

Respirators to the Rescue: Why Tort Law Should Encourage, Not Deter, the Manufacture of Products that Make Us Safer

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Abstract

Protective respirator manufacturers have been named in tort actions involving asbestos or silica, but their purpose in the litigation seems to be a result of the search for a solvent bystander. Respirators are subject to strict regulation regarding both their design and warnings. This Article examines the public policy link between federal regulatory compliance and liability exposure. Should compliance with federal regulations preclude liability?

I. Introduction

A fundamental goal of the tort system is to promote development of safe products to reduce the future occurrence of injury.¹ Encompassed within this goal, and of special importance, is the law's interest in encouraging the manufacture of products that protect individuals against

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¹ See VICTOR E. SCHWARTZ ET AL., PROSSER, WADE AND SCHWARTZ'S TORTS 737 (11th ed. 2005).

hazardous materials or environments. Protective equipment, which ranges from a chemist's hazard shielding eyewear² to a police officer's bullet resistant vest³ or a nuclear technician's radiation suit,⁴ serves an immeasurable value to, not only the user of the protective equipment, but to society as a whole. They prevent injuries and reduce the need for individuals to rely on the tort or workers' compensation systems if harmed. Yet, in spite of these vital needs, some manufacturers of protective equipment face potentially crippling litigation, not for the harms their products caused, but for the risks their products are designed to reduce and protect against.⁵ Such lawsuits, premised on the allegation of product defect, have arisen even where the safety device at issue complies with comprehensive regulatory standards governing the product's design and labeling.⁶ As this Article shows, in some cases, these types of lawsuits pose a significant threat to a proper balance within the tort system, can stymie innovation, and threaten the availability of potentially life-saving safety and emergency products.

This Article approaches the tort system's role and function with regard to safety products through the microcosm of respirator safety. Respirators are personal safety devices designed to protect the wearer from inhaling harmful dusts, fumes, vapors, or gases, and to provide perhaps the most prevalent example of protective equipment used throughout the world by both private industry and the public.⁷ Respirators are heavily regulated and must meet specific standards that vary depending on their intended use.⁸ They are not a perfect or absolute means of injury prevention, but rather the result of a balancing of competing objectives: filtration and breathability.⁹ What has taken place with regard to respirator litiga-

² See, e.g., 29 C.F.R. § 1910.133 (2008) (general safety regulations for protective eyewear).

³ See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. f, illus. 10 (1997) (discussing the safety and cost tradeoffs in the production of bullet-resistant police vests).

⁴ See, e.g., 29 C.F.R. § 1910.132(a) (2008) (general requirements).

⁵ See *infra* Section IV.

⁶ See *infra* Section III.

⁷ See 29 C.F.R. § 1910.134 (2008) (respiratory protection).

⁸ See *id.* § 1910.134(a)(2) (stating an "employer shall provide the respirators which are applicable and suitable for the purpose intended").

⁹ See *id.*

tion over the past decade is a cautionary tale illustrative of a continuing problem that could spread to and threaten other types of protective equipment. As the world prepares for a potential pandemic of influenza, the availability of respirators could not be more critically important.

The purpose of this Article is to examine how tort law has addressed liability for respirator safety and how the civil justice system can most effectively encourage the development of protective equipment while balancing the need to provide an appropriate remedy to those who are injured by a true flaw in the device. Section II of the Article begins with a view from the “forest,” examining general tort law principles that have developed to promote safety by authorizing exceptions to traditional liability rules. Section III narrows the focus to respirator products, providing background on their use and importance and the comprehensive regulatory oversight of these devices. Section IV discusses the litigation environment for respirators and its consequences. Section V explores the public policy tradeoffs in sustaining litigation against respirator manufacturers and makes recommendations for states to move their common law toward a more uniform liability system.

The Article concludes by suggesting an optimal and practical framework for respirator liability based on clear federal regulations and longstanding tort principles. It finds that for protective equipment such as respirators, which are heavily regulated by the federal government, compliance with design and labeling standards should conclusively, as a matter of public policy, preclude liability, absent a manufacturing defect. In addition, when a lawsuit effectively challenges elements of design or labeling that are approved by federal regulators for a device that federal law requires for use in the workplace, principles of preemption should also apply.¹⁰ Finally, the Article concludes that if courts faithfully apply these principles of law, not only will respirator manufacturers continue to design and produce these protective devices, but most importantly, workers and the general public will continue to have access to these much-needed respirators.

¹⁰ 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, posted Jan. 9, 2009, available at <http://www.osha.gov/prevwutsnew/jan09.html> (follow “January 13—Interpretation—OSHA’s position on conflict preemption precluding state court findings with regard to defective NIOSH-certified respirators”) (last visited Sept. 30, 2009).

II. Tort Law's Encouragement of Rescue and Safety

Prevention of injury is a basic objective of tort law. In some circumstances, however, this goal is at tension with traditional liability rules and the civil justice system is pressed to make a public policy tradeoff. Where this balancing has been achieved throughout the tort system, whether it be through common law, statute, court rule, or regulation, the outcome demonstrates a preference for encouraging reduction of injury above imposing liability.

A. Common Law Liability Rules Provide for Favorable Treatment of Rescuers

The tort system's treatment of voluntary rescuers is a universally accepted area that demonstrates a public policy preference for injury reduction over traditional liability standards.¹¹ This group includes those persons who, as bystanders to another's perilous situation and "[u]nder the impulse of danger," take action to render aid.¹² They do so not out of any affirmative legal duty to intercede, but out of compassion, morality, heroism, or reward.¹³ In such situations, the common law has developed to provide the rescuer with certain inducements for, at least, attempting to reduce physical injury in society.

¹¹ See, e.g., Malia T. McLaughlin, *Imminent Peril Inviting Rescue Attempt*, 7 AM. JUR. 3D *Proof of Facts* § 415 (2009).

¹² *Brown v. Nat'l Oil Co.*, 105 S.E.2d 81, 87 (S.C. 1958).

¹³ The leading case regarding the rescue doctrine is *Wagner v. International Railway Co.*, 133 N.E. 437 (N.Y. 1921). In *Wagner*, a train conductor failed to close a door, allegedly causing a passenger, Wagner's cousin, to fall off during a turn over a bridge. *Id.* at 437. The train stopped and Wagner went looking for his cousin back by the bridge, lost his footing and fell to the ground beneath the bridge. *Id.* Wagner then sued the railway company for his injuries. Justice Cardozo, reversing the appellate court's decision denying relief and granting a new trial, wrote:

Danger invites rescue. The cry of distress is the summons to relief. The law does not ignore these reactions of the mind in tracing conduct to its consequences. . . . The wrong that imperils life is a wrong to the imperiled victim; it is a wrong also to his rescuer. . . . The risk of rescue, if only it be not wanton, is born of the occasion.

Id. at 437-38.

As a starting point, it is a long-established feature of the American tort law system that an individual generally owes no legal duty to affirmatively act to aid a stranger in peril.¹⁴ Commentators have identified various rationales for this basic rule, most notably the “American” ideals of individual freedom and personal autonomy.¹⁵ Compulsory rescue, some have argued, would represent too much of an invasion of an individual’s fundamental rights, and would necessarily distort existing and well-settled limits on the scope of liability and proximate causation.¹⁶ At the opposite end of the spectrum, other legal commentators have severely criticized the rule as anachronistic and morally objectionable.¹⁷

¹⁴ See WILLIAM L. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 56, at 338-43 (4th ed. 1971); RESTATEMENT (SECOND) OF TORTS § 314 (1965); see also *Lacey v. United States*, 98 F. Supp. 219, 220 (D. Mass. 1951) (“It is well settled common law that a mere bystander incurs no liability where he fails to take any action, however negligently or even intentionally, to rescue another in distress.”); *Williams v. California*, 664 P.2d 137, 139 (Cal. 1983) (“As a rule, one has no duty to come to the aid of another. A person who has not created a peril is not liable in tort merely for failure to take affirmative action to assist or protect another”); *Union Pac. Ry. Co. v. Cappier*, 72 P. 281, 283 (Kan. 1903) (“The moral law would obligate an attempt to rescue a person in a perilous position—as a drowning child—but the law of the land does not require it, no matter how little personal risk it might involve”).

¹⁵ See, e.g., Richard A. Epstein, *A Theory of Strict Liability*, 2 J. LEGAL STUD. 151, 197-204 (1973) (discussing individual freedom and providing an economic analysis); James A. Henderson, Jr., *Process Constraints in Tort*, 67 CORNELL L. REV. 901, 928-43 (1982) (discussing procedural aspects); Saul Levmore, *Waiting for Rescue: An Essay on the Evolution and Incentive Structure of the Law of Affirmative Obligations*, 72 VA. L. REV. 879, 938 (1986) (discussing the problem of multiple potential rescuers); Philip W. Romohr, *A Right/Duty Perspective on the Legal and Philosophical Foundations of the No-Duty-to-Rescue Rule*, 55 DUKE L.J. 1025, 1042-46 (2006) (discussing personal autonomy and individual rights).

¹⁶ See Steven J. Heyman, *Foundations of the Duty to Rescue*, 47 VAND. L. REV. 673, 675-76 (1994).

¹⁷ See David A. Hyman, *Rescue Without Law: An Empirical Perspective on the Duty to Rescue*, 84 TEX. L. REV. 653, 663 n.20 (2006) (“The overwhelming majority of published articles support the imposition of a generalized duty to assist.”); Romohr, *supra* note 15, at 1025 (“[T]he absence of a duty to rescue, especially when such rescue could be accomplished with little or no risk to the rescuer . . . has been criticized by the vast majority of legal scholarship on the subject.”); see also JEREMY BENTHAM, *AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION* 293 (J.H. Burns & H.L.A. Hart eds. 1970) (1789); MARSHALL S. SHAPO, *THE DUTY TO ACT: TORT LAW, POWER & PUBLIC POLICY* 64-73 (1977); James Barr Ames, *Law and Morals*, 22 HARV. L. REV. 97, 111-13 (1908); Heyman, *supra* note 16, at 674-77; Ernest J. Weinrib, *The Case for a Duty to Rescue*, 90 YALE L.J. 247, 248-49 (1980).

Regardless of these views or justifications, however, the rule, for better or worse,¹⁸ provides the prevailing common law approach.¹⁹

Over time, the common law has developed five exceptions to this rule, imposing a duty to render aid where: (1) an individual is responsible for imperiling another person, (2) a special relationship exists giving rise to a duty of care (*e.g.*, parent-child relationship), (3) a duty is created by contract, (4) the duty is imposed by statute, and (5) a voluntary rescuer enters and takes charge of rendering assistance.²⁰ In all but the final exception for voluntary rescuers, the law recognizes a duty to act before any rescue is attempted.²¹ The voluntary rescuer is therefore in the

¹⁸ Professor David Hyman, for example, attempted to empirically analyze the frequency of rescue in America, concluding,

[I]f the no-duty rule that prevails in forty-seven of the fifty states is “sending the wrong message” about the desirability of undertaking a rescue, it is doing a singularly poor job of it. Indeed, even in the absence of a statutory duty, Americans appear to be too willing to undertake rescue if one judges by the number of injuries and deaths among rescuers.

Hyman, *supra* note 17, at 656-57. Professor Hyman further pointed out that “confirmable instances of non-rescue are actually extraordinarily rare events, occurring about 1.6 times per year in the entire United States during the past decade.” *Id.* at 665.

¹⁹ A minority of states also take a more invasive approach and impose a duty to rescue where there is no reasonably apparent danger on the part of the rescuer with violations subject to a civil fine. See MINN. STAT. § 604a.01(1) (2000); R.I. GEN. LAWS § 11-56-1 (2002); VT. STAT. ANN. tit. 12, § 519(a) (2002); WIS. STAT. § 940.34(2)(a) (2005). Vermont’s statute, for example, states:

(a) A person who knows that another is exposed to grave physical harm shall, to the extent that the same can be rendered without danger or peril to himself or without interference with important duties owed to others, give reasonable assistance to the exposed person unless that assistance or care is being provided by others. . . .

(c) A person who willfully violates subsection (a) of this section shall be fined not more than \$100.00.

VT. STAT. ANN. tit. 12, § 519(a), (c) (2002).

²⁰ See RESTATEMENT (SECOND) OF TORTS § 314 cmt. a (1965); RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 37-44 (Proposed Final Draft No. 1, 2005); see also Jay Silver, *The Duty to Rescue: A Reexamination and Proposal*, 26 WM. & MARY L. REV. 423, 425-27 (1985); Marin Roger Scordato, *Understanding the Absence of a Duty to Reasonably Rescue in American Tort Law*, 82 TUL. L. REV. 1447, 1460-63 (2008).

²¹ See, *e.g.*, RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL HARM § 42-44.

unique position of being “free” to choose whether to take on the potential liability.

The tort system, cognizant of individuals’ unwillingness to take on potential liability with uncertain or no potential for personal benefit, makes two accommodations to lessen the rescuer’s potential downside risks. Each of these involves modifying traditional tort law standards in the event of an unsuccessful or imperfect rescue. First, where a voluntary rescuer takes control over rendering assistance to an individual in imminent peril, or where the rescuer reasonably believes the person was in imminent peril,²² the rescuer is traditionally “under a duty to exercise reasonable care to prevent such further harm.”²³ In practice, this has developed into a low threshold. The inquiry often turns on whether the rescuer assumes control over the rescue effort only to abandon it, or the rescuer knowingly acts to put an imperiled individual in a worse position than that in which the rescuer found him.²⁴ Indeed, some courts may consider whether the rescuer’s attempt was conducted in a reckless, willful, or wanton manner, a standard that lowers the rescuer’s exposure to liability.²⁵

This public policy encouraging voluntary rescue is reinforced by state legislatures. Every state and the District of Columbia has enacted at least one so-called “Good Samaritan” law,²⁶ which codifies common law liability rules, and may in some cases lower liability exposure further.²⁷

²² See, e.g., *Estate of Solomon v. Shuell*, 457 N.W.2d 669, 683 (Mich. 1990) (stating that the issue is not whether the victim is in actual danger, but whether the rescuer acted as a reasonable person would in the same or similar circumstances).

²³ RESTATEMENT (SECOND) OF TORTS §322 (1965).

²⁴ See *Jackson v. City of Joliet*, 715 F.2d 1200, 1202 (7th Cir. 1983) (“[I]f you do begin to rescue someone you must complete the rescue in a nonnegligent fashion even though you had no duty of rescue in the first place.”); WILLIAM L. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 56, at 346 (4th ed. 1971) (“Where performance clearly has been begun, there is no doubt that there is a duty of care.”); see also *Fochtman v. Honolulu Police & Fire Dep’t*s, 649 P.2d 1114, 1116-17 (Haw. 1982) (police generally have no affirmative duty to act to protect citizens, but once officers act, they may be held liable if their actions worsen the situation); 57 AM. JUR. 2D *Negligence* § 46 (1971).

²⁵ See, e.g., *Furka v. Great Lakes Dredge & Dock Co.*, 755 F.2d 1085, 1088 (4th Cir. 1985), *rev’d on other grounds*, 824 F.2d 330, 331-32 (4th Cir. 1987).

²⁶ Silver, *supra* note 20, at 427; Scordato, *supra* note 20, at 1495.

²⁷ See Danny R. Veilleux, Annotation, *Construction and Application of “Good Samaritan” Statutes*, 68 A.L.R.4th 294 (1989).

Some states expressly modify duty standards by statute to include gross negligence,²⁸ or frame the question in a different way, such as whether the rescuer acted in “good faith” when conducting the rescue, an even lower standard.²⁹ Often liability will only be imposed on the rescuer where the imperiled individual experiences a greater physical injury as a result of the unsuccessful rescue.³⁰

A second accommodation or inducement occurs under a similar fact pattern, except that the rescuer is the injured party. An example would be someone pushing another out of the way of an oncoming vehicle and being struck by that vehicle in the process. Under these circumstances, the tort system permits the imperfect rescuer to recover from the party who negligently created a need for rescue.³¹ This is in spite of the very real possibility that the rescued party may have no relationship with, prior knowledge of, or have even come into contact with the rescuer, any of which is generally a prerequisite for imposing tort liability.³² Essentially, a total stranger can successfully sue for damages related to an unsuccessful rescue and do so even where the “rescued” individual was not actually in danger, but only reasonably appeared to be in danger.

