 ("OSH Act") requires employers to provide their employees with a workplace free of recognized hazards and to comply with occupational safety and health standards promulgated under the Act.<sup>14</sup> As the federal agency primarily responsible for workplace health and safety, OSHA promulgates binding occupational safety and health standards.<sup>15</sup> These regulations require employers to provide their employees with respirators "which are applicable and suitable for the purpose intended."<sup>16</sup>

To define appropriate respirator use, OSHA mandates the use of NIOSH-certified respirators<sup>17</sup> and further mandates that employers provide their employees with specific types of NIOSH-certified respirators when they are exposed to certain contaminants.<sup>18</sup> Specifications for minimum acceptable respiratory protection are provided in a table included in the regulation.<sup>19</sup> The regulatory framework is thus set up in such a way that a "suitable" respirator is one that is approved by NIOSH and specifically tailored to: (1) the hazardous substance, (2) the environmental conditions of the area of exposure to that substance, and (3) the intended duration of that exposure.<sup>20</sup>

## Striking the Optimum Balance Between Competing Values

Overall, this federal regulatory system strikes an important balance between two competing values to result in the optimal level of functionality: breathability and filtration. As NIOSH has so aptly explained:

Breathing resistance is significant to respirator wearers in three ways. First, higher breathing resistance increases leakage at the face seal of the respirator. Face seal leakage is directly proportional to breathing resistance, other factors being equal. Second, respirators with lower breathing resistance are more comfortable and more acceptable to wearers. If a respirator is uncomfortable to wear, workers are less inclined to use their respirator as often as they should. Third, high breathing resistance can be an unacceptable physiological burden on some workers. For a worker with impaired pulmonary or cardiovascular function, high breathing resistance may make respirator use impossible.<sup>21</sup>

<sup>4</sup> The N-95 respirator, as the number indicates, is designed to filter at least 95% of particles 0.3 microns and larger. The "N" in N-95 also differentiates classes of air-purifying respirators based on their ability to remain effective in the presence of oil particles: "N" for not oil resistant, "R" for oil resistant, and "P" for oil proof.

<sup>5</sup> 29 U.S.C. § 671.

<sup>6</sup> 42 C.F.R. § 84.3(a)(1)-(2).

<sup>7</sup> *Id.* §§ 84.3, 84.11, 84.31, 84.33, 84.41, 84.42, 84.43; see also NIOSH, National Personal Protective Technology Laboratory (NPPTL) Respirator Branch, Standard Application Procedure for the Certification of Respirators Under 42 CFR 84 (Revision 1, July 2005, available at <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPJul2005.pdf> (hereinafter "NIOSH Application")) (detailing the approval process and application requirements).

<sup>8</sup> See NIOSH Application, *supra*, at 21-22, 37-38.

<sup>9</sup> 42 C.F.R. § 84.33(b).

<sup>10</sup> *Id.* § 84.31(d).

<sup>11</sup> See *id.* § 84.33(c).

<sup>12</sup> *Id.* § 84.35.

<sup>13</sup> See *id.* § 84.34.

<sup>14</sup> 29 U.S.C. § 654(a).

<sup>15</sup> 42 U.S.C. §§ 655, 659.

<sup>16</sup> *Id.* § 1910.134(a)(2).

<sup>17</sup> See *id.* § 1910.134(d)(1)(ii).

<sup>18</sup> See, e.g., *id.* § 1910.1001(g)(2)(ii).

<sup>19</sup> See 29 C.F.R. § 1910.134 tbl. 1.

<sup>20</sup> See 29 C.F.R. § 1910.134(d).

<sup>21</sup> See Respirator Protective Devices, 60 Fed. Reg. 30,336, 30,352 (June 8, 1995).

In other words, as the level of protection increases, it becomes more difficult for the user to breath and users with certain conditions may be unable to make use of the protection.

There is also danger of requiring respirators that provide a higher level of protection in the workplace: the discomfort may lead workers not to regularly wear them, even if required by their employer to do so. Almost anyone who has visited a factory has seen some workers wearing masks up on their foreheads. This practice can lead to serious worker injuries. For this reason, NIOSH has “maintained the breathing resistance at a level that still will minimize adverse impacts on the respirator user.”<sup>22</sup>

Likewise, NIOSH approves respirator labeling that most effectively communicates instructions and warnings to workers.<sup>23</sup> The regulatory system incorporates the input of virtually all party interests and scientific disciplines, shows considerable deference to expert advice derived from state-of-the-art research and testing, and provides a widespread enforcement presence.<sup>24</sup>

It is against this backdrop of a comprehensive, balanced, and longstanding system of certification and regulation that tort litigation alleging design and warning defects of respirator products raises serious concern.

