

PROVIDING A SAFE HARBOR FOR THOSE WHO PLAY BY THE  
RULES: THE CASE FOR A STRONG REGULATORY COMPLIANCE  
DEFENSE

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I. INTRODUCTION

On September 25, 2003, a fire broke out at the National Health Care (NHC) nursing home facility in Nashville, Tennessee, causing sixteen deaths and a number of injuries from smoke inhalation.<sup>1</sup> Thirty-two victims subsequently filed suit against the nursing home, alleging that NHC was negligent for failing to install sprinklers in its facility.<sup>2</sup> This claim was made notwithstanding the fact that applicable federal, state, and local safety regulations did not require the installation of sprinklers in this particular type of building, and notwithstanding that the NHC facility had been inspected by state fire inspectors just months before the fire and was found to be in compliance with all requirements of the fire code.<sup>3</sup> NHC eventually settled these lawsuits in order to avoid the uncertainty and expense of further litigation.

The NHC case illustrates how good-faith compliance with applicable safety regulations provides businesses with almost no protection against potentially devastating tort liability. The problem is with the legal rule that governs compliance with government regulations. In effect, most courts treat a defendant's

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<sup>1</sup> See *infra* Part V. The authors represented NHC in the ensuing Nashville fire litigation. The views expressed in this article are the authors' alone and do not necessarily reflect the views of NHC or Bass, Berry & Sims PLC.

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

compliance with governmental regulations as evidence of due care, but allow the jury to find that a defendant was negligent, notwithstanding his or her compliance with legislative or administrative regulations.<sup>4</sup> We shall refer to this as the “traditional approach” to regulatory compliance.

The traditional approach originated in *Grand Trunk Railway Co. of Canada v. Ives*,<sup>5</sup> decided by the United States Supreme Court in the late nineteenth century.<sup>6</sup> Later, § 288C of the Second Restatement of Torts endorsed this version of the rule, declaring that compliance with safety regulations was not conclusive evidence that a defendant exercised due care.<sup>7</sup> The American Law Institute is currently in the process of drafting the Third Restatement of Torts, and the revised version of the regulatory compliance defense is substantially similar to that of the Second Restatement.<sup>8</sup>

In our view, there are many problems with the traditional approach. First, legislatures and administrative agencies have more expertise than lay juries when it comes to determining efficient levels of safety, but the traditional approach allows lay juries to second guess them. Second, under our constitutional system, legislative bodies and administrative agencies, not courts, are responsible for making resource allocation and other policy decisions. Therefore, courts should accept the trade-offs that are often embodied in safety regulations instead of allowing plaintiffs to use the litigation process to substitute their own policy choices for those of legislative bodies and administrative agencies. Third, the

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<sup>4</sup> See, e.g., *Tufariello v. Long Island R.R. Co.*, 458 F.3d 80, 91 (2d Cir. 2006) (holding that railroad’s compliance “with OSHA regulations regarding hearing protection . . . does not conclusively demonstrate that [it] was free from negligence”); *Martinez de Jesus v. P.R. Elec. Power Auth.*, 256 F. Supp. 2d 122, 126–27 (D.P.R. 2003) (declaring that compliance by electric utility with electric line clearances established by National Electrical Safety Code does not entitle it to judgment as a matter of law); *Bayer v. Crested Butte Mountain Resort, Inc.*, 960 P.2d 70, 78–79 (Colo. 1998) (finding that standards of conduct defined by statute, ordinance or regulation are usually minimum standards that do not prevent a court from concluding that a reasonable person would take additional precautions); *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997) (stating that compliance with federal automobile safety standards is merely “a factor for the jury to consider in deciding” whether an automobile’s design is defective or not); *Cronk v. Iowa Power & Light Co.*, 138 N.W.2d 843, 848 (Iowa 1965) (ruling that electric utility’s “compliance with the standards furnished by the National Electrical Safety Code was not conclusive” on the question of whether it used due care in the location of electric power lines); *In re Flood Litig.*, 607 S.E.2d 863, 877 (W. Va. 2004) (concluding that compliance with state and federal mining regulations “does not give rise to a presumption that the landowner acted reasonably . . . in his or her extraction and removal activities”).