The effect of altering tort standards to lower barriers for the rescuer to sue and to heighten barriers for the rescuer to be sued is that the rescuer has greater incentive to attempt action that prevents injury or loss of life. Such conduct is optimal because of the high value the law places on life.³³

²⁸ See, e.g., ALASKA STAT. § 9.65.090 (2008); ME. REV. STAT. ANN. tit. 14, § 164 (2003).

²⁹ See, e.g., GA. CODE ANN. § 51-1-29 (2000).

³⁰ See Veilleux, *supra* note 27.

³¹ See DAN B. DOBBS, *THE LAW OF TORTS* 456 (2000); see also Kiel Berry, Espinoza v. Schulenberg: *Arizona Adopts the Rescue Doctrine and Firefighter’s Rule*, 49 ARIZ. L. REV. 171, 172-73 (2007); Yasamine J. Christopherson, *The Rescue Doctrine Following the Advent of Comparative Negligence in South Carolina*, 58 S.C. L. REV. 641, 646-47 (2007).

³² See RESTATEMENT (SECOND) OF TORTS § 314 cmt. a (1965).

³³ See, e.g., *Furka v. Great Lakes Dredge & Dock Co.*, 755 F.2d 1085, 1088 (4th Cir. 1985) (“[T]he law has so high a regard for human life that it will not impute negligence to an effort to preserve it, unless made under such circumstances as to constitute rashness.” (quoting *Scott v. John H. Hampshire, Inc.*, 227 A.2d 751, 753-54 (Md. 1967)); *Allison v. Sverdrup & Parcel & Assocs.*, 738 S.W.2d 440, 450 (Mo. Ct. App. 1987) (citing *Doran v. Kansas City*, 237 S.W.2d 907, 912 (Mo. Ct. App. 1951)) (stating that, because the law values human life, “the rescuer was justified in exposing himself to a danger”).

The implication for the tort system under common law is that when presented with the choice between potentially reducing or preventing injury and maintaining traditional liability standards, tort law favors the former. While more may need to be done,³⁴ these principles demonstrate an overriding commitment to injury prevention in tort law and in society generally.

B. Rules of Evidence

Demonstrate Paramount Concern for Safety

In addition to the tort system's encouragement of voluntary rescue of those who are in imminent danger, rules of evidence provide a similar incentive for those who, following an accident or event, volunteer to take affirmative steps to prevent recurring injury. Courts have widely adopted a rule that bars introduction of evidence of subsequent remedial measures. A related principal, the self-critical analysis privilege, is also gaining increased acceptance in the states.

1. Evidence of Subsequent Remedial Measures

The general rule adopted by federal and state courts provides:

When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction.³⁵

³⁴ For example, some major hotel chains have shown reluctance to install automated external defibrillators on their property because they believe "Good Samaritan" laws do not offer them sufficient protection from liability. Although courts have found that hotels do not have a tort duty to install defibrillators, if they do so, they place themselves at risk of liability for not having enough units, for failing to place them in the most useful location, or failing to replace the batteries or maintain them properly. See Scott McCartney, *Why Hotels Resist Having Defibrillators*, WALL ST. J., Feb. 24, 2009, at D1, available at <http://online.wsj.com/article/SB123543325221454001.html> (last visited Sept. 30, 2009).

³⁵ FED. R. EVID. 407.

This rule is an exception to the general rule that all relevant evidence is admissible.³⁶ This evidentiary bar shields potential defendants from incurring additional liability or exacerbating their existing liability when taking action designed to improve safety.

Although embodied in Federal Rule of Evidence 407 and its state equivalents,³⁷ the origins of the subsequent remedial measures rule derive from English courts during the latter half of the nineteenth century.³⁸ Soon thereafter, the rule gradually gained acceptance in the common law of American courts.³⁹ In 1892, the Supreme Court solidified the rule's place in American law, holding that a subsequent alteration or repair by a defendant is not competent evidence of negligence.⁴⁰ In *Columbia & Puget Sound Railroad Co. v. Hawthorne*, the plaintiff sued a saw-mill owner after a pulley fell on him, and, to prove negligence, introduced evidence that the saw-mill owner changed the machinery after the accident to prevent the pulleys from falling.⁴¹ In precluding introduction of such evidence, the Court reasoned:

A person may have exercised all the care which the law required, and yet, in the light of his new experience, after an unexpected accident has occurred, and as a measure of extreme caution, he may adopt additional safeguards. The more careful a person is, the more regard he has for the lives of others, the more likely he would be to do so; and it would seem unjust that he could

³⁶ FED. R. EVID. 402.

³⁷ See, e.g., ARIZ. R. EVID. 407; ARK. R. EVID. 407; COLO. R. EVID. 407; DEL. R. EVID. 407; OHIO. R. EVID. 407.

³⁸ See 23 CHARLES A. WRIGHT & KENNETH W. GRAHAM, JR., FEDERAL PRACTICE AND PROCEDURE: EVIDENCE § 5282 (Supp. 2006) (citing *Hart v. Lancashire & Yorkshire Ry. Co.*, 21 L.T.R. (N.S.) 261 (1869)); see also Mark G. Boyko & Ryan G. Vacca, *Who Knew? The Admissibility of Subsequent Remedial Measures When Defendants Are Without Knowledge of the Injuries*, 38 MCGEORGE L. REV. 653, 654-55 (2007).

³⁹ See *Nalley v. Hartford Carpet Co.*, 51 Conn. 524 (Sup. Ct. Err. 1884); *Hodges v. Percival*, 23 N.E. 423 (Ill. 1890); *Terre Haute & Indianapolis Ry. v. Clem*, 23 N.E. 965 (Ind. 1890); *Shinners v. Proprietors of Locks & Canals*, 28 N.E. 10 (Mass. 1891); *Lombar v. East Tawas*, 48 N.W. 497 (Mich. 1891); *Morse v. Minneapolis & St. Louis Ry.*, 16 N.W. 358 (Minn. 1883); *Corcoran v. Peekskill*, 15 N.E. 309 (N.Y. 1888); *Ely v. St. Louis, Kansas City & N. Ry.*, 77 Mo. 34 (1882); *Mo. Pac. Ry. v. Hennessey*, 12 S.W. 608 (Tex. 1889).

⁴⁰ 144 U.S. 202, 208 (1892).

⁴¹ *Hawthorne*, 144 U.S. at 204.

not do so without being liable to have such acts construed as an admission of prior negligence. We think such a rule puts an unfair interpretation upon human conduct, and virtually holds out an inducement for continued negligence.⁴²

This same reasoning provided the primary justification for subsequent efforts by Congress to codify the evidentiary rule.⁴³ The Advisory Committee's 1972 Notes accompanying Rule 407 make this explicit, stating that the "more impressive" basis for the evidentiary rule "rests on a social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety."⁴⁴ Hence, like voluntary rescue, the subsequent remedial measures rule is primarily rooted in public policy considerations developed at common law favoring enhanced safety over imposing tort liability.

2. Self-Critical Analysis Privilege

Where, thus far, we have examined how tort law encourages injury reduction as individuals face danger and after the fact so as to prevent further injury, a final avenue in which the tort system promotes injury prevention generally is before an injury occurs in the first place. To accomplish this precautionary objective, and do so on a broader level than specific areas of tort law such as products liability, a growing number of courts have authorized a "self-critical analysis privilege."⁴⁵ This rule

⁴² *Id.* at 208 (quoting *Morse*, 16 N.W. at 359).

⁴³ The Advisory Committee's 1972 Notes accompanying Rule 407 indicate that Congress was adopting the common law's subsequent remedial measures rule. *See* FED. R. EVID. 407 advisory committee's notes. The Advisory Committee stated that Rule 407 rests on two grounds: a concern that evidence of subsequent remedial measures is logically irrelevant in assessing liability and the fear of deterring safety measures. *See id.*

⁴⁴ FED. R. EVID. 407 advisory committee's notes.

⁴⁵ The privilege for self-critical analysis has been given a variety of names by courts and commentators. *See* *Emerson Elec. Co. v. Schlesinger*, 609 F.2d 898, 907 (8th Cir. 1979) ("privilege against disclosure of self-evaluative documents"); *Reynolds Metals Co. v. Rumsfeld*, 564 F.2d 663, 667 (4th Cir. 1977) ("qualified privilege for self-evaluative documents"), *cert. denied* 425 U.S. 995 (1978); *Webb v. Westinghouse Elec. Corp.*, 81 F.R.D. 431, 433 (E.D. Pa. 1978) ("privilege of 'self-critical' analysis" and "defense of self-critical analysis"); Lynne Charlotte Hermle, Note, *A Balanced Approach to Affirmative Action Discovery in Title VII Suits*, 32 HASTINGS L.J. 1013,

of evidence shields certain institutional self-evaluations from discovery.⁴⁶ Its overriding purpose is to encourage a thorough, frank, and unbiased appraisal of existing safety conditions associated with a business or other enterprise.⁴⁷

Bredice v. Doctors Hospital, Inc. provides a classic example of how the self-critical analysis privilege operates.⁴⁸ In that case, a federal court held that the minutes of hospital committee meetings addressing medical care procedures were protected from discovery.⁴⁹ During these meetings, hospital staff members were asked for their frank analyses of hospital procedures to assist in developing recommended improvements.⁵⁰ The court denied discovery of this confidential information for the purpose of a medical malpractice action, grounding its reasoning in the potential adverse public policy implications flowing from such a disclosure.⁵¹ As the court explained:

[T]hese meetings are essential to the continued improvement in the care and treatment of patients. Candid and conscientious evaluation of clinical practices is a *sine qua non* of adequate hospital care. To subject these discussions and deliberations to the discovery process, without a showing of exceptional necessity, would result in terminating such deliberations. Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit.⁵²

This notion of a “chilling effect” on both the evaluation and improvement of safety measures is the core justification for the self-critical

1024 (1981) (“public policy privilege”); Clyde C. Kahrl, Comment, *The Attorney-Client Privilege, the Self-Evaluative Report Privilege, and Diversified Indus., Inc. v. Meredith*, 40 OHIO ST. L.J. 699 (1979) (“self-evaluative report privilege”).

⁴⁶ See *infra* notes 48-52 and accompanying text; see also Note, *The Privilege of Self-Critical Analysis*, 96 HARV. L. REV. 1083, 1084-86 (1983); Joseph E. Murphy, *The Self-Evaluation Privilege*, 7 J. CORP. L. 489 (1982).

⁴⁷ See Note, *supra* note 46, at 1086-87.

⁴⁸ 50 F.R.D. 249 (D.D.C. 1970), *aff'd*, 479 F.2d 920 (D.C. Cir. 1973).

⁴⁹ *Bredice*, 50 F.R.D. at 251.

⁵⁰ See *id.* at 250.

⁵¹ *Id.*

⁵² *Id.* at 250-51.

analysis privilege.⁵³ Similar to the origins of liability rules regarding rescue and subsequent remedial measures, the self-critical analysis privilege is rooted in common law.⁵⁴ Unlike these other areas in tort, however, the development of the self-critical analysis privilege is primarily a product of federal court jurisprudence.⁵⁵ Federal Rule of Evidence 501 instructs federal courts to develop and interpret privileges under common law “in the light of reason and experience.”⁵⁶ The rule reflects Congress’s “affirmative intention not to freeze the law of privilege.”⁵⁷ Its purpose, rather, was to “‘provide the courts with the flexibility to develop the rules of privilege on a case-by-case basis,’ and to leave the door open to change.”⁵⁸ On this basis, many federal courts have adopted, albeit unevenly,⁵⁹ the self-critical analysis privilege, recognizing its public policy

⁵³ See Note, *supra* note 46, at 1091-94.

⁵⁴ See FED. R. EVID. 501 (stating that all federal privileges “shall be governed by the principles of the common law as they may be interpreted by the courts of the United States”).

⁵⁵ See *id.*; Note, *supra* note 46, at 1084-86.

⁵⁶ FED. R. EVID. 501.

⁵⁷ *Trammel v. United States*, 445 U.S. 40, 47 (1980).

⁵⁸ *Id.* (quoting 120 CONG. REC. 40891 (1974) (statement of Rep. Hungate)); see also *United States v. Weber Aircraft Corp.*, 465 U.S. 792, 804 n.25 (1984) (stating that “Rule 501 was adopted precisely because Congress wished to leave privilege questions to the courts rather than attempt to codify them”); *United States v. Gillock*, 445 U.S. 360, 367 (1980); S. REP. NO. 93-1277, at (1974), *reprinted in* 1974 U.S.C.C.A.N. 7051, 7059. Rule 501 also gives primacy to state law in the federal courts, at least in cases in which state law provides the rule of decision. See FED. R. EVID. 501; see also H.R. REP. NO. 93-650 (1973), *reprinted in* 1974 U.S.C.C.A.N. 7075, 7082.

⁵⁹ There is presently considerable ambiguity among federal courts as to the status of the self-critical analysis privilege. See, e.g., *Burden-Meeks v. Welch*, 319 F.3d 897, 899 (7th Cir. 2003) (noting that the Seventh Circuit has yet to recognize the self-critical analysis privilege, but basing its decision on waiver); *In re Grand Jury*, 103 F.3d 1140 (3d Cir. 1997) (for the proposition that it is unlikely the Third Circuit recognizes a self-critical analysis privilege); *Coates v. Johnson & Johnson*, 756 F.2d 524, 551 (7th Cir. 1985) (stating that “[t]he prevailing view is that self-critical portions of affirmative action plans are privileged and not subject to discovery by plaintiffs,” but neither accepting nor rejecting privilege); *MacNamara v. City of New York*, No. 04 Civ. 9612, 2007 WL 755401, at *9, *12 (S.D.N.Y. Mar. 14, 2007) (noting the uncertain status of the self-critical analysis privilege in the Second Circuit); *Davis v. Kraft Foods N. Am.*, No. Civ. A. 03-6060, 2006 WL 237512 (E.D. Pa. Jan. 31, 2006) (citing *Armstrong v. Dwyer*, 155 F.3d 211 (3d Cir. 1998)).

There is also a split among federal courts over whether to allow the self-critical analysis privilege, which is in part based on the privilege’s case-by-case approach.

goal of improving safety at the cost of potentially increasing a plaintiff's burden.⁶⁰ These federal courts are joined by numerous state courts and legislatures recognizing the privilege.⁶¹

Through exceptions to general liability rules, such as the self-critical analysis privilege, subsequent remedial measures rule, and voluntary rescue doctrine, the tort system demonstrates a clear and consistent commitment to preventing injury and improving safety. In each of these instances, the common law has developed to find greater benefit in the public policy that supports enhanced safety than in the policy of permitting traditional tort recovery. This tort canvas draws important parallels to the discussion of respirator safety, a subject in which the public policy encouraging improved safety is at odds with traditional liability rules. As the following sections demonstrate, respirators are indispensable safety products with a uniquely troubled past and present that the tort system must seek to remedy.

Compare ASARCO, Inc., Tenn. Mines Div. v. N.L.R.B., 805 F.2d 194, 199 (6th Cir. 1986) (stating that disclosure of self-critical analysis would seriously affect the candor of future critiques and have a chilling effect that would defeat the critique's primary purpose) *with* Union Pac. R.R. v. Mower, 219 F.3d 1069 (9th Cir. 2000) (declining to apply privilege in injunction proceeding against former employee to prevent disclosure of confidential information); FTC v. TRW, Inc., 628 F.2d 207 (D.C. Cir. 1980) (rejecting privilege, but limiting the holding to documents sought by government agencies).

⁶⁰ *See, e.g.,* Reid v. Lockheed Martin Aeronautics Co., 199 F.R.D. 379 (N.D. Ga. 2001) (allowing privilege in a racial discrimination case); *In re* Crazy Eddie Sec. Litig., 792 F. Supp. 197 (E.D.N.Y. 1992) (applying privilege to audit and peer review reports in a securities law case); Bradley v. Melroe Co., 141 F.R.D. 1 (D.D.C. 1992) (recognizing privilege for statements made in a products liability accident report); Granger v. Nat'l R.R. Passenger Corp., 116 F.R.D. 507 (E.D. Pa. 1987) (recognizing privilege to prevent disclosure of portions of a railroad accident investigation report); Roberts v. Nat'l Detroit Corp., 87 F.R.D. 30 (E.D. Mich. 1980) (permitting limited privilege in equal employment opportunity cases); Lloyd v. Cessna Aircraft Co., 74 F.R.D. 518 (E.D. Tenn. 1977) (suggesting privilege might be applied to certain product safety assessments, but not under case facts); Banks v. Lockheed-Georgia Co., 53 F.R.D. 283 (N.D. Ga. 1971) (allowing privilege for records relating to an employer's equal opportunity employment program).