## DOL's 2009 Position on Preemption

In early 2009, DOL issued an interpretive opinion, in response to a request from the International Safety Equipment Association (ISEA), finding that “principles of conflict preemption preclude state courts from finding that OSHA-required, NIOSH-certified respirators are defective when such respirators comply with NIOSH requirements.”<sup>25</sup>

The opinion, which came after eight months of internal review, emphasized that once NIOSH certifies a respirator, the manufacturer is “locked into” the approved design and labeling specifications, which cannot be altered via tort suit.<sup>26</sup>

DOL also recognized NIOSH’s careful balancing of risks and benefits associated with design specifications and warnings related to respirators. Certification occurs only after NIOSH “has deliberately, after extensive testing and research, created requirements that respirator manufacturers must follow if they are to sell respirators to employers.”<sup>27</sup>

Tort law claims that seek to impose different design standards or labeling than that required by NIOSH and OSHA, DOL found, are impermissible. “To allow juries to enforce their own views of respirator design specifications and labeling for which NIOSH, as an expert agency, has already created standards and requirements, would directly conflict with OSHA’s mandate that employers only use respirators designed and

manufactured in accordance with NIOSH requirements.”<sup>28</sup>

The DOL’s 2009 position on preemption does not find that federal regulations preempt *all* tort claims involving respirators. For example, claims alleging manufacturing flaws would not be subject to preemption. In addition, federal regulation would not preempt claims involving non-NIOSH certified respirators, which may be sold in the United States but do not fulfill OSHA requirements for worker protection in the workplace. Claims involving NIOSH-certified respirators when used outside of the workplace also would not be subject to preemption. Finally, courts are unlikely to find that tort claims arising from elements of respirator design, marketing, or workplace practices not regulated by OSHA or NIOSH, such as torque pressure for tightening of attachment straps, dimensions of attachment straps, or lubricants used with respirators are subject to preemption.

## The 2010 Reversal

In March 2009, less than three months after DOL issued its opinion letter on preemption, the president of AAJ, Les Weisbrod, asked that the Department reconsider its position. There were two developments that provided an opening for such a change in that short period of time, and a third factor soon followed.

First, the administration changed hands. Then, in March 2009, the U.S. Supreme Court issued a preemption-restricting ruling in *Wyeth v. Levine* in the context of warnings related to brand-name prescription drugs.

AAJ received further ammunition after President Obama issued an executive memorandum to the heads of agencies requiring them to closely review the legal basis for their positions on preemption of state law in May 2009.<sup>29</sup>

In February 2010, DOL accepted AAJ’s invitation to reverse itself. In doing so, DOL found that the 2009 interpretive letter “did not take full account of relevant jurisprudence regarding preemption principles at the time it was written,” and was also out of step with recent Supreme Court jurisprudence and the policy of the current administration. DOL placed significant reliance on the OSH Act’s savings clause as preserving any tort law claim.<sup>30</sup>

## Flaws in DOL's New Position

The 2010 letter has several fatal flaws that should lead courts to provide the DOL’s reversal of its interpre-

<sup>28</sup> *Id.*

<sup>29</sup> See Memorandum to the Heads of Executive Departments and Agencies, The White House Office of the Press Secretary, May 20, 2009. This memorandum was also a direct result of a substantial lobbying effort of the personal injury bar and its allies. See Victor E. Schwartz & Cary Silverman, *Preemption of State Common Law by Federal Agency Action: Striking the Appropriate Balance that Protects Public Safety*, 84 Tulane L. Rev. 1203, 1219-21 (2010).

<sup>30</sup> 29 U.S.C. § 653(b)(4) provides that “[n]othing in this Act shall be construed to supersede or in any manner affect any workmen’s compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.”

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 30,345.

<sup>24</sup> See, e.g., *id.* at 30,337-49 (summarizing and responding to numerous comments).

<sup>25</sup> See U.S. Dep’t of Labor, Occupational Safety & Health Admin., Standard Interpretations, OSHA’s Position on Conflict Preemption Precluding State Court Filings with Regard to Defective NIOSH-certified Respirators, Jan. 9, 2009.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

tation of the impact of federal regulations on preemption of state tort claims with little, if any, deference.