⁶¹ *See, e.g.,* NEB. REV. STAT. § 71-2048 (1990); WIS. STAT. ANN. § 146.38 (West 1988); *In re* Petition of Ill. Judicial Inquiry Bd., 471 N.E.2d 601 (Ill. App. Ct. 1984) (recognizing as privileged a bar association's records relating to the evaluation of judges); Estate of Hussain v. Gardner, 624 A.2d 99 (N.J. Super. Ct. Law Div. 1993) (acknowledging New Jersey's adoption of privilege). The self-critical analysis privilege has also been applied to specific industries or business practices. *See, e.g.,* N.D. CENT. CODE § 26.1-51-02 (2002).

III. Respirator Use and Regulation

A. Respirators in the Workplace

To reduce or prevent injury from exposure to virtually any hazardous airborne substance or agents, workers and the general public commonly rely on, and often are required by workplace regulations to use, respirators. Respirators are personal protective equipment (PPE) worn over the mouth, face, or head. PPE's either operate as a filter to remove dusts, gases, chemicals, or other contaminants from the air to make the air safer and more breathable, or function to supply clean respirable air from a separate source.⁶² PPE's provide a basic safety measure to prevent respiratory illness, disease, or other physical impairment, and to control the spread of infectious diseases.⁶³

It should be noted that respirators are intended to be the last, not first, line of defense against hazardous contaminants in the workplace.⁶⁴ Employers must prevent air contamination "as far as feasible by accepted engineering control measures."⁶⁵ In other words, employers must manage the work environment and provide controls to reduce harmful exposure as much as practicable. Only after feasible steps to eliminate the hazard by substitution, and following the implementation of administrative and engineering controls to reduce the hazard, should workers rely on respirators for additional protection.⁶⁶ When respirators are needed, employers must develop a protective program with worksite-specific procedures.⁶⁷ Such a program includes medical evaluations and fit testing for employees using respirators, procedures for proper use of respirators, procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators, and employee training in the hazards to which they are exposed.⁶⁸

⁶² See NIOSH Safety & Health Topic, Respirators, <http://www.cdc.gov/niosh/npptl/topics/respirators/> (last visited Sept. 30, 2009).

⁶³ See *id.*

⁶⁴ *Id.*

⁶⁵ 29 C.F.R. § 1910.134(a)(1) (2008).

⁶⁶ See *id.*

⁶⁷ *Id.* § 1910.134(c).

⁶⁸ See *id.* § 1910.134(a)(1).

Because respirators have a singular objective of air purification, their use is highly beneficial to a broad range of activities and industries. For example, respirators are used throughout the industrial workplace, particularly in the manufacturing, mining, construction and chemical industries; they are also regularly used in household activities such as painting indoors, working in the garage, or performing yard work. According to a 2002 survey conducted by the United States Department of Labor, Bureau of Labor Statistics, approximately 4.5% of private industry, and over 3.3 million American workers, use respirators in the workplace.⁶⁹ Separate from such routine respirator use is the device's necessity in times of emergency and crisis. Use and effective deployment of respirators are critical to first responders' activities, such as firefighting, rescue efforts, or providing emergency medical treatment, and to disaster relief or containment efforts, such as that resulting from an outbreak of disease, natural disaster, or terrorist act.

The multitude of potentially hazardous or infectious airborne substances to protect against, at varying levels of concentration and durations of exposure, demands a diverse array of respirator protections to effectively respond to specific hazards. As previously stated, all respirators fit within two main types: air-purifying respirators and atmosphere-supplying respirators.⁷⁰ Included in each of these types are three main classes of respirators. For air-purifying respirators, there are particulate respirators (which capture airborne particles such as dusts, fumes, paint sprays, and pesticides), gas and vapor respirators (which use chemical filters, called cartridges or canisters, to remove dangerous gases or chemical agents), and combination respirators (which include both particulate and gas and vapor filters).⁷¹ Generally speaking, these air-purifying respirators are worn over the mouth or face, as opposed to the

⁶⁹ See Press Release, U.S. Dep't of Labor, Bureau of Labor Statistics, Respirator Use and Practices (Mar. 20, 2002), available at <http://www.bls.gov/iif/oshwc/osh/os/osnr0014.txt> (last visited Sept. 30, 2009).

⁷⁰ See sources cited *supra* note 61; see also OSHA Respiratory Protection Program, Environment, Health & Safety Online, <http://www.ehso.com/RespProtectionTypes.htm> (last visited Sept. 30, 2009).

⁷¹ See OSHA Respiratory Protection Program, Environment, Health & Safety Online, <http://www.ehso.com/RespProtectionTypesAir.htm> (last visited Sept. 30, 2009); see also OSHA Quick Card Protect Yourself Respirators, Occupational Safety & Health Administration, available at http://www.osha.gov/OshDoc/data_Hurricane_Facts/respirators.pdf (last visited Sept. 30, 2009).

entire head, and represent the most common respirator products. Non-powered respirators depend solely on the inhalation and exhalation of the wearer to provide an adequate supply of purified breathing air. For example, the disposable filtering face piece respirators regularly worn in hospitals to protect against infection are N-95 respirators, a basic type of particulate respirator.⁷²

Atmosphere-supplying respirators, in comparison, typically cover the entire face or head, often as part of a hood or helmet, and include their own air supply.⁷³ The three main classes of atmosphere-supplying respirators include air-supplied respirators (which make use of a hose to deliver compressed air from a stationary source), self-contained breathing apparatus (SCBA) (which consist of a wearable clean-air supply pack), and combination respirators (which have both a hose and an auxiliary SCBA in the event the primary air supply fails).⁷⁴ Given this more complete level of protection, the use of atmosphere-supplying respirators is generally reserved for high-risk environments with elevated concentrations of hazardous airborne substances.⁷⁵

In addition to these varied types and classes of respirator products, respirators are further distinguished, in the case of air-purifying respirators, by their level of effectiveness or degree of filtration.⁷⁶ Particulate respirators are manufactured to meet one of three filtration standards such that 95%, 99%, or 99.75% of particles 0.3 microns and larger are properly filtered out.⁷⁷ For instance, the N-95 respirator, as the number indicates, is designed to filter at least 95% of these sized particles, and their

⁷² See Respirator Fact Sheet, Dep't Health & Human Servs. (NIOSH), <http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respfact.html> (last visited Sept. 30, 2009).

⁷³ OSHA Respiratory Protection Program, Environment, Health & Safety Online, <http://www.ehso.com/RespProtectionTypesSupl.htm> (last visited Sept. 30, 2009).

⁷⁴ *Id.*

⁷⁵ See 29 C.F.R. § 1910.134(d)(2) (2008) (discussing requirements for respiratory protection in atmospheres that are immediately dangerous to life or health).

⁷⁶ See OSHA Respiratory Protection Program, Environment, Health & Safety Online, <http://www.ehso.com/RespProtectionSelection.htm#exposure> (last visited Sept. 30, 2009).

⁷⁷ See NIOSH GUIDE TO THE SELECTION AND USE OF PARTICULATE RESPIRATORS CERTIFIED UNDER 42 CFR 84, DEP'T HEALTH & HUMAN SERVICES (NIOSH) Pub. No. 96-101 (Jan. 1996), *available at* <http://www.cdc.gov/niosh/userguid.html> (last visited Sept. 30, 2009).

government-mandated use in certain work environments recognizes that a small percentage of contaminants will get through. 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.⁷⁸ Here, three additional categories exist: “N” for not oil resistant, “R” for oil resistant, and “P” for oil proof.⁷⁹ Thus, the selection of the appropriate respirator for a specific activity is determined by the presence of oil particles and the concentration of airborne particles and duration of exposure, which may require greater degrees of filtration or cartridge replacement if a cartridge is needed. Where there is no appropriate air-purifying filter for a particular environment or activity, an atmosphere-supplying respirator will likely be required. Importantly, these respirator selections are not made in a vacuum. Rather, the appropriate level of filtration for the intensity and duration of an exposure to a hazardous airborne substance is the product of comprehensive scientific testing, analysis, and regulation.

This Article focuses primarily on the N-95 respirator, the most commonly used and widely available equipment to protect wearers from contaminants and diseases potentially spread through the air. N-95 respirators are commonly used at construction sites and hospitals. Health officials also recommend use of N-95 respirators as protection against airborne transmission of infectious agents, such as Measles, Severe Acute Respiratory Syndrome (SARS), Varicella (chickenpox), Mycobacterium tuberculosis, and Swine Influenza.⁸⁰ N-95 respirators may be purchased at local hardware stores and pharmacies, in addition to being mandatory protective equipment provided to workers in many occupations by their employers.

B. Federal Regulation of Respirator Safety

The federal government has closely regulated respirator safety since 1934, when the Bureau of Mines tested and approved certain protective

⁷⁸ *See id.*

⁷⁹ *Id.*

⁸⁰ *See, e.g.*, Occupational Safety & Health Admin., Guidance on Preparing Workplaces for an Influenza Pandemic, *available at* http://www.osha.gov/Publications/influenza_pandemic.html#organizations_protect (last visited Sept. 30, 2009).

devices and their labeling.⁸¹ Today, three federal agencies share primary responsibility for respirator safety. The National Institute for Occupational Safety and Health (NIOSH) is a research-centered agency that develops recommendations on workplace safety practices to prevent injury and certifies respirators as meeting certain performance standards. The successor to the United States Bureau of Mines, the Mine Safety and Health Administration (MSHA), sets mandatory, science-based and clinically-supported safety standards to “most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health” given regular exposure to coal mining hazards.⁸² The Occupational Safety and Health Administration (OSHA) regulates workplace safety through regulations that are binding on employers. The complimentary efforts of these agencies establish a rigorous regulatory approval process that provides an optimal level of workplace safety for those exposed to various dangerous contaminants.

1. The NIOSH/MSHA Certification Process

As the expert federal agency charged by Congress to “develop and establish recommended occupational safety and health standards,”⁸³ NIOSH bears responsibility for much of the public research and scientific analysis regarding the effectiveness of respirators and numerous other protective devices used in the workplace.⁸⁴ The agency, which is part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services, commands a staff of over 1400 individuals to accomplish this basic purpose, and employs a wide range of disciplines to do so, including epidemiology, medicine, industrial hygiene, safety, psychology, engineering, chemistry, and statistics.⁸⁵ In addition to developing recommended safety standards, NIOSH helps to

⁸¹ See U.S. Bureau of Mines, Schedule 21, Procedure for Testing Filter-type Dust, Fume, and Mist Respirators for Permissibility (Aug. 20, 1934).

⁸² 30 U.S.C. § 811(a)(6)(A) (2000).

⁸³ 29 U.S.C. § 671 (2000).

⁸⁴ See About NIOSH, Centers for Disease Control: National Institute for Occupational Health and Safety, <http://www.cdc.gov/niosh/about.html> (last visited Sept. 30, 2009).

⁸⁵ See *id.*

assure safe working conditions by providing “research, information, education, and training in the field of occupational safety and health.”⁸⁶ NIOSH, therefore, works directly with workers and employers, in addition to an extensive grouping of scientists and experts, and incorporates each of these groups’ input into the development of its recommended standards.

NIOSH has operated a respirator research, testing, and certification program since the 1970s, taking on the function previously under the jurisdiction of the United States Bureau of Mines.⁸⁷ Under the authorization of the Federal Mine Safety and Health Act of 1977 and the Occupational Safety and Health Act of 1970, NIOSH provides an approval process for both respirators and industrial hazard measuring instruments.⁸⁸ All applications are jointly reviewed and the certifications issued by both NIOSH and the MSHA.⁸⁹ This joint program independently tests and certifies three classes of filters (N-, R-, and P- series) and three levels of efficiency (95, 99, and 100), which account for varying occupational conditions and potential exposure to different types of contaminants.⁹⁰ NIOSH’s certification program also closely considers 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.⁹¹ An application for NIOSH certification must include NIOSH tests and satisfaction of all regulatory perfor-

⁸⁶ *Id.* In addition to NIOSH’s six offices located across the United States, it maintains sixteen regional Education and Research Centers and thirty-five Training Project Grants. *See id.*

⁸⁷ The initial testing criteria was codified at 30 C.F.R. part 14 and amended on April 19, 1955. The requirements for investigation, testing, and certification of respirators were subsequently expanded January 19, 1965, and amended March 23, 1965 and June 19, 1969, respectively.

⁸⁸ 42 C.F.R. § 84 (2008).

⁸⁹ *Id.* § 84.3(a)(1)-(2).

⁹⁰ *Id.* § 84.170 (b)-(c).

⁹¹ *Id.* §§ 84.11, 84.41, 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 (July 2005), *available at* <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPJul2005.pdf> (last visited Sept. 30, 2009) [hereinafter NIOSH Application] (detailing the approval process and application requirements).

mance requirements.⁹² 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.⁹³ NIOSH even reviews and certifies the manufacturer's quality assurance plan.⁹⁴

NIOSH regulations are highly specific with respect to the information and warnings imparted to potential users through the product's labeling. 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."⁹⁵ NIOSH maintains responsibility for notifying the manufacturer "when additional labels, markings, or instructions will be required."⁹⁶

NIOSH carefully reviews all of the information submitted by the applicant in exercising its statutorily authorized judgment as to whether the respirator meets regulatory safety standards. It specifically approves engineering specifications, drawings, test reports, quality assurance and control documents, respirator markings, instruction manuals, packaging, and labeling.⁹⁷ In fact, the certificate of approval is accompanied by a reproduction of the approved label design.⁹⁸ A manufacturer may not modify any of these elements without prior NIOSH approval,⁹⁹ a fact that is noted explicitly in each approval letter. A respirator manufacturer that deviates from conditions of certification may be subject to rescission of its NIOSH certificates.¹⁰⁰

Post-approval, NIOSH conducts manufacturing site visits and inspections, respirator audits (re-inspections and re-tests), and compliance investigations.¹⁰¹ NIOSH investigates complaints of non-conformance,

⁹² 42 C.F.R. § 84.11; *see also* 42 C.F.R. pt. 84 (2008) (defining more than one hundred tests).

⁹³ *See* NIOSH Application, *supra* note 91, at 21-22, 37-38.

⁹⁴ *See* 42 C.F.R. § 84.42 (2008).

⁹⁵ *Id.* § 84.33(b).

⁹⁶ *Id.* § 84.33(c).

⁹⁷ *Id.* §§ 84.3, 84.31, 84.33, 84.42.

⁹⁸ *Id.* § 84.31(d).

⁹⁹ *Id.* § 84.35.

¹⁰⁰ *See id.* § 84.34.

¹⁰¹ *See id.* § 85a.3(a).

such as “misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval,”¹⁰² and conducts injury and fatality investigations. NIOSH notifies manufacturers of any non-compliance found and may require corrective actions, such as retrofit and user notification, or revocation of approval.¹⁰³ NIOSH occasionally adds requirements to assure the quality, effectiveness, and safety of approved respirators, address emerging hazards, address new technologies, permit new classes of respirators (CBRN), or update regulations or standards. When NIOSH finds that the manufacturer provided false or material misinformation during the certification process, it withdraws its approval and issues a public notice informing users that it may no longer be used where regulations require a NIOSH-approved respirator.¹⁰⁴

To help meet the increasingly complex occupational safety and health challenges of the twenty-first century, and in the wake of the September 11, 2001 terrorist attacks, NIOSH, in 2001, established the National Personal Protective Technology Laboratory (NPPTL), which is charged with ensuring the development, certification, deployment, and use of personal protective equipment.¹⁰⁵ NPPTL now directs and carries out

¹⁰² *Id.* § 84.43(c).

¹⁰³ *See id.* § 84.34; *see also id.* § 85a.8.

¹⁰⁴ *See, e.g.,* U.S. Department of Health & Human Services., Centers for Disease Control & Prevention, National Institute for Occupational Safety and Health, Respirator User Notice (June 30, 2006), *available at* <http://www.cdc.gov/Niosh/npptl/usernotices/pdfs/CRICertVoid-062306correction1.pdf> (last visited Sept. 30, 2009) (This notice informed users that NIOSH revoked certificates of approval for Crews, Inc., Models RPN951 and RPN952 Filtering Facepiece Respirators due to “false and material misstatements in the applications submitted to NIOSH for the approval of these respirators” and that these models “should not be used in workplaces requiring a NIOSH approved or NIOSH certified respirator. Respirators bearing these approval numbers may no longer be manufactured, assembled, sold, or distributed.”).

¹⁰⁵ *See* About NPPTL, Centers for Disease Control: National Institute for Occupational Health and Safety, <http://www.cdc.gov/niosh/npptl/about.html> (last visited Sept. 30, 2009). The critical need for reliable personal protective equipment became evident in the aftermath of the terrorist events of September 11, 2001. Congress outlined the need for this new division:

It has been brought to the Committee’s attention the need for design, testing and state-of-the-art equipment for this nation’s . . . miners, firefighters, healthcare, agricultural and industrial workers. . . . [Also] the Committee encourages NIOSH

NIOSH's respirator certification program and related laboratory, field, quality, and records activities.¹⁰⁶ NPPTL builds on that program to test and approve respirators for use by first responders against Chemical, Biological, Radiological, and Nuclear (CBRN) agent inhalation hazards.¹⁰⁷ NPPTL also expands on NIOSH's extensive research on personal protective equipment performance, conducts work site surveillance of hazards, and helps to manage the integrity of the national inventory of respirators for emergency responders and other worker groups.¹⁰⁸

The wealth of expertise and breadth of activities undertaken by NIOSH, and NPPTL in particular, demonstrate a highly successful product safety program for respirators, and a model for other regulatory entities. However, while NIOSH's expert certification is required for all respirators, its recommendations and safety standards lack binding authority and, standing alone, have no legal effect.¹⁰⁹ Rather, a distinction exists between the agency and OSHA/MSHA such that NIOSH represents the research and technical expertise behind the regulatory scheme, while OSHA and MSHA wield the rulemaking authority and enforcement muscle.

to carry out research, testing and related activities aimed at protecting workers who respond to public health needs in the event of a terrorist incident. The Committee encourages CDC to organize and implement a national personal protective equipment laboratory.

S. REP. NO. 106-293 (1999).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* NIOSH, along with the United States Army Soldier Biological and Chemical Command (SBCCOM), and the National Institute for Standards and Technology (NIST) are working to develop appropriate standards and test procedures for all classes of respirators that will provide respiratory protection from CBRN agents. CBRN Respirator Standards Development, Centers for Disease Control: National Institute for Occupational Health and Safety, <http://www.cdc.gov/niosh/npptl/standardsdev/cbrn/default.html> (last visited Sept. 30, 2009).

¹⁰⁸ *See* About NPPTL, Centers for Disease Control: National Institute for Occupational Health and Safety, <http://www.cdc.gov/niosh/npptl/about.html> (last visited Sept. 30, 2009).

¹⁰⁹ *See* 29 U.S.C. § 671 (2000) (establishing NIOSH's purpose as "to develop and establish *recommended* occupational safety and health standards" and provide research, information, education and training) (emphasis added).

2. OSHA's Workplace Safety Requirements Mandating Use of Proper Respiratory Safety Equipment

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.¹¹⁰ OSHA, which is an entity of the Department of Labor, has the authority to promulgate binding occupational safety and health standards as the federal agency primarily responsible for workplace health and safety.¹¹¹ The agency exercises this authority over a broad range of workplace safety products and environmental conditions, such as those related to hazardous material use,¹¹² fire protection,¹¹³ welding and cutting,¹¹⁴ and medical and first aid.¹¹⁵ OSHA regulations not only set safety standards in these areas, but also require employers to establish a comprehensive protection program that monitors, responds to, and prevents potential hazards.¹¹⁶ Together, these safety regulations make for an extensive body of controlling law.

Subpart I of OSHA's standards governs types of personal protective equipment, including respirators.¹¹⁷ OSHA regulations require employers to provide their employees with respirators "which are applicable and suitable for the purpose intended."¹¹⁸ To define appropriate respirator use, OSHA mandates the use of NIOSH-certified respirators¹¹⁹ and further mandates that employers provide their employees with specific types of NIOSH-certified respirators when they are exposed to certain contami-

¹¹⁰ 29 U.S.C. § 654(a) (2000).

¹¹¹ 42 U.S.C. §§ 655, 659 (2000).

¹¹² See 29 C.F.R. §§ 1910.101–.126 (2008).

¹¹³ See *id.* §§ 1910.155–.165.

¹¹⁴ See *id.* §§ 1910.251–.255.

¹¹⁵ See *id.* § 1910.151.

¹¹⁶ See, e.g., *id.* § 1910.134(c) (requiring a respirator protection program).

¹¹⁷ See *id.* §§ 1910.132–.138.

¹¹⁸ *Id.* § 1910.134(a)(2). *But see id.* § 1910.1000(e) (showing that the Occupational Safety and Health Act (OSH Act) generally states that engineering controls should provide the foremost level of protection).

¹¹⁹ See *id.* § 1910.134(d)(1)(ii).

nants.¹²⁰ For example, OSHA provides that, with regard to asbestos, “[e]ach person entering a regulated area shall be supplied with and required to use a respirator,” and that the respirator must be a “tight-fitting, powered air-purifying respirator.”¹²¹ This specific class of respirator product is further refined based upon the varying intensity and duration of exposure to asbestos. Specifications for minimum acceptable respiratory protection are provided in a table included in the regulation.¹²² 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.¹²³ The respirator standards are individually tailored to each of a laundry list of airborne contaminants,¹²⁴ yet are flexible enough that the general regulations still adequately safeguard workers.¹²⁵

In addition to promulgating detailed standards for respirator safety, OSHA is principally responsible for their enforcement.¹²⁶ Generally,

¹²⁰ See, e.g., *id.* § 1910.1001(g)(2)(ii).

¹²¹ *Id.* §§ 1910.1001(e)(4), (g)(2)(ii).

¹²² See 29 C.F.R. § 1910.134 tbl. 1.

¹²³ 29 C.F.R. § 1910.134(d).

¹²⁴ See, e.g., *id.* §§ 1910.1003(d)(1) (carcinogens); 1910.1017(f), (g), (h) (vinyl chloride); 1910.1018(f)(4), (h) (inorganic arsenic); 1910.1025(f) (lead aerosols); 1910.1027(g) (cadmium); 1910.1028(g) (benzene); 1910.1029(g) (coke oven emissions); 1910.1043(f) (cotton dust); 1910.1044(h) (DBCP); 1910.1045(h) (acrylonitrile); 1910.1047(g) (airborne ethylene oxide); 1910.1048(g) (formaldehyde); 1910.1050(h) (methylenedianiline); 1910.1051(h) (airborne butadiene); 1910.1052(g) (methylene chloride).

¹²⁵ 29 C.F.R. § 1910.1000(e) provides generally that “whenever respirators are used, their use shall comply with 1910.134.” Air contaminants regulated by § 1910.1000 include mineral dusts, such as silica. While there is no specific regulation providing respirator standards for exposure to silica, employers must abide by the general requirements of § 1910.134. According to an OSHA opinion letter, “The minimum respiratory protection for a worker who is working with crystalline silica dust, but is not doing abrasive-blasting, may be an N95 NIOSH-approved respirator. However, the exposure to crystalline silica must not exceed the assigned protection factor of the respirator.” See Letter from Richard E. Fairfax, Director, Directorate of Compliance Programs to Mr. David Koch, Senior Technical Service Specialist, Dalloz Safety (May 12, 1999), available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22737 (last visited Sept. 30, 2009).

¹²⁶ See OSHA’s Role, U.S. Dep’t of Labor, Occupational Safety & Health Admin., <http://www.osha.gov/oshinfo/mission.html> (last visited Sept. 30, 2009).

OSHA accomplishes this considerable task through inspections of workplace conditions and by responding to workplace complaints. To this end, the agency and its state partners employ approximately 2100 inspectors, in addition to complaint discrimination investigators, engineers, physicians, educators, standards writers, and other technical and support personnel spread over more than two hundred offices in the United States.¹²⁷

3. MSHA's Regulations Mandate the Highest Degree of Health and Safety Protection for Miners

While OSHA regulates respiratory protection in most workplaces, the MSHA focuses specifically on worker safety in mines. Since 1910, Congress charged MSHA, then the United States Bureau of Mines, with “conduct[ing] inquiries and scientific and technologic investigations concerning mining, and the preparation, treatment, and utilization of mineral substances with a view to improving health conditions and increasing safety.”¹²⁸ In 1969, Congress passed the Federal Coal Mine Health and Safety Act “to establish interim mandatory health and safety standards.”¹²⁹ Relevant provisions were reenacted in the Federal Mine Safety and Health Act of 1977.¹³⁰ Congress intended this law to serve as part of a comprehensive regulatory scheme for expanding research and development aimed at preventing mine accidents and occupationally-caused diseases.¹³¹

To achieve the Act's goals, Congress directed the MSHA to “set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.”¹³² Congress charged the MSHA with “attainment of the highest degree of health and safety protection for the miner” through issuance of mandatory

¹²⁷ *Id.*

¹²⁸ 30 U.S.C. § 3 (2000).

¹²⁹ *Id.* § 801(g).

¹³⁰ *See id.* §§ 801-962.

¹³¹ *Id.* § 801(g).

¹³² *Id.* § 811(a)(6)(A).

health and safety standards.¹³³ Specifically, Congress authorized MSHA to protect miners by regulating limits for dust concentrations, establishing sampling procedures, conducting inspections, requiring medical examinations for coal miners, implementing engineering controls to limit rock dust, setting noise standards, enforcing safe roof control, and explosive use and methane gas measures.¹³⁴ Congress also authorized MSHA to regulate the critical element of respirator protection, which required mine operators to make approved respiratory protection available to miners exposed to concentrations above the limits established by the Act.¹³⁵ MSHA's regulations, in turn, provide that mine operators may only provide respirators certified by NIOSH as safe and effective for mine workers.¹³⁶

In 1995, MSHA's specific testing and certification procedures, and performance standards specific to exposure to contaminants in mines,¹³⁷ were replaced and incorporated into NIOSH's process.¹³⁸ MSHA and NIOSH now operate under a Memorandum of Understanding through which NIOSH has the lead role in respirator certification; but, MSHA and NIOSH jointly review and approve respirators used for mine emergencies and mine rescue, as well as user's manuals and other documentation, because of MSHA's "expertise in identifying the special needs and considerations for respirators used in the mining environment."¹³⁹ MSHA also continues to test and approve electrical and electronic components of respirators for use in potentially explosive atmospheres, and it has primary responsibility for investigating complaints and potential deficiencies of approved respirators used in mines.¹⁴⁰

¹³³ *Id.*

¹³⁴ *See id.* §§ 842, 843, 844, 846, 861.

¹³⁵ *Id.* § 842(h).

¹³⁶ 30 C.F.R. § 70.300 (2008).

¹³⁷ MSHA's performance standards with respect to mines, application procedures, and the design, labeling, markings, etc., were previously contained in 30 C.F.R. § 11 (2000).

¹³⁸ *See* Respirator Protective Devices, 60 Fed. Reg. 30,336, 30,338-39, 30,343, 30,349-51 (June 8, 1995).

¹³⁹ *See id.* at 30,339, 30,343; *see also* 42 C.F.R. § 84.3 (2008) (providing for joint certification).

¹⁴⁰ *See* Respirator Protective Devices, 60 Fed. Reg. 30,336, 30,338-39, 30,343, 30,349-51 (June 8, 1995).

C. Impact of the Regulatory Scheme

Overall, the joint efforts of multiple federal agencies in regulating and certifying respirators establish a product safety system that provides an optimal level of workplace protection.¹⁴¹ This process 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.¹⁴²

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

¹⁴¹ OSHA regulations require employers to provide appropriate personal protective equipment, including “face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices” that “does not permit blood or other potentially infectious materials to pass through to or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.” 29 C.F.R. § 1910.1030 (2008). The United States Food & Drug Administration (FDA) plays a role in the regulation respirators by approving surgical N95 respirators as medical devices for use in healthcare settings, primarily under Section 510k of the Medical Device Amendments of 1976, 21 U.S.C. § 360k(a) (2000). Surgical N95 respirators cover the mouth and nose during medical procedures and help protect the caregiver and patient against microorganisms, body fluids, and small particles in the air. The FDA’s Center for Devices and Radiological Health evaluates the performance of these devices in areas including fluid resistance and filtration efficiency to ensure that they are at least as safe and effective as similar devices already on the market. In addition, the FDA approved for marketing the first respirators for use in protecting against public health medical emergencies, such as an influenza pandemic in 2007. See Press Release, U.S. Food & Drug Admin., FDA Clears First Respirators for Use in Public Health Medical Emergencies (May 8, 2007), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108911.htm> (last visited Sept. 30, 2009).

¹⁴² See Respirator Protective Devices, 60 Fed. Reg. 30,336, 30,352 (June 8, 1995).

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 to not regularly wear them, even if required by their employer to do so, exposing them to even greater harm. One can envision a factory filled with workers wearing masks up on their foreheads. Such regulations might do more harm than good. For this reason, NIOSH has “maintained the breathing resistance at a level that still will minimize adverse impacts on the respirator user.”¹⁴³ Likewise, NIOSH approves respirator labeling that most effectively communicates instructions and warnings to workers.¹⁴⁴ Moreover, 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.¹⁴⁵ It is against this backdrop of a comprehensive, balanced, and longstanding regulatory and certification system that the recent spike in litigation alleging design and warning defects of respirator products raises serious concern and represents an area in which the tort system should respond.

IV. The Landscape of Respirator Litigation

A. The “Endless Search for the Solvent Bystander” Ensnarls Respirator Makers

Understanding the development of litigation involving respirators is aided by a working knowledge of the underlying litigation of the hazardous substances that the safety device protects against. Claims against respirator manufacturers have tracked two mass tort litigations: asbestos and silica sand.¹⁴⁶ In many respects, respirator lawsuits represent the

¹⁴³ *Id.*

¹⁴⁴ *Id.* at 30,345.

¹⁴⁵ *See, e.g., id.* at 30,337-49 (summarizing and responding to numerous comments).

¹⁴⁶ Silica is present in sand, gravel, soil, and rocks. In its natural form, silica is not harmful, but when fragmented into tiny particles (such as through abrasive blasting, in foundry operations, or through road construction and repair, and other construction activities), silica can be dangerous if inhaled. *See* U.S. Dep’t of the Interior & U.S.

byproduct of excesses and abuses in these mass tort litigations. First, plaintiffs sued the wrongdoers, those who produced asbestos products. After the primary defendants declared bankruptcy, litigation surged against “peripheral defendants,” those that have a connection to asbestos, such as premises owners; equipment manufacturers whose products incorporated some asbestos; brake, gasket, and sealant manufacturers; and general construction contractors. Silica litigation also suddenly increased.¹⁴⁷ Increasingly in recent years, the protectors, those who manufactured respirators, are named among the laundry list of defendants in a quest for the solvent bystander. This has significant public policy implications.

1. Overview of the Asbestos and Silica Litigation Environment

Courts and commentators have recognized since the early 1990s the extraordinary problems created by the “elephantine mass of asbestos cases.”¹⁴⁸ Many of these problems stem from the lack of reasonable

Bureau of Mines, Crystalline Silica Primer, Special Publication 2, 5-6 (1992), available at <http://minerals.usgs.gov/minerals/pubs/commodity/silica/780292.pdf> (last visited Sept. 30, 2009); see also Victor Schwartz & Christopher Appel, *Effective Communication of Warnings in the Workplace: Avoiding Injuries in Working with Industrial Materials*, 73 MO. L. REV. 1, 28-29 (2008).