First, the DOL's new position ignores several important aspects of established law. The agency's new view on preemption of claims against respirator makers disregards the express preemption provision of the OSH Act, which requires a state that seeks to impose its own safety and health standards, where a federal standard exists, to submit and obtain approval of a state plan from DOL.<sup>31</sup> The Supreme Court has recognized that state requirements that are subject to preemption not only include "positive law," such as statutes and regulations, but also common law claims. As the Court found in the context of FDA-approved medical devices, "excluding common-law duties from the scope of preemption would make little sense" because common law claims may disrupt federal regulation no less than state regulatory law.<sup>32</sup> Even if express preemption does not apply, the Court has explained that a savings clause, such as that contained in the OSH Act, does not foreclose application of ordinary principles of conflict preemption.<sup>33</sup>

Second, the DOL opinion letter misreads *Wyeth v. Levine*, which is actually supportive of precluding certain state tort claims in the respirator context. In *Levine*, the Court ruled that federal law does not broadly preempt tort claims challenging the adequacy of the labeling of brand-name prescription drugs.<sup>34</sup> The foundation of the Court's decision was its recognition that federal regulations applicable to brand-name drug makers permit them to unilaterally alter safety information on a label. Given their ability to change labels without prior federal approval, the Court found it was not impossible for brand-name drug manufacturers to comply with both federal labeling law and any state law warning requirements that would be derived from litigation in which it is deemed that its current warnings were inadequate.<sup>35</sup>

By way of contrast, two years later, in *Pliva, Inc. v. Mensing*, which the Supreme Court issued after the new DOL view of preemption, the Court found that failure-to-warn claims against generic drug makers are preempted because federal law requires labeling generic drugs with the same information as the brand-name equivalent.<sup>36</sup> While a generic-drug maker may be able to ask the FDA to order a change to a label, the manufacturer cannot alter the label on its own. The mere chance that an agency may approve such a request, the Court found, does not turn the "impossibility" of altering warnings into a "possibility."<sup>37</sup>

Respirator manufacturers fall on the *Mensing* side of the preemption line. As noted earlier, federal regulations recognize that NIOSH maintains responsibility for notifying the manufacturer "when additional labels, markings, or instructions will be required."<sup>38</sup> The regulations require NIOSH to affirmatively approve aspects

of the respirator design, packaging, or labeling referenced by the certificate of approval before alteration.<sup>39</sup> Thus, as is the case for generic drug manufacturers, respirator makers may not alter a design or labeling on their own initiative to address the alternative sought in a lawsuit.

Finally, DOL's stark reversal in its position is a transparently political decision, not one based on law or a reasoned policy change. This decisionmaking process provides another reason the opinion deserves little deference in the courts. As the Supreme Court recognized in *Levine*, an agency interpretation of the preemptive effect of its regulations does not merit deference when it represents a sudden "dramatic change" from the agency's previous position.<sup>40</sup> Here, there is no question that DOL's quick 180-degree turn was prompted by plaintiffs' bar lobbying efforts that may have helped convince a new administration to make the change. The highly political, self-serving nature of the change, which puts a premium on more lawsuits rather than well-reasoned public policy and law, provides a third reason for disregarding the 2010 opinion letter.

## The Threat of Liability to Manufacturers and the Public

The DOL's change in position places increased pressure on respirator manufacturers, which already face mounting litigation expenses stemming primarily from asbestos litigation. Even as courts and legislatures have attempted to address the excesses in this area,<sup>41</sup> a Washington Supreme Court decision in August shows that a significant liability threat remains.

Although respirator manufacturers make products that shield workers from contaminants, rather than asbestos-containing products that cause serious disease, those who make the protective equipment are often named among numerous defendants in asbestos and silica-related lawsuits. Despite this important distinction, the number of claims against respirator manufacturers skyrocketed over the past decade.<sup>42</sup> According to an industry group, more than 325,000 individual asbestos and silica lawsuits have included claims against respirator manufacturers between 2000 and 2008.<sup>43</sup>

That this increase in claims against respirator manufacturers occurred in the absence of a reported mass failure of a product is astonishing. It has occurred as a result of the domino effect of bankruptcies of traditional asbestos defendants in an "endless search for a

<sup>39</sup> 42 C.F.R. § 84.35.

<sup>40</sup> *Levine*, 555 U.S. at 557-59.

<sup>41</sup> See generally Mark Behrens, *What's New in Asbestos Litigation?*, 28 Rev. Litig. 501 (2009).