¹⁴⁷ See Mark A. Behrens et al., *Silica: An Overview of Exposure and Litigation in the United States*, 20:2 MEALEY’S LITIG. REP.: ASBESTOS 33 (Feb. 21, 2005); see also Jonathan D. Glater, *Suits on Silica Being Compared to Asbestos Cases*, N.Y. TIMES, Sept. 6, 2003, at C1, available at 2003 WLNR 5662921; Susanne Sclafane, *Silica Dust: The Next Asbestos? Hard Hat Maker With Former RIMS President Among 160 Defendants Facing Dust Claims*, NAT’L UNDERWRITER PROP. & CAS.-RISK & BEN. MGMT., May 10, 2004, at 10, available at 2004 WLNR 14746125 (reporting that E.D. Bullard Co., the inventor of the hard hat, faced a “surge” of silica claims in 2003, from 62 cases filed by roughly 200 plaintiffs in 1999 to 156 cases filed by 4305 plaintiffs in 2002 to 643 cases filed by 17,288 plaintiffs in 2003); Bob Sherwood, *Weighing the Risk From Food and Phones*, FIN. TIMES, Apr. 27, 2003, at 12 (“Silicosis claims are climbing at such a rate that one company has 17,000 suits against it—and it just makes masks designed to protect people from silica dust.”); Susan Warren, *Silicosis Suits Rise Like Dust*, WALL ST. J., Sept. 4, 2003, at B5, abstract available at 2003 WLNR 3129046.

¹⁴⁸ *Norfolk & W. Ry. v. Ayers*, 538 U.S. 135, 166 (2003) (quoting *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 821 (1999)); see also *In re Combustion Eng’g, Inc.*, 391 F.3d 190, 200 (3d Cir. 2005) (“For decades, the state and federal judicial systems have struggled with an avalanche of asbestos lawsuits.”); Mark A. Behrens, *Some Proposals for Courts Interested in Helping Sick Claimants and Solving Serious Problems in*

controls and guidance by courts that have permitted an influx of inappropriate claims. For example, studies have shown that the vast majority of recent asbestos claimants—up to ninety percent—are not sick.¹⁴⁹ Rather, they are “people who have been exposed to asbestos, and who (usually) have some marker of exposure such as changes in the pleural membrane covering the lungs, but who are not impaired by an asbestos-related disease and likely never will be.”¹⁵⁰ They are part of a massive plaintiff recruitment effort orchestrated by plaintiffs’ lawyers and their agents and conducted through highly suspect X-ray medical screenings.¹⁵¹ These screenings, frequently conducted in areas with high concentrations of workers who may have worked in jobs where they were exposed to asbestos¹⁵² and often performed when there is no medical purpose or physician follow up, have “driven the flow of new asbestos claims by healthy plaintiffs.”¹⁵³ Further, many of the X-ray interpreters hired by plaintiffs’ lawyers are “so biased that their readings [are] simply unreliable.”¹⁵⁴ The combined effect has created and perpetuated what the

Asbestos Litigation, 54 BAYLOR L. REV. 331 (2002); Paul F. Rothstein, *What Courts Can Do in the Face of the Never-Ending Asbestos Crisis*, 71 MISS. L.J. 1 (2001).

¹⁴⁹ See, e.g., Stephen J. Carroll et al., *Asbestos Litigation* 76 (RAND Inst. for Civil Justice 2005), available at http://www.rand.org/pubs/monographs/2005/RAND_MG162.sum.pdf (last visited Sept. 30, 2009) [hereinafter RAND Report].

¹⁵⁰ *The Fairness in Asbestos Compensation Act of 1999: Hearing on H.R. 1283 Before the H. Comm. on the Judiciary*, 106th Cong. 5 (July 1, 1999) (statement of Christopher Edley, Jr., Professor, Harvard Law School).

¹⁵¹ See John M. Wylie, II, *The \$40 Billion Scam*, READER’S DIG., Jan. 2007, at 74.

¹⁵² See *Owens Corning v. Credit Suisse First Boston*, 322 B.R. 719, 723 (D. Del. 2005) (“Labor unions, attorneys, and other persons with suspect motives [have] caused large numbers of people to undergo X-ray examinations (at no cost), thus triggering thousands of claims by persons who had never experienced adverse symptoms.”). It is estimated that over one million workers have undergone attorney-sponsored screenings. See Lester Brickman, *On the Theory Class’s Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality*, 31 PEPP. L. REV. 33, 69 (2003); see also Lester Brickman, *Ethical Issues in Asbestos Litigation*, 33 HOFSTRA L. REV. 833 (2005).

¹⁵³ Hon. Griffin B. Bell, *Asbestos & The Sleeping Constitution*, 31 PEPP. L. REV. 1, 5 (2003); see also Pamela Sherrid, *Looking for Some Million Dollar Lungs*, U.S. NEWS & WORLD REP., Dec. 17, 2001, at 36, available at 2001 WLNR 7718069.

¹⁵⁴ *Owens Corning*, 322 B.R. at 723; see also AMERICAN BAR ASSOC. COMM’N ON ASBESTOS LITIG., REPORT TO THE HOUSE OF DELEGATES (2003), available at http://www.abanet.org/leadership/full_report.pdf (last visited Sept. 30, 2009) (litigation screening companies find x-ray evidence that is “consistent with” asbestos exposure

Supreme Court has referred to as a litigation “crisis,”¹⁵⁵ and enabled an unwieldy and unjustified pool of claimants to recover from a comparatively small pool of bona fide defendants.

Escalating asbestos liabilities, fueled by questionable claims, have pushed companies into bankruptcy.¹⁵⁶ In 2005, the RAND Institute for Civil Justice found: “Following 1976, the year of the first bankruptcy attributed to asbestos litigation, 19 bankruptcies were filed in the 1980s and 17 in the 1990s. Between 2000 and mid-2004, there were 36 bankruptcy filings, more than in either of the prior two decades.”¹⁵⁷ Asbestos litigation has forced an estimated eighty-five employers into bankruptcy¹⁵⁸ “including nearly all major manufacturers of asbestos-containing products.”¹⁵⁹

As a result of these and other bankruptcies, “the net has spread from the asbestos makers to companies far removed from the scene of any putative wrongdoing.”¹⁶⁰ Over 8500 defendants have been named in

at a “startlingly high” rate, often exceeding 50% and sometimes reaching 90%). One of the earliest detailed reviews of X-ray readers in litigation arose out of information distributed to tire workers, which said that 94% of the workers screened at one location and 64% at another were found to have asbestosis. *See* *Raymark Indus. v. Stemple*, No. 88-1014-K, 1990 WL 72588 (D. Kan. May 30, 1990). In 1986, NIOSH found that only 0.2% of the workers they evaluated had physical changes consistent with asbestosis. *See* J. Jankovic & R.B. Reger, *Health Hazard Evaluation Report*, NIOSH Rep. No. HETA 87-017-1949 (1989). In 1998, an audit by the Manville Settlement Trust determined that 59% of X-ray readings relied upon by plaintiffs’ counsel to show asbestos-related abnormalities were inaccurate. *See In re* Joint E. & S. Dists. Asbestos Litig., 237 F. Supp. 2d 297, 309 (E.D.N.Y. & S.D.N.Y. 2002). Another review conducted by medical experts appointed by an Ohio federal judge found that 65% of the claimants reviewed had no asbestos-related conditions and 20% presented only pleural plaques. *See* Hon. Carl Rubin & Laura Ringenbach, *The Use of Court Experts in Asbestos Litigation*, 137 F.R.D. 35, 37-39 (1991).

¹⁵⁵ *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 597 (1997).

¹⁵⁶ *See, e.g., In re Combustion Eng’g, Inc.*, 391 F.3d 190, 201 (3d Cir. 2005).

¹⁵⁷ RAND Report, *supra* note 145, at xxvii, available at http://www.rand.org/pubs/monographs/2005/RAND_MG162.sum.pdf.

¹⁵⁸ *See* Martha Neil, *Backing Away from the Abyss*, 92-Sep A.B.A. J. 26, 29 (2006).

¹⁵⁹ *See* American Academy of Actuaries’ Mass Torts Subcommittee, *Overview of Asbestos Claims and Trends* 5 (Aug. 2007), available at http://www.actuary.org/pdf/casualty/asbestos_aug07.pdf (last visited Sept. 30, 2009).

¹⁶⁰ Editorial, *Lawyers Torch the Economy*, WALL ST. J., Apr. 6, 2001, at A14, abstract available at 2001 WLNR 1993314; *see also* Steven B. Hantler et al., *Is the Crisis in the Civil Justice System Real or Imagined?*, 38 LOY. L.A.L. REV. 1121, 1151-52 (2005) (discussing spread of asbestos litigation to “peripheral defendants”).

asbestos litigation.¹⁶¹ The Congressional Budget Office, for instance, observed that asbestos suits have expanded “from the original manufacturers of asbestos-related products to include customers who may have used those products in their facilities.”¹⁶² One well-known plaintiffs’ attorney has described the litigation as an “endless search for a solvent bystander.”¹⁶³ There are now more than 8500 defendants “ensnarled in the litigation,”¹⁶⁴ with nontraditional defendants accounting for more than half of asbestos expenditures.¹⁶⁵

As the well for asbestos recovery dried up and momentum grew for a federal trust fund that would have virtually eliminated asbestos litigation and replaced it with an administrative compensation system, plaintiffs’ lawyers turned their sights to a new pool of solvent defendants, those with a connection to silica, the industrial sand that may be released in abrasive blasting, in foundry operations, or through road construction and repair, and other construction activities.¹⁶⁶ For years, the total litigation against industrial sand manufacturers and other industrial mineral companies, respirator makers, and related safety equipment manufacturers concerning silica exposure was stable with relatively few people pursuing silica claims each year.¹⁶⁷ Although greater workplace safety

¹⁶¹ See Deborah R. Hensler, *California Asbestos Litigation—The Big Picture*, HARRISMARTIN COLUMNS: ASBESTOS, Aug. 2004, at 5.

¹⁶² CONGRESSIONAL BUDGET OFFICE, THE ECONOMICS OF U.S. TORT LIABILITY: A PRIMER 8 (Oct. 2003), available at <http://www.cbo.gov/ftpdocs/46xx/doc4641/10-22-TortReform-Study.pdf> (last visited Sept. 30, 2009).

¹⁶³ ‘Medical Monitoring and Asbestos Litigation’—A Discussion with Richard Scruggs and Victor Schwartz, 17:3 MEALEY’S LITIG. REP.: ASBESTOS 5 (Mar. 1, 2002) (quoting Mr. Scruggs).

¹⁶⁴ *In re Joint E. & S. Dists. Asbestos Litig.*, 129 B.R. 710, 747-48 (E.D.N.Y. & S.D.N.Y. 1991), vacated, 982 F.2d 721 (2d Cir. 1992); Deborah R. Hensler, *California Asbestos Litigation—The Big Picture*, HARRISMARTIN COLUMNS:, Aug. 2004, at 5.

¹⁶⁵ See RAND Report, *supra* note 145, at 94.

¹⁶⁶ Between 2003 and 2006, Congress considered the Fairness in Asbestos Injury Resolution Act (FAIR Act). In April 2004, the bill gained significant momentum in the Senate, receiving fifty votes, but not enough to invoke cloture. S. 2290, 108th Cong., 2d Sess., Vote No. 69, Apr. 22, 2004, available at <http://www.govtrack.us/congress/bill.xpd?bill=s108-2290> (last visited Sept. 30, 2009). After the failed cloture vote, meetings between Senate staff and stakeholders, hearings, and amendments continued in earnest, see S. REP. NO. 109-97, at 5-12 (2005), available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_reports&docid=f:sr097.pdf (last visited Sept. 30, 2009), providing optimism for the bill.

¹⁶⁷ Mark A. Behrens et al., Commentary, *Silica: An Overview of Exposure and Litigation in the United States*, 20-2 MEALEY’S LITIG. REP.: ASBESTOS 4 (Feb. 21, 2005).

measures, which include use of respirators, resulted in a dramatic decline in silica-related harms over many decades,¹⁶⁸ there was a significant increase in the number of lawsuits arising out of the use of industrial sand between 1999 and 2004, reaching its highest point in 2003.¹⁶⁹ Some companies reported a tenfold increase in the number of claims during this period.¹⁷⁰

¹⁶⁸ According the CDC, from 1968 to 2002, the number of silicosis deaths decreased from 1,157 to 148, a 93% decline in the overall mortality rate. Dep't of Health & Human Servs., Centers for Disease Control & Prevention, Nat'l Institute for Occupational Safety & Health, *Silicosis Mortality, Prevention, and Control—United States, 1968-2002* (Apr. 29, 2005), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5416a2.htm> (last visited Sept. 30, 2009); see also Dep't of Health & Human Servs., Centers for Disease Control & Prevention, Nat'l Institute for Occupational Safety & Health, *Worker Health Chartbook*, 2004 169 (Pub. No. 2004-146, Sept. 2004), available at <http://www.cdc.gov/niosh/docs/2004-146/> (last visited Sept. 30, 2009); Dep't of Health & Human Servs., Centers for Disease Control & Prevention, *Silicosis Mortality, Prevention, and Control—United States, 1968-2002*, MMWR Wkly., Apr. 29, 2005, at 1, printed in 29:21 J.A.M.A. 2585 (June 1, 2005), available at <http://jama.ama-assn.org/cgi/content/full/293/21/2585> (last visited Sept. 30, 2009). Another study by federal Occupational Safety & Health Administration staff found that “a downward trend in the airborne silica exposure levels was observed during 1988-2003.” A.S. Yassin et al., *Occupational Exposure to Crystalline Silica Dust in the United States, 1988-2003*, 113 ENV'T'L HEALTH PERSPECTIVES 3255, 3255 (Mar. 1, 2005), available at <http://www.ehponline.org/members/2004/7384/7384.html> (last visited Sept. 30, 2009); see also Joe Walker, *Silicosis Fraud*, PADUCAH SUN (Ky.) (Aug. 6, 2006), available at 2006 WLNR 13624456 (“Modern industrial practices had led to a steady decline in silicosis for decades . . .”).

¹⁶⁹ See Mark A. Behrens et al., Commentary, *Silica: An Overview of Exposure and Litigation in the United States*, 20-2 MEALEY'S LITIG. REP.: ASBESTOS 33 (Feb. 21, 2005); see also Kelly Barron, *Bonanza or Boondoggle? Plaintiffs' Lawyers Hope Silica Dust Could Be the Next Asbestos*, CRAIN'S CHI. BUS., Feb. 28, 2005, at 35, available at 2005 WLNR 3322581 (explaining that the inhalation of silica dust particles has led to explosive silica litigation and approximately 17,000 silica suits were filed in the first half of 2003); Jonathan D. Glater, *Suits on Silica Being Compared to Asbestos Cases*, N.Y. TIMES, Sept. 6, 2003, at C1, available at 2003 WLNR 5662921 (reporting that the recent increase in the number of silica related lawsuits has begun to cause concern among insurance companies); Nathan A. Schachtman, *Silica Litigation: Screening, Scheming & Suing* (Wash. Legal Found., Critical Legal Issues, Working Paper No. 135, Dec. 2005), available at <http://www.wlf.org/upload/1205WPSchachtman.pdf> (last visited Sept. 30, 2009).

¹⁷⁰ See Behrens et al., *supra* note 163; see also Susan Warren, *Silicosis Suits Rise Like Dust/Lawyers in Asbestos Cases Target Many of the Same Companies*, WALL ST. J., Sept. 4, 2003, at B5, available at <http://www.tortreform.com/node/117> (asserting that insurance companies are beginning to see large increases in the number of silica claims) (last visited Sept. 30, 2009).

Tellingly, the same lawyers and law firms who for years specialized in asbestos cases filed many of these silica suits.¹⁷¹ The same tactics these lawyers used to generate asbestos claims were applied, such as plaintiff recruitment through direct mailings and internet advertising, free mass screenings, and mobile X-ray vans.¹⁷² Some lawyers even filed asbestos “re-tread” cases, bringing silica lawsuits on behalf of people who have already received an asbestos-related recovery.¹⁷³ As the *National Law Journal* reported, “[o]ne of the most explosive revelations that has emerged from the [federal court silica litigation] is that at least half of the approximately 10,000 plaintiffs . . . had previously filed asbestos claims.”¹⁷⁴ “Suffering from both asbestosis and silicosis is, statistically speaking, nearly impossible.”¹⁷⁵

In a watershed event in June 2005, the manager of the federal court silica docket, United States District Court Judge Janis Graham Jack of the Southern District of Texas, issued a scathing opinion in which she recommended that all but one of the 10,000 federal court silica claims should be dismissed because the diagnoses were fraudulently prepared.¹⁷⁶

¹⁷¹ See Victor E. Schwartz & Leah Lorber, *A Letter to the Trial Judges of America: Help the True Victims of Silica Injuries and Avoid Another Litigation Crisis*, 28 AM. J. TRIAL ADVOC. 295, 305-06 (2004).

¹⁷² See Editorial, *Beware the B-Readers*, WALL ST. J., at A16, abstract available at 2006 WLNR 1332176, available at <http://www.tortreform.com/node/233> (last visited Sept. 30, 2009); Editorial, *Screening for Corruption*, WALL ST. J., at A10, abstract available at 2005 WLNR 19447615, available at <http://www.tortreform.com/node/50> (last visited Sept. 30, 2009); see also Peter Geier, *Silicosis Screener is Fined \$80,500; Allegations that Silica Practice Improperly Built on Mass Screenings*, 29:25 NAT'L L.J., Feb. 26, 2007, at 7, available at 2/26/2007 NAT'L L.J. 7.

¹⁷³ See Mike Tolson, *Accusations of 'Double Dipping'—Trying to Use the Same Client for Two Different Claims—Surface/Silicosis Attorneys in Cross Hairs*, HOUSTON CHRON., Sept. 10, 2006, at B1, available at 2006 WLNR 15713259.

¹⁷⁴ David Hechler, *Silica Plaintiffs Suffer Setbacks: Broad Effects Seen in Fraud Allegations*, 27:25 NAT'L L.J., Feb. 28, 2005, at 18, available at 2/28/2005 NAT'L L.J. 1; see also Roger Parloff, *A Court Battle Over Silicosis Shines a Harsh Light on Mass Medical Screeners—The Same People Whose Diagnoses Have Cost Asbestos Defendants Billions*, FORTUNE, June 13, 2005, at 96, available at 2005 WLNR 8694138; Jonathan D. Glater, *Companies Get Weapon In Injury Suits; Many Silica-Damage Plaintiffs Also Filed Claims Over Asbestos*, N.Y. TIMES, Feb. 2, 2005, at C1, available at 2005 WLNR 1415209.

¹⁷⁵ Carlyn Kolker, *Spreading the Blame: The So-Called Phantom Epidemic of Silicosis has Become a Hot Potato for the Plaintiffs' Bar*, 27:10 AM. LAW., Oct. 2005, at 24, available at 10/2005 AM. LAW. 24.

¹⁷⁶ See *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d 563 (S.D. Tex. 2005); see also Peter Geier, *Judge Blasts Silica Suits, Advises a Sanction*, 27 NAT'L L.J., July 11,

Judge Jack stressed in her opinion that “these diagnoses were driven by neither health nor justice: they were manufactured for money.”¹⁷⁷

Included in the ever-expanding net of potential defendants in asbestos and silica cases are respirator manufacturers. Unlike most other attenuated defendants who have been pulled into these litigations,¹⁷⁸ however, respirator manufacturers designed protective equipment to guard against the harmful effects of prolonged exposure to such airborne contaminants. Yet, in spite of this important distinction, the number of claims against respirator manufacturers skyrocketed over the past decade. 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 4305 plaintiffs in 2002; and 643 cases with 17,288 plaintiffs in 2003.¹⁷⁹ As the *Financial Times* reported, “[s]ilicosis claims [in the United States]

2005, at 4; Editorial, *Silicosis Scandal*, WALL ST. J., Aug. 12, 2005, at A8, available at <http://online.wsj.com/article/0,,SB112381120616111638,00.html> (last visited Sept. 30, 2009); Editorial, *The Silicosis Sheriff*, WALL ST. J., July 14, 2005, at A10, available at <http://online.wsj.com/article/SB112129552607885138.html> (last visited Sept. 30, 2009).

¹⁷⁷ *In re Silica Prods. Liab. Litig.*, 398 F. Supp. 2d at 635; see also Mary Alice Robbins, *Plaintiff Lawyers Raked Over the Coals Regarding Silica Suits*, 22:22 TEX. LAW., July 31, 2006, at 1, available at 7/31/2006 TEXLAW 1 (Westlaw); Mike Tolson, *A Dozen Doctors, 20,000 Silicosis Cases / By Signing Off, X-Ray Readers Put Names on Scandal*, HOUSTON CHRON., May 8, 2006, at A1, available at 2006 WLNR 7893249; Mike Tolson, *Exposing the Truth Behind Silicosis*, HOUSTON CHRON., May 7, 2006, at A1, available at 2006 WLNR 7842508; Mike Tolson, *Attorneys Behind Silicosis Suits Draw U.S. Judge's Wrath / Houston Legal Firm Fined; Order From Bench Says Diagnoses Made for the Money*, HOUSTON CHRON., July 2, 2005, at A1, available at 2005 WLNR 24613373; Editorial, *Silicosis, Inc.*, WALL ST. J., Oct. 27, 2005, at A20, available at 2005 WLNR 17413061.

¹⁷⁸ Professor James Henderson, a Reporter of the *Restatement (Third) of Torts: Products Liability* (1998), has examined another instance of manufacturers who did not make or sell asbestos products but have been unduly pulled into the asbestos litigation web: those who produce component parts, such as pumps or valves, that were incorporated into products including asbestos, or were insulated with asbestos post-sale by others. See James A. Henderson, *Sellers of Safe Products Should Not be Required to Rescue Users from Risks Presented by Other, More Dangerous Products*, 37 SW. U. L. REV. 595 (2008).

¹⁷⁹ 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, available at http://findarticles.com/p/articles/mi_hb5249/is_200405/ai_n20030335/ (discussing the noted increase in the number of silica suits filed by plaintiffs in 2003) (last visited Sept. 30, 2009).

are climbing at such a rate that one company has 17,000 suits against it—and it just makes masks designed to protect people from silica dust.”¹⁸⁰ According to an industry group, more than 325,000 individual asbestos and silica lawsuits have included claims against respirator manufacturers since 2000.¹⁸¹

That this increase in claims against respirator manufacturers occurred in the absence of a reported mass failure of a product is astonishing. In fact, there are few reported verdicts against respirator manufacturers. Consider, for example, a Mississippi case that illustrates why respirator manufacturers may be cautious in taking such cases to trial.¹⁸² Over 150 plaintiffs brought suit against approximately sixty-two defendants (seven of which remained at the time of trial).¹⁸³ One of the remaining defendants was respirator manufacturer Minnesota Mining and Manufacturing Company, known as 3M, who produced two masks, the 8500 and 8710, allegedly used by the plaintiffs.¹⁸⁴ The trial court authorized an initial joint trial of ten plaintiffs against all the defendants.¹⁸⁵ The result was a \$25 million verdict for each of six of the ten plaintiffs.¹⁸⁶ 3M’s share was twenty to twenty-five percent of the \$25 million for four of the plaintiffs.¹⁸⁷ Remarkably, the jury rendered a verdict against 3M even as the plaintiffs’ own screening doctor testified that each plaintiff had told him during the examination that he rarely, if ever, wore a mask while exposed to asbestos, or where testimony indicated that they did not use 3M products.¹⁸⁸ Although the plaintiffs’ expert witness suggested that the product’s labeling or advertising more strongly warn that it was not

¹⁸⁰ Bob Sherwood, *Weighing the Risk from Food and Phones*, FIN. TIMES LONDON, Apr. 28, 2003, at 12.

¹⁸¹ Letter from Daniel K. Shipp, President, Int’l Safety Equip. Manuf. 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), available at <http://www.safetysystem.org/DOLpreemption08may.pdf> (last visited Sept. 30, 2009).

¹⁸² See *3M Co. v. Johnson*, 895 So. 2d 151 (Miss. 2005).

¹⁸³ *Id.* at 154.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.* at 158.

¹⁸⁸ *Id.* at 155-57, 164-65.

suitable for protection from asbestos, there was no evidence that the workers or their employers relied on any such marketing, nor did the expert suggest a reasonable alternative design.¹⁸⁹ Three years after the verdict, in reaching its decision to grant judgment notwithstanding the verdict (JNOV) for 3M due to the lack of evidence, the Mississippi Supreme Court noted that the 8500 mask's NIOSH-approved packaging stated that it was suitable only for non-toxic substances and never advertised for use with asbestos.¹⁹⁰ The 8710 mask was initially approved by OSHA for protection against exposure to asbestos, but when OSHA reduced the permissible exposure limit (PEL) for asbestos from 2 fibers/cc of air to 0.2 fibers/cc of air, 3M voluntarily withdrew the respirator for use with asbestos.¹⁹¹ In sum, 3M complied with OSHA regulations and the design and labeling of its products were certified by NIOSH, yet it was caught in the asbestos net.

The vast majority of cases, however, never make it to trial. Even where settled for small amounts that are no greater than litigation costs, however, the cumulative effect of these lawsuits can strike a fatal blow to respirator manufacturers. In 2004 alone, United States respirator manufacturers spent ninety percent of net income from respirator sales on litigation costs.¹⁹² Respirator manufacturer 3M, for example, paid out nearly \$300 million that year to resolve about 300,000 respirator claims.¹⁹³ That translates to less than \$1000 per claim, hardly an amount most plaintiffs would be willing to settle for if the respirator actually was defective and caused their life-threatening illness or disease.

These claims against respirator makers are not only damaging to the manufacturers, but have a broader adverse effect on the public interest. Beyond sacrificing basic fairness and justice to the litigants, the financial impact provides a strong disincentive for respirator manufacturers to

¹⁸⁹ *See id.* at 165-67.

¹⁹⁰ *Id.* at 154, 164.

¹⁹¹ *Id.* at 154, 165.

¹⁹² *See* Press Release, Coalition for Breathing Safety, Can the U.S. Afford a Shortage of Respirator Masks to Fight Flu Pandemic? (Sept. 19, 2006), *available at* http://breathingsafety.interactive.biz/press/release/2006/09_19.htm (last visited Sept. 30, 2009).

¹⁹³ *See* Greg Gordon, *Immunity for Makers of Dust Masks? Bill Would Protect Companies Such as 3M from Injury Suits Over Respirator Safety*, STAR TRIB. (Minn.-St. Paul), July 6, 2005, at D1, *available at* 2005 WLNR 11629945.

continue producing these safety devices for sale in the United States. Further, 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.

Such negative effects are heightened in times of emergency or crisis. In fact, a respirator supply shortage has become a legitimate concern since 2004, when public health agencies such as the Center for Disease Control, World Health Organization, and other health officials expressed the need to prepare for an avian flu pandemic.¹⁹⁴ An integral part of the United States emergency planners and first responders strategy if the disease reached this country is the use of N-95 respirators to prevent its spread; a strategy which, depending on the severity of the outbreak, may fail due to litigation costs depleting the capital resources among the major United States respirator manufacturers. For example, the United States Department of Health and Human Services purchased and stockpiled 150

¹⁹⁴ See Centers for Disease Control, Interim Recommendations for Infection Control in Health-Care Facilities Caring for Patients with Known or Suspected Avian Influenza, May 21, 2004, at 3, *available at* <http://www.cdc.gov/flu/avian/professional/pdf/infectcontrol.pdf> (last visited Sept. 30, 2009) (noting need for healthcare workers to wear a fit-tested respirator, at least as protective as a NIOSH-approved N-95 filtering face piece, when entering the room to treat a patient with symptoms consistent with avian flu); Centers for Disease Control, Interim Guidance for Protection of Persons Involved in U.S. Avian Influenza Outbreak Disease Control and Eradication Activities, Feb. 17, 2004, at 2, *available at* <http://www.cdc.gov/flu/avian/professional/pdf/protectionguid.pdf> (last visited Sept. 30, 2009) (recognizing that use of disposable particulate respirators (*e.g.*, N-95, N-99, or N-100) are the minimum level of respiratory protection that should be worn by those involved in the response to an outbreak of high pathogenic avian influenza); INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, REUSABILITY OF FACEMASKS DURING AN INFLUENZA PANDEMIC: FACING THE FLU 17 (2006), *available at* http://books.nap.edu/catalog.php?record_id=11637 (last visited Sept. 30, 2009) (finding that the supply of N95 respirators may not be sufficient to meet demand in the event of a severe influenza pandemic); WORLD HEALTH ORGANIZATION, WHO GLOBAL INFLUENZA PREPAREDNESS PLAN 50 (2005), *available at* http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5/en/ (last visited Sept. 30, 2009) (recommending that healthcare workers who will be within three feet of infected patients use medical masks when caring for patients either with, or suspected to have, pandemic influenza, and that “if resources allow and such respirators are available,” N95 or comparable respirators should be used by health-care workers during aerosol-producing procedures in pandemic influenza settings).

million masks, including 94.8 million N95 masks and 63.7 million surgical masks, in response to the avian flu threat in 2006.¹⁹⁵ In 2008, the Department of Labor proposed guidance recommending that employers purchase and stockpile respirators in preparation for an influenza epidemic, and providing a method of calculating workplace stockpiling needs.¹⁹⁶ Today, as fear of a Swine Flu pandemic rises, the CDC has recommended use of respirators to reduce the risk of contracting influenza, emphasizing the need for other preventive measures, such as avoiding close contact with others, frequent hand-washing, and covering coughs, as a first-line defense.¹⁹⁷

Yet, the United States is far behind the emergency preparedness curve with respect to other countries.¹⁹⁸ Most respirator production has moved

¹⁹⁵ See DEP'T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS, PANDEMIC INFLUENZA PREPAREDNESS SPENDING 3 (2006), available at <http://www.hhs.gov/aspr/barda/mcm/panflu/hhspanflusing-0606.pdf> (last visited Sept. 30, 2009).

¹⁹⁶ See Request for Comments on Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza, 73 Fed. Reg. 26,431 (May 9, 2008); U.S. Dep't of Labor, Occupational Health & Safety Admin., Proposed Guidance on Workplace Stockpiling of Respirators and Facemasks for Pandemic Influenza, <http://www.osha.gov/dsg/guidance/stockpiling-facemasks-respirators.html> (last visited Sept. 30, 2009).

¹⁹⁷ Centers for Disease Control & Prevention, Interim Recommendations for Face-mask and Respirator Use in Certain Community Settings Where Swine Influenza A (H1N1) Virus Transmission Has Been Detected, Apr. 27, 2009, <http://www.cdc.gov/swineflu/masks.htm> (last visited Sept. 30, 2009). The CDC distinguishes between facemasks, which are loose-fitting, and designed largely to help stop droplets from spreading from the person wearing the mask, from respirators, which protect the wearer by filtering very small particles. *Id.* The CDC recommends use of facemasks by individuals who enter crowded settings to protect from coughs, but that those for whom close contact with an infectious person is unavoidable, such as individuals who must care for a sick person, use respirators. *See id.*

¹⁹⁸ See Bevan Schneck, *A New Pandemic Fear: A Shortage of Surgical Masks*, TIME, May 19, 2009, available at <http://www.time.com/time/health/article/0,8599,1899526,00.html> (last visited Sept. 30, 2009) (reporting that the CDC Strategic National Stockpile contains only 119 million masks—39 million surgical and 80 million respirator, which is less than one percent of the goal health officials set in 2007 following the devastation of Hurricane Katrina, and that the United States has one mask for every three Americans compared with 2.5 and 6 per resident in Australia and Great Britain, respectively). France has also purchased hundreds of millions of masks for its citizens. See Kelly M. Pyrek, *U.S. Pandemic Could Severely Strain Face Mask, Other PPE Supply Pipeline*, INFECTION CONTROL TODAY, Oct. 4, 2008, at <http://www.infectioncontrolday.com/articles/pandemic-and-face-mask-shortage.html> (last visited Sept. 30, 2009).

outside the United States with nine out of ten masks (respirators and the less sturdy surgical masks) manufactured in China and Mexico,¹⁹⁹ where they are not subject to American tort liability. This foreign reliance has led some to question whether sufficient respirators would be available to Americans in the case of an emergency situation because foreign manufacturers are likely to divert their supplies to the countries in which they are located.²⁰⁰ Even if stockpiling is not the answer, some suggest that “stepping up domestic manufacturing of [personal protective equipment] items is the single best way to be prepared for a pandemic or other emergency event.”²⁰¹ The continued risk from similar threats such as natural disasters, terrorism, or other diseases, 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, labeling, and use of respirators.

V. The Impact of Regulatory Compliance on Tort Liability

As discussed earlier, NIOSH develops design and labeling standards for respirators, and it tests and certifies each product for compliance with its requirements.²⁰² In turn, OSHA mandates the use of NIOSH-certified respirators in the workplace and its regulations specify the appropriate level of protection for exposure to certain hazardous substances. This section examines how compliance with this comprehensive regulatory structure impacts the potential liability of respirator manufacturers.