<sup>42</sup> For example, E.D. Bullard Company, the inventor of the hard hat and a maker of respirators, witnessed an incredible jump in the number of claims over a few short years: 62 cases with 200 plaintiffs in 1999; 156 cases with 4,305 plaintiffs in 2002; and 643 cases with 17,288 plaintiffs in 2003. See Susanne Sclafane, *Silica Dust: The Next Asbestos? Hard Hat Maker with Former RIMS President Among 160 Defendants Facing Dust Claims*, 108-18 Nat'l Underwriter Prop. & Casualty-Risk & Benefits Mgmt., May 10, 2004.

<sup>43</sup> Letter from Daniel K. Shipp, president, Int'l Safety Equip. Ass'n to Edwin G. Foulke, Jr., asst. sec. of labor for occupational safety & health, and Leon R. Sequeira, asst. sec. of labor for policy, U.S. Dep't of Labor (May 19, 2008).

<sup>31</sup> 29 U.S.C. § 667(b).

<sup>32</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008).

<sup>33</sup> See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-74 (2000).

<sup>34</sup> *Wyeth v. Levine*, 555 U.S. 555 (2009).

<sup>35</sup> *Id.* at 573.

<sup>36</sup> *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

<sup>37</sup> See *id.* at 2578 ("State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.")

<sup>38</sup> See *id.* § 84.33(c).

solvent bystander.”<sup>44</sup> There are few reported verdicts against respirator manufacturers. The vast majority of cases are settled for small amounts that are no greater than litigation costs, however, the cumulative effect of the cost of settling these lawsuits can strike a fatal blow to respirator manufacturers.<sup>45</sup>

One case that did not settle was that of Leo Macias, who worked for 24 years as a tool keeper in a shipyard in Seattle, Washington.<sup>46</sup> After Mr. Macias was diagnosed with mesothelioma, he claimed that his duties in cleaning respirators, during which he did not wear protective equipment himself, exposed him to asbestos dust that caused his injury.

Mr. Macias claimed that respirator manufacturers had a duty to warn him of the dangers of exposure to asbestos when respirators were cleaned and reused. The manufacturers countered that tort law does not recognize a duty to warn about products for which they were not in the chain of distribution, and that respirators are used to guard against a wide range of harmful substances in addition to asbestos, such as paint and welding fumes. The law appeared to support the manufacturers since the Washington Supreme Court, in two companion cases, had found that makers of pumps and valves are not subject to liability when asbestos-containing insulation made by third parties is attached to their own products post-sale.<sup>47</sup>

In a sharply divided decision issued in August 2012, the Washington Supreme Court overturned a grant of summary judgment for the respirator manufacturers. The majority held that its two earlier opinions—rejecting a duty to warn about asbestos products sold by third parties—did not control “because the duty at issue is to warn of the danger of asbestos exposure inherent in the use and maintenance of the defendant manufacturers’ own products, the respirators.”<sup>48</sup> The dissent, however, echoed the court’s earlier decisions finding that manufacturers should not be liable unless they are in the chain of distribution of the asbestos-containing products.<sup>49</sup> “If anything,” the dissenters reasoned, “the safety purpose of the respirators cuts against imposing liability here.”<sup>50</sup>

Such liability is not only damaging to respirator makers, but has a broader adverse effect on the public interest. Beyond sacrificing basic fairness and justice to the litigants, the financial impact of the litigation provides a strong disincentive for respirator makers to continue producing these safety devices for sale in the United States. In fact, a significant amount of respirator manufacturing has moved outside the United States to places

such as China and Mexico, where companies are not subject to American tort liability.<sup>51</sup> If the evolution of mass tort litigation in asbestos and silica provides any guide, mounting liabilities may force respirator manufacturers to shut down.

Either of these results, at the very least, would reduce the availability and affordability of respirators. Should their supply fail to keep pace with demand, industrial workers and the public would be exposed to considerable, and entirely unnecessary, risk. In addition, respirator supply may fall short to meet demands should there be an outbreak of a contagious disease, natural disaster, or terrorism.<sup>52</sup> The continued risk from such threats represents an important outstanding issue for the tort system to address, and one that is particularly disturbing in light of the level of regulation already dedicated to approving the design and labeling of respirators, and regulating their proper use in the workplace.

### Regulatory Compliance: A State-Based Alternative to Federal Preemption

Courts have another option for giving weight to NIOSH’s expertise in testing and certifying respirators, and OSHA’s responsibility for workplace safety, when considering litigation challenging aspects of federally-approved respirators. Rather than rely on federal preemption, they can apply a common law compliance-with-standards defense. Respirator regulation provides a strong case doing so.