Respirator manufacturers are not alone in complying with strict federal regulations. For example, the FDA approves and monitors prescription drugs and medical devices as safe and effective, and the National Highway Traffic Safety Administration (NHTSA) has developed Federal Motor Vehicle Safety Standards that require vehicles to meet crash-

¹⁹⁹ See Schneck, *supra* note 198.

²⁰⁰ See *id.*; see also Pyrek, *supra* note 198.

²⁰¹ Pyrek, *supra* note 198.

²⁰² See SAFETY EQUIP. STANDARDS: YOUR KEYS TO BUS. SUCCESS 13 (2007), available at http://www.safetysystem.org/ISEA_Standards.pdf (last visited Sept. 30, 2009).

worthiness standards.²⁰³ In these and other areas, government policy-makers consult with experts, evaluate data, and engage in a risk-benefit analysis. Often, their regulations are a result of extensive public notice and comment, industry participation, and consideration by experts.

Nearly any product can be made safer in some respect. Often, measuring “safety” is a complex judgment. A product made safer for some situations may become more dangerous in others. For instance, an enclosed forklift may protect its operator from falling out, but OSHA recommends an open design because the ability to exit quickly in the case of an emergency is more important to the operator’s safety.²⁰⁴ Even when incorporation of a safety device would increase overall safety, in some cases, adding the extra device may not be financially practical or desirable for the consumer. For example, if the addition of a safety device will significantly increase the cost of the product, consumers might either be unable to afford to purchase it or feel the nominal reduction in the risk of injury does not warrant the higher price. These consumers might be drawn to purchase a less-safe product of a competitor.

Likewise, if OSHA requires respirators with greater filtration in the workplace, it does so at the expense of breathability and may discourage workers from using protective equipment. When NIOSH revised its respirator certification requirements in 1995, for example, some commentators on the proposed rule urged the Institute to require all filters to have greater than 99% efficiency.²⁰⁵ NIOSH rejected this suggestion.²⁰⁶ It found that “[s]uch high filter efficiency poses technologic challenges, increases costs to manufacturers and users, and increases breathing difficulty for respirator wearers.”²⁰⁷ NIOSH instead concluded that “a 95% minimum efficiency best balances the public health concern and these competing considerations.”²⁰⁸ This is the type of balancing for

²⁰³ See 49 C.F.R. pt. 571 (2008).

²⁰⁴ See 29 C.F.R. § 1910.178 (2006) (adopting by reference the American National Standards Institute’s Powered Industrial Truck for design and construction of forklifts, which recommends against operator enclosures because “rapid and unobstructed ingress or egress for the operator is considered more desirable”).

²⁰⁵ See Respirator Protective Devices, 60 Fed. Reg. 30336, 30345 (June 8, 1995).

²⁰⁶ See *id.*

²⁰⁷ *Id.*

²⁰⁸ *Id.*

which government agencies are in the best position to accomplish when they set regulatory standards.

A. Common Law Treatment of Regulatory Standards and Approvals

Regardless of whether a manufacturer of a respirator or other product meets the design and labeling requirements of a government agency, and even when the product is used in a manner in compliance with federal or state safety regulations, a manufacturer may face negligence or strict product liability claims. Such lawsuits may claim that a reasonably prudent manufacturer should have done more to protect product users or that the product was “unreasonably dangerous” due to its design or failure to warn of a known risk.²⁰⁹ Plaintiffs may also seek punitive damages by claiming that the manufacturer recklessly released the product for public use when it knew of a risk of injury.²¹⁰

In the absence of a statute instructing courts on how to weigh compliance with a government safety standard or product approval, state courts vary on how they consider such evidence.²¹¹ Most courts consider compliance with government standards as a factor for the jury in determining whether or not a product is unreasonably dangerous.²¹² Some of these courts reason that government regulations provide only “minimum standards,” and, therefore, are not dispositive.²¹³ On the other hand, most

²⁰⁹ See *Worsham v. A.H. Robins Co.*, 734 F.2d 676, 685 (11th Cir. 1984).

²¹⁰ See *Campbell v. Robert Bosch Power Tool Corp.*, 795 F. Supp. 1093, 1097 (M.D. Ala. 1992).

²¹¹ See, e.g., *Sours v. General Motors Corp.*, 717 F.2d 1511, 1517 (6th Cir. 1983) (holding that GM’s alleged compliance with industry customs and standards in the absence of federal safety standards “was properly left to jurors to factor into the calculus that comprises reasonable design in a case of strict products liability”).

²¹² See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 Rpt. Note, cmt. (d) (1998); see also Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1242 (1996) (“[M]ost courts agree that federal safety regulations are relevant evidence in products liability cases.”).

²¹³ See Ausness, *supra* note 212, at 1241-47 (providing examples of cases in which courts gave little weight to federal safety regulations spanning a variety of areas, such as flammability standards for clothing, pesticide warnings, automobile design, prescription drug warnings, aircraft design, and workplace safety standards).

jurisdictions consider violation of a safety regulation as evidence that a product is defective as a matter of law, but do not accord evidence of compliance with government regulations similarly deferential treatment.²¹⁴

In other cases, courts have accorded weight to government safety standards and approvals, even if it finds compliance is not conclusive of whether liability should be imposed.²¹⁵ Courts occasionally find that meeting a safety standard set by government regulations precludes tort liability.²¹⁶ For example, Maryland's highest court has recognized that "where no special circumstances require extra caution, a court may find that conformity to the statutory standard amounts to due care as a matter of law."²¹⁷ Courts frequently cite compliance with safety regulations as a factor used to justify a directed verdict for a defendant.²¹⁸

In 1991, the American Law Institute (ALI), a well-respected organization composed of judges, lawyers, and law professors, published a Reporter's Study recommending that compliance with regulatory requirements imposed by a government agency preclude tort liability in certain situations.²¹⁹ Under the Reporter's Study recommendation, tort liability would be precluded when: (1) a legislature has placed the risk at issue under the authority of a specialized administrative agency; (2) that agency has established and periodically revises regulatory safety controls; (3) the manufacturer or other entity complied with the relevant regulatory standards; and (4) the manufacturer or other entity disclosed to the agency

²¹⁴ *See id.*

²¹⁵ *See, e.g.,* *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559 (Tex. Ct. App. 1995) ("Compliance with government regulations is strong evidence, although not conclusive, that a machine was not defectively designed.").

²¹⁶ *See, e.g.,* *Lorenz v. Celotex Corp.*, 896 F.2d 148 (5th Cir. 1990) (compliance with safety regulation is strong and substantial evidence of lack of defect); *Dentson v. Eddins & Lee Bus Sales, Inc.*, 491 So. 2d 942, 944 (Ala. 1986) (ruling that a school bus which is not equipped with seatbelts is not defective when the legislature has not required seatbelts); *Ramirez v. Plough, Inc.*, 863 P.2d 167, 176 (Cal. 1993) (concluding that "the prudent course is to adopt for tort purposes the existing legislative and administrative standard of care").

²¹⁷ *Beatty v. Trailmaster Prods., Inc.*, 625 A.2d 1005, 1014 (Md. 1993).

²¹⁸ *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIABILITY § 7 cmt. e (1998) (citing *Hawkins v. Evans Cooperage Co.*, 766 F.2d 904, 909 (5th Cir. 1985)).

²¹⁹ *See* 2 AM. LAW INST., REPORTER'S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 96-97 (1991).

any material information in its possession or of which it has reason to be aware concerning the products' risks and means of controlling them.²²⁰

Ultimately, the ALI officially incorporated a similar approach into the *Restatement (Third) of Torts: Products Liability*.²²¹ It says that a product should not be considered defective as a matter of law

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.²²²

Conversely, the *Restatement (Third) of Torts: Products Liability* acknowledges that this liability protection would not apply “when the deliberative process that led to the safety standard . . . was tainted by the supplying of false information to, or the withholding of necessary and valid information from, the agency that promulgated the standard or certified or approved the product.”²²³

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.²²⁴ The

²²⁰ See *id.*; see also Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System*, 88 GEO. L.J. 2167, 2168-70 (2000).

²²¹ See generally RESTATEMENT (THIRD) OF TORTS: PRODS. LIABILITY § 4 (1998).

²²² *Id.* § 4 cmt. e; see also James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 321 (1990) (“Courts recognizing the limits of their institutional capabilities should refuse to second-guess the judgments of agencies who possess not only expertise but also a capacity for knowledge and memory which the courts cannot match.”); Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 335 (1985) (“Once that determination has been made by an expert licensing agency, the courts should respect it.”).

²²³ See RESTATEMENT (THIRD) OF TORTS: PRODS. LIABILITY § 4 cmt. e (1998).

²²⁴ Seven 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. COLO. REV. STAT. § 13-21-403(1) (2003); KAN. STAT. ANN. § 60-3304(a) (1981); KY. REV. STAT. ANN. § 411.310(2) (2006); MICH. COMP. LAWS § 600.2946(4) (1995); TENN. CODE ANN. § 29-28-104 (1978); TEX. CIV. PRAC. & REM. CODE ANN. § 82.008 (2003); UTAH CODE ANN. § 78B-6-703(2) (2008). The standard

application regulations are kept up to date in that NPPRL's expert staff continuously researches the performance of respiratory protective equipment and conducts work site surveillance of hazards. Moreover, OSHA promulgated its respiratory protection standard in 1998²²⁵ and has revisited and updated on several recent occasions.²²⁶ NIOSH's history of developing respiratory protection standards, and testing and certifying such products over the last three decades should provide courts with confidence that the process reflects its substantial expertise.

NIOSH's testing and certification process and OSHA respiratory protection standards are likely to specifically address many of the product liability claims raised in state tort lawsuits, such as adequacy of the product's labeling or level of filtration of the product's design. Thus, when there is a tort or product liability claim against a respirator manufacturer, and these aspects of the product were specifically considered

for a plaintiff to overcome this preemption varies from state to state. For example, in Kansas, a plaintiff may show that "a reasonably prudent product seller could and would have taken additional precautions," KAN. STAT. ANN. § 60-3304(a), while in Texas, a plaintiff may show either that the applicable regulations were inadequate to protect the public from unreasonable risks of injury or damage, or the manufacturer withheld or misrepresented information or material relevant to the agency's determination of adequacy of the safety standards or regulations at issue, TEX. CIV. PRAC. & REM. CODE ANN. § 82.008(b). 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. In addition, five states have enacted statutes providing that manufacturers may not be held liable for punitive damages when their product was approved or licensed by the FDA with certain exceptions. *See* ARIZ. REV. STAT. ANN. § 12-701(A) (1989) (prescription drugs); N.J. STAT. ANN. § 2A:58C-5c (West 1987) (drugs, devices, food, or food additives); OHIO REV. CODE ANN. § 2307.80(C) (2004) (prescription drugs, medical devices, and over-the-counter drugs); OR. REV. STAT. § 30.927 (1987) (prescription drugs); UTAH CODE ANN. § 78B-8-203(1) (2008) (prescription drugs). Michigan and Texas law provides a rebuttable presumption that a drug is not defective or unreasonably dangerous if the drug is approved for safety and efficacy by the FDA. *See* MICH. COMP. LAWS § 600.2946(5) (1995); TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (2003).

²²⁵ *See* 29 C.F.R. § 1910.134 (2008) (effective Apr. 8, 1998 with compliance required Oct. 5, 1998).

²²⁶ *See, e.g.*, 69 Fed. Reg. 46,993 (Aug. 4, 2004) (revising mandatory fit testing procedures); 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); 73 Fed. Reg. 75,584 (Dec. 12, 2008) (revising requirement that employers are to provide employees with applicable and suitable respiratory protective equipment).

during the certification process or through workplace safety requirements, the *Restatement* view suggests that there is no liability.

B. Federal Preemption of Conflicting State Tort Law Claims

A state's choice to provide strong deference to the decision-making of government agencies with regard to liability determinations is a matter of public policy for its courts and legislatures. The constitutional principle of preemption, however, mandates that state law, including common law claims, may not conflict with federal requirements.²²⁷ In other words, the theory of a lawsuit may not suggest that a defendant is liable because of conduct that was prohibited by federal law or regulations, or based on a theory that would stand as an obstacle to accomplishing a federal regulatory goal.

Preemption is rooted in the Supremacy Clause of the United States Constitution.²²⁸ Congress occasionally provides that a federal law preempts state statutes and common law within the text of a statute, a practice known as "express preemption."²²⁹ In other cases, preemption can be implied through the purpose or structure of the federal law. The Supreme Court has recognized that "[e]ven without an express provision for preemption, we have found that state law must yield to a congressional Act."²³⁰ This occurs in two situations: (1) when Congress intends to occupy an entire regulatory field leaving no room for state law making (field preemption) or (2) when there is a conflict between the state and the federal law (conflict preemption).²³¹ Under conflict preemption

²²⁷ See generally U.S. CONST. art. VI, cl. 2.

²²⁸ *Id.* "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

²²⁹ Victor E. Schwartz, Cary Silverman & Christopher E. Appel, "That's Unfair!" *Says Who—The Government or the Litigant?: Consumer Protection Claims Involving Regulated Conduct*, 47 WASHBURN L.J. 93, 117 (2007).

²³⁰ *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

²³¹ *Id.*

principles, state laws are preempted if the regulated party cannot comply with both the state and federal regulation.²³² Additionally, courts may find state statutes or common law claims preempted where, under the circumstances of a particular case, state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”²³³

In the respirator context, application of traditional principles of conflict preemption strongly suggest that comprehensive regulation of respirator safety by NIOSH, OSHA, and MSHA preclude conflicting tort law claims that challenge the design or labeling of such products. With respect to the design of the respirator, a tort claim seeking “stronger” protection would shift the delicate balance between filtration and breathability in a manner unintended by federal regulators.²³⁴ There can be only one police officer directing traffic at this intersection. Tort claims that seek to add warnings to respirator labels that are not in accordance with NIOSH’s certification would lead to an endless list.²³⁵ Comprehensive, encyclopedic warning labels are not necessarily effective due to issues of reader retention, the potential to deemphasize the most significant

²³² See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985).

²³³ *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)); see also *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-74 (2000).

²³⁴ See *supra* notes 217-19 and accompanying text; cf. *Bic Pen Corp. v. Carter*, 251 S.W.3d 500, 507 (Tex. 2008) (holding that a design defect claim was impliedly preempted when the product was tested and certified by the Consumer Product Safety Commission (CPSC) as meeting federal safety standards for child-resistant lighters because imposing higher standards would interfere with the reasonable balance struck by the CPSC “to create a standard that encouraged the manufacture of child-resistant lighters and yet did not discourage adults from using them,” thereby exposing children to greater risk).

²³⁵ For example, specific warnings sought by plaintiffs in lawsuits involving N-95 model respirators include that facial hair may impact effectiveness; that the silica dust test performed by NIOSH is inadequate; that moisture, heat, humidity cause filter degradation; that the filter does not protect against submicron particles; creating an artificial seal during the user fit check process; that electrostatically-charged filters are not for use in underground coal mines; and that the respirators should have been tested in the workplace, though not required by NIOSH. In addition, plaintiffs often allege more broadly that the manufacturer misrepresented the safety and efficacy of the respirator or that the respirator contained inadequate warnings.

risks, and the likelihood that busy workers will choose to ignore an extraordinarily long label.²³⁶

As discussed above, NIOSH closely reviews and approves product specifications, instructions, labeling, and packaging, tests the respirators, and inspects manufacturing facilities, while OSHA mandates use of certain NIOSH-approved respiratory protection devices in the workplace.²³⁷ The Supreme Court has “held repeatedly that state laws can be pre-empted by federal regulations as well as by federal statutes.”²³⁸ Aside from the tort claims substantially interfering with the federal objective of establishing this comprehensive regulatory system, it is physically impossible for a manufacturer to abide by both federal regulation and tort claims challenging a respirator’s design or warning. As the Department of Labor has recognized, “it is unlawful to change the characteristics of a respirator without further NIOSH approval . . . manufacturers are locked into an approved design once NIOSH has issued a certificate.”²³⁹

The OSH Act includes an express preemption provision.²⁴⁰ Section 667(a) provides that “[n]othing in this Act shall prevent any State agency or court from asserting jurisdiction under State law over any occupational safety or health issue with respect to which no [OSH Act] standard is in

²³⁶ See Victor E. Schwartz & Christopher E. Appel, *Effective Communication of Warnings in the Workplace: Avoiding Injuries in Working with Industrial Materials*, 73 MO. L. REV. 1, 12, 15 (2008); Jessue Y.C. Chen et al., *Perceived Risk Dilution With Multiple Warnings*, Proceedings of the Human Factors and Ergonomics Society, 41st Annual Meeting, at 834 (1997) (finding that the perceived risk of significant warnings decline when imbedded with other lower-criticality warnings and that the perceived hazard of the product also declines when there is a high number of collateral warnings); J. Paul Frantz et al., *Potential Problems Associated With Overusing Warnings*, Proceedings of the Human Factors and Ergonomics Society, 43rd Annual Meeting, at 919 (1999) (concluding that “there is virtually total agreement in the warnings-related literature that providing product warnings about all risks associated with a product is an ill-fated and incorrect approach”).

²³⁷ See *supra* notes 83-124 and accompanying text.

²³⁸ See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985); see also *Fidelity Fed. Savs. & Loan Ass’n v. Cuesta*, 458 U.S. 141, 153-54 (1982) (“Federal regulations have no less pre-emptive effect than federal statutes.”).

²³⁹ 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, http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=27334 (last visited Sept. 30, 2009).

²⁴⁰ See 29 U.S.C. § 667 (2000).

effect.”²⁴¹ Moreover, Congress has established presumptive federal regulatory control over the standards for occupational safety.²⁴² The OSH Act provides a specific mechanism for states to regulate matters in which OSHA has adopted a standard so as to avoid tension. A state may regulate such an area only if it submits and obtains OSHA approval of an alternative plan.²⁴³ Federal standards are clearly in effect with regard to respiratory protective devices, suggesting that express preemption should apply to state regulation of the same. While some may argue that state common law claims are different from state statutes or regulations, the Supreme Court has recognized that common law regulation can be an even more potent form of regulation than a legislative enactment.²⁴⁴

A savings clause in the OSH Act, however, has been a source of confusion in some courts. The Act states that it is not to be construed to “enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers or employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.”²⁴⁵ Some courts have viewed this savings clause as allowing preemption of state occupational safety and health statutes or regulations, while preserving private state tort law actions.²⁴⁶ Such a reading, however, is in tension with Section 667(a) and ordinary principles of conflict preemption.²⁴⁷

Courts have applied these principles to find that tort law claims that conflict with the OSH Act are preempted.²⁴⁸ For example, in *Gonzalez*

²⁴¹ *Id.* § 667(a).

²⁴² See Richard J. Pierce, Jr., *Regulation, Deregulation, Federalism, and Administrative Law: Agency Power to Preempt State Regulation*, 46 U. PITT. L. REV. 607 (1985).

²⁴³ See 29 U.S.C. § 667(c)(2); 29 C.F.R. pt. 1952 (2008).

²⁴⁴ See, e.g., *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) (recognizing that state regulation “can be as effectively exerted through an award of damages as through some form of preventive relief”).

²⁴⁵ 29 U.S.C. § 653(b)(4) (2000).

²⁴⁶ See, e.g., *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 52-54 (1st Cir. 1991); *Lindsey v. Caterpillar, Inc.*, 480 F.3d 202, 208 (3d Cir. 2007).

²⁴⁷ See *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-74 (2000) (holding that a savings clause in the National Traffic and Motor Vehicles Safety Act did not foreclose or limit the operation of ordinary conflict preemption principles).

²⁴⁸ *Gonzalez v. Ideal Tile Importing Co.*, 877 A.2d 1247, 1251 (N.J. 2005).

v. Ideal Tile Importing Co., an employee who was struck by a forklift operated by a coworker argued that the manufacturer should have installed additional audio or visual alarms on the machine in order to make its operation safe.²⁴⁹ The OSHA regulation at issue, however, required only an operator-controlled horn with “other devices” installed only if the user finds a need dependent upon the intended area of use.²⁵⁰ For this reason, the Supreme Court of New Jersey found that requiring a manufacturer to install additional warning devices on all forklifts would conflict with the federal standard and actually lead to a less safe work environment.²⁵¹ Therefore, the court found conflict preemption applied to the specific tort law claim at issue.²⁵²

Such opinions draw support from the United States Supreme Court’s 1992 ruling in *Gade v. National Solid Wastes Management Ass’n*.²⁵³ In *Gade*, Illinois attempted to require licensing of hazardous equipment operators and laborers.²⁵⁴ While that case involved a state statute and regulations, rather than tort law, the Court found that conflict preemption principles apply under the OSH Act.²⁵⁵ The Court found that “Congress intended to subject employers and employees to only one set of regulations, be it federal or state, and that the only way a State may regulate an OSHA-regulated . . . health issue is pursuant to an approved state plan that displaces federal standards.”²⁵⁶ The opinion repeatedly speaks of uniformity of occupational safety and health standards and avoidance of duplicity.²⁵⁷ Ultimately, the Court found that, even if both the federal and state standards promote worker safety, the state standard is preempted if it interferes with the federal regulation.²⁵⁸ A state’s only option under the OSH Act, where a federal standard is in place, is to seek OSHA

²⁴⁹ See *Gonzalez*, 877 A.2d at 1248-50.

²⁵⁰ See *id.* at 1252.

²⁵¹ See *id.* at 1252-53.

²⁵² See *id.*; accord *Arnoldy v. Forklift L.P.*, 927 A.2d 257, 266 (Pa. Super. Ct. 2007); *Kiak v. Crown Equip. Corp.*, No. 3340, 2008 WL 2090791 (Pa. Com. Pl. Feb. 29, 2008).

²⁵³ 505 U.S. 88 (1992).

²⁵⁴ See *Gade*, 505 U.S. at 91.

²⁵⁵ *Id.* at 99.

²⁵⁶ *Id.*

²⁵⁷ *Id.* at 100, 102.

²⁵⁸ *Id.* at 107.

approval to provide its own standard.²⁵⁹ Thus, where NIOSH has adopted a federal standard for respirators, and those respirators are required by OSHA, a state may not regulate respirators through tort law claims because such claims are not subject to OSHA approval, conflict with federal objectives in regulating respirator safety and, in some cases, compliance with both the tort claim and conditions of NIOSH-certification are physically impossible.²⁶⁰

As of the time of this writing, at least one court has applied these principles to find that the OSH Act preempts state tort law actions alleging defective design of a NIOSH-approved respirator.²⁶¹ Most recently, the Department of Labor issued an interpretive opinion on “whether ordinary principles of conflict preemption preclude state courts from finding that OSHA-required, [NIOSH] certified respirators have been defectively designed, labeled, or packaged when their design, packaging, and labeling comply with all applicable federal regulatory standards and conditions of certification” in response to a request from the International Safety Equipment Association (ISEA).²⁶² The Department of Labor’s January

²⁵⁹ See *id.* at 104.

²⁶⁰ OSHA standards apply to “employment performed in a workplace.” 29 U.S.C. § 653(a) (2000). For this reason, some courts have found that OSHA regulations do not regulate product design. See, e.g., *Brown v. Crown Equip. Corp.*, 181 S.W.3d 268, 280 (Tenn. 2005) (reversing directed verdict for the manufacturer in a product liability action in which the plaintiff claimed a forklift should have included a door, and stating that “[r]egulations from both OSHA and NIOSH are applicable to an employer’s conduct and not to a manufacturer’s conduct”). A few courts have gone so far as to find that evidence that a product met OSHA standards is inadmissible in product liability cases. See, e.g., *Nesbitt v. Sears, Roebuck & Co.*, No. Civ. A. 03-6747, 2005 WL 2704884, at *3 (E.D. Pa. Oct. 20, 2005) (finding in a case involving a saw that, under Pennsylvania law, “[i]t is clear that a manufacturer may not introduce evidence of compliance with industry and OSHA standards to demonstrate the absence of a product defect”); cf. David G. Owen, *Special Defenses in Modern Products Liability Law*, 70 MO. L. REV. 1, 17-19 (2005) (finding that some courts allow evidence of a product’s compliance with OSHA standards in product defect cases because they have “at least some minimal relevance to product defectiveness,” while other courts have barred such evidence). Even if such decisions are correct, the NIOSH/OSHA combination, in which NIOSH clearly requires manufacturers to meet certain standards to receive the approval needed for their products to be used in the workplace in compliance with OSHA regulations, would seem to uniquely regulate both manufacturer and employer conduct.

²⁶¹ See *King v. Custom Spraying & Reglazing Co.*, No. 121677, slip op. at 4 (N.Y. Sup. Ct. Mar. 31, 2005).

²⁶² See U.S. Dep’t of Labor, Occupational Safety & Health Admin., Standard Interpretations, OSHA’s Position on Conflict Preemption Precluding State Court Filings

9, 2009 opinion 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.²⁶³ The Department concluded:

NIOSH has carefully calculated the risks and benefits associated with various design specifications and labeling of respirators, and it has deliberately, after extensive testing and research, created requirements that respirator manufacturers must follow if they are to sell respirators to employers. OSHA has, pursuant to its authority under the OSH Act, mandated that employers provide only NIOSH-approved respirators. 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.

For these reasons, OSHA believes that the principles of conflict preemption preclude state courts from finding that OSHA-required, NIOSH-certified respirators are defective when such respirators comply with NIOSH requirements.²⁶⁴

Although the Department of Labor’s interpretation of its regulations as preemptive may not rise to the “*Chevron*-level” deference as a

with Regard to Defective NIOSH-certified Respirators (Jan. 9, 2009), http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=27334 (last visited Sept. 30, 2009).

²⁶³ *Id.* It is not likely that a court would find that federal regulations preempt *all* tort claims involving respirators. For example, claims alleging manufacturing defects 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.

²⁶⁴ *Id.* OSHA appears to be careful and selective in finding preemption based on the particular law, regulatory scheme, and facts at issue. For example, soon after issuance of its standard interpretation finding preemption in the respirator context, the same Department of Labor official who signed that opinion found that the OSH Act did not preempt state laws regarding possession of firearms on company property. *See* Letter from Thomas Stohler, Acting Assistant Sec’y of Labor, to Jerry Ellis, Oklahoma State Senate (Jan. 16, 2009); *see also* *Ramsey Winch Inc. v. Henry*, 555 F.3d 1199, 1208-09 n.9 (10th Cir. 2009) (recognizing Department of Labor position and adopting a consistent position).

regulation that went through formal notice and comment,²⁶⁵ the Supreme Court has made clear that agency positions on the preemptive effect of federal law, even when not a result of formal rulemaking, are “entitled to respect”²⁶⁶ and accorded “substantial” deference.²⁶⁷ In such instances, “[t]he weight of such a[n agency] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”²⁶⁸ In fact, the Supreme Court has encouraged federal agencies to make their views known on preemption through whatever means are available.²⁶⁹ As the Court recognized, “because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretative statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive.”²⁷⁰ It is also likely that courts will give significant respect to an agency’s scientific findings related to a specific product that is within their expertise,²⁷¹ such as NIOSH’s development of safety standards and testing of the product at issue in its own laboratories.

The Supreme Court’s latest foray into preemption is actually supportive of precluding certain state tort claims in this context. Recently, the Court ruled in *Wyeth v. Levine* that the Food, Drug & Cosmetic Act (FDCA) did not broadly preempt tort claims challenging the adequacy

²⁶⁵ See *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

²⁶⁶ *Christensen v. Harris County*, 529 U.S. 576, 586 (2000).

²⁶⁷ *Spreitsma v. Mercury Marine*, 537 U.S. 51, 67-68 (2002).

²⁶⁸ *Skidmore v. Swift & Co.*, 323 U.S. 134, 139 (1944).

²⁶⁹ See *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985).

²⁷⁰ *Id.*

²⁷¹ See *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 261 (3d Cir. 2008) (dismissing claims that anti-depressant drugs were defective and resulted in suicides because they should have carried a stronger warning that they might cause suicidality in adults where it would be physically impossible for the manufacturer to alter its warnings as sought by the plaintiffs because the FDA required the manufacturer to use the precise labeling approved, and the FDA had repeatedly found insufficient scientific evidence to support the sought warning), vacated and remanded for further consideration in light of *Wyeth v. Levine*, 129 S. Ct. 1187 (2009); *Dobbs v. Wyeth Pharms.*, 530 F. Supp. 2d 1275 (W.D. Okla. 2008).

of prescription drug labeling because manufacturers may unilaterally alter product warnings so long as they submit the changes for eventual FDA review and potential rejection.²⁷² Federal regulations applicable to respirators, however, present a situation where it is impossible for manufacturers to alter a design or labeling on their own initiative to address the alternative sought in a lawsuit. That is because, as noted earlier, federal regulations require NIOSH to affirmatively approve aspects of the respirator design, packaging, or labeling referenced by the certificate of approval *before* alteration.²⁷³ It is also important to consider that, unlike the prescription drug context in which FDA review and approval largely relies upon clinical studies and test results submitted by the manufacturer to the FDA, NIOSH conducts its own testing of respirators to ensure that products meet government safety standards.

For these reasons and others, the Department of Labor interpretive opinion on the preemptive effect of federal certification and regulation is deserving of substantial deference in the courts. Its letter does not suffer from the procedural irregularity that led the Supreme Court to find the FDA's opinion "inherently suspect," particularly that the original notice of proposal rulemaking in that proceeding stated that the regulation would not have a preemptive effect, yet the FDA inserted a "sweeping provision" in the preamble of the final regulation.²⁷⁴ Rather, the targeted opinion came in response to an inquiry from the industry after eight months of internal review.²⁷⁵ Moreover, the Department answered what appears to be a novel question. The Department's viewpoint is unlike the "dramatic change" between the FDA's historic position that prescription drug regulation provides only "minimum standards" for drug labels,

²⁷² 129 S. Ct. 1187, 1196-99 (2009) (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008)).

²⁷³ See 42 C.F.R. § 84.35 (2008).

²⁷⁴ See *id.*

²⁷⁵ Letter from Daniel K. Shipp, President, Int'l Safety Equip. Mfr. 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, available at <http://www.safetysystem.org/DOLpreemption08may.pdf> (last visited Sept. 30, 2009); 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, posted Jan. 9, 2009, http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=27334 (last visited Sept. 30, 2009).

which led the Supreme Court to discredit the FDA's conclusion expressed in the preamble.²⁷⁶ In these circumstances, post-*Levine*, agency opinions issued based on objective and thorough review, even issued through informal means, continue to be worthy of deference, as the Supreme Court did not express an intent to overrule its well-established precedent on this point.

Whatever level of deference courts ultimately accord to the Department's opinion, the language of the OSH Act, NIOSH's certification of an individual respirator and OSHA regulations requiring use of that type of respirator in certain workplaces provides a highly persuasive case for preemption of state tort claims that conflict with the conditions of certification and approved use. When the adverse public policy implications of the barrage of tort suits against respirator manufacturers on the availability of protective equipment is considered, the case becomes even more compelling.

VI. Conclusion

Respirators are essential protective equipment for workers in a wide range of industries, yet their availability and affordability may be placed in jeopardy by thousands of marginal lawsuits. The surge in claims against respirator manufacturers is staggering, particularly when considering the absence of a mass recall. These claims are not based upon a flaw in the respirator, but are part of an ever-broadening net seeking a solvent bystander to take on the liability of now-bankrupt companies that manufactured asbestos-containing products. These often vague, add-on claims to complaints name respirator manufacturers among dozens of defendants—the others of which either manufactured products containing asbestos or had asbestos on their premises—attack the protector rather than the potential wrongdoer.

As this Article shows, three federal agencies test and certify the respirators, allow no deviation from the certified design and labeling without prior approval, and require that employers provide their workers with specific respirators to protect them in the workplace. The design decisions and workplace requirements are based on a delicate balancing

²⁷⁶ *See id.*

between breathability and filtration intended to optimize protection while not discouraging use due to discomfort. Likewise, while labeling could contain a nearly infinite number of potential warnings, the agencies, following sound principles of effective communications, limit such content to emphasize and impart the most significant information for use by workers in their job environment. This comprehensive regulation of respiratory protective devices should give courts pause and sound guidance in determining whether such claims are sustainable under common law principles of regulatory compliance and federal preemption, particularly in light of tort law's encouragement of rescue and safety and sound public policy.