Generally, the Restatement (*Third*) of Torts: *Products Liability* recognizes that a product’s compliance with applicable product safety standards is properly considered when determining whether a product is defective.<sup>53</sup> Commentary to the Restatement recognizes that in certain circumstances, a product that complies with safety standards should not be considered defective as a matter of law, such as:

when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.<sup>54</sup>

This common law approach to considering regulatory compliance in determining liability suggests that respirator manufacturers, in achieving NIOSH-certification, satisfy their duty of care and that their approved products are not defective in design or labeling as a matter of law. OSHA regularly revisits and updates its respiratory protection standards.<sup>55</sup> NIOSH’s long history of de-

<sup>44</sup> “Medical Monitoring and Asbestos Litigation”—A Discussion with Richard Scruggs and Victor Schwartz, 17:3 *Mealey’s Litig. Rep.: Asbestos* 5 (Mar. 1, 2002).

<sup>45</sup> See Press Release, Coalition for Breathing Safety, Can the U.S. Afford a Shortage of Respirator Masks to Fight Flu Pandemic? (Sept. 19, 2006), at [http://breathingsafety.interactive.biz/press/release/2006/09\\_19.htm](http://breathingsafety.interactive.biz/press/release/2006/09_19.htm) (stating that in 2004 alone, United States respirator manufacturers spent 90 percent of net income from respirator sales on litigation costs).

<sup>46</sup> *Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069 (Wash. 2012).

<sup>47</sup> See *Simonetta v. Viad Corp.*, 197 P.3d 127 (Wash. 2008); *Braaten v. Saberhagen Holdings*, 198 P.3d 493 (Wash. 2008).

<sup>48</sup> *Macias*, 282 P.3d at 1072 (emphasis in original).

<sup>49</sup> See *id.* at 1080 (Johnson, J., dissenting).

<sup>50</sup> *Id.* at 1082.

<sup>51</sup> See Bevan Schneck, *A New Pandemic Fear: A Shortage of Surgical Masks*, *Time*, May 19, 2009, available at <http://www.time.com/article/,8599,899526,00>.

<sup>52</sup> Some have suggested that the United States is far behind the emergency preparedness curve with respect to other countries. See Schneck, *supra*.

<sup>53</sup> Restatement (Third) of Torts: Prods. Liability § 4(b) (1998).

<sup>54</sup> *Id.* § 4 cmt. e.

<sup>55</sup> See, e.g., 73 Fed. Reg. 75,584 (Dec. 12, 2008) (revising requirement that employers are to provide employees with ap-

veloping these standards, and testing and certifying respirators, should provide courts with confidence that the process reflects its substantial expertise.

Several states have codified similar treatment by providing that compliance with federal or state government safety regulations creates a rebuttable presumption that a product is not defective.<sup>56</sup> At minimum, these laws assure that the jury will receive an instruction emphasizing the importance of considering the manufacturer's compliance with government safety standards in determining whether a product was unreasonably dangerous.

Thus, when there is a tort challenge to the adequacy of an aspects of a respirator that was specifically con-

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plicable and suitable respiratory protective equipment); 71 Fed. Reg. 50,187 (Aug. 24, 2006) (providing "assigned protection factors," the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees); 69 Fed. Reg. 46,993 (Aug. 4, 2004) (revising mandatory fit testing procedures).

<sup>56</sup> See, e.g., Colo. Rev. Stat. § 13-21-403(1); Kan. Stat. Ann. § 60-3304(a); Ky. Rev. Stat. Ann. § 411.310(2); Mich. Comp. Laws § 600.2946(4); Tenn. Code Ann. § 29-28-104(a); Tex. Civ. Prac. & Rem. Code Ann. § 82.008; Utah Code Ann. § 78B-6-703(2).

sidered during the certification process or through workplace safety requirements, state common judges, following the new Restatement's selective principles, should give due deference to the federal regulatory process and allow a compliance with safety standards defense.

## Conclusion

The DOL's current, blanket interpretation of federal regulation of respirator safety as not preempting tort claims should receive little deference in the courts given the Department's "here today, gone tomorrow" approach. Plaintiffs' lawyer desire to expand liability and self-interest, not safety, was the clear driver of this change in DOL policy.

Ultimately, courts should determine the question of whether federal law preempts a specific common law tort claim on a case-by-case basis. If NIOSH has mandated or approved an aspect of a respirator's design or labeling, and a tort claim challenges that element of the product, courts should give due deference to that reasoned decisionmaking through preemption or a regulatory compliance defense.

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