<sup>5</sup> 144 U.S. 408 (1892).

<sup>6</sup> See Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2049–50 (2000).

<sup>7</sup> RESTATEMENT (SECOND) OF TORTS § 288C (1965).

<sup>8</sup> RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16 (Proposed Final Draft 2007).

traditional approach wrongly assumes that government safety regulations merely set minimum standards, while, in reality, modern regulations typically reflect state-of-the-art standards. Thus, by adding jury-created safety standards on top of existing regulatory requirements, the traditional approach to regulatory compliance adds to the cost of doing business without achieving significant safety gains. Fourth, the traditional approach to regulatory compliance undermines the principle of uniform application of regulatory standards. Because jury verdicts are seldom consistent, business entities are often subjected to nonuniform safety “standards.” Finally, the traditional approach deters useful economic activity by imposing potentially crushing tort liability upon those who have complied in good faith with regulatory standards.

Part II of this Article examines the traditional approach to the regulatory compliance defense, beginning with the Supreme Court’s opinion in *Grand Trunk Railway Co. of Canada v. Ives*, and proceeding to the Restatement (Second) § 288C and the Restatement (Third) of Torts: Liability for Physical Harm § 16. In Part III, we discuss a number of cases that explicitly recognize a strong regulatory compliance defense, as well as cases that achieve a similar objective by expressly or impliedly applying the Second Restatement’s § 16, comment (a) exception. Part IV reviews some of the arguments that support a stronger regulatory compliance defense. These include: (1) the institutional competence argument, (2) the separation of powers argument, (3) the regulatory efficiency argument, (4) the nonuniform standards argument, and (5) the overdeterrence argument. In Part V, we focus on nursing home regulation to see what impact a stronger regulatory compliance defense would have on this socially useful industry. Finally, in Part VI, we set forth a proposed alternative to the current version of Restatement (Third) of Torts: Liability for Physical Harm § 16.

## II. ORIGINS OF THE TRADITIONAL APPROACH TO REGULATORY COMPLIANCE

The traditional approach to regulatory compliance assumes that government regulations establish only minimum standards of safety.<sup>9</sup> Consequently, courts treat compliance with governmental regulations as merely evidence of due care and allow a jury to hold a defendant negligent even though he or she has complied with applicable legislative or administrative regulations. This approach was first proposed by the United States Supreme Court in *Grand Trunk Railway Co. of Canada v. Ives* and was later adopted by the drafters of the Second and Third Restatement of Torts.<sup>10</sup>

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<sup>9</sup> See Teresa Moran Schwartz, *The Role of Federal Safety Regulations in Products Liability Actions*, 41 VAND. L. REV. 1121, 1135–36 (1988).

<sup>10</sup> See *supra* notes 7–8.

## A. Grand Trunk Railway Co. of Canada v. Ives

One of the first cases to consider whether compliance with safety regulations barred tort liability was *Grand Trunk Railway Co. of Canada v. Ives*, decided by the Supreme Court in 1892.<sup>11</sup> In that case, the decedent, Elijah Smith, and his wife were struck and killed by a train at a railroad crossing in the city of Detroit.<sup>12</sup> The administrator of Mr. Smith's estate brought a negligence action against the railroad, arguing that it should have placed a flagman at the crossing or provided gates to protect travelers from oncoming trains.<sup>13</sup> The jury found in favor of the plaintiff and the defendant-railroad appealed.<sup>14</sup>

One of the principal issues on appeal was the validity of a jury instruction declaring that because the crossing was a busy one located in a large city, the jury could find that it was reasonable to expect the railroad company to provide additional safeguards beyond those required by statute to protect persons using the crossing.<sup>15</sup> The railroad contended that it was not required to take extra precautions "because the whole subject of signals and flagmen, gates, etc., at crossings in Michigan is regulated by statute."<sup>16</sup> According to the railroad, the statute provided that the railroad commissioner was responsible for determining whether or not a flagman should be posted at a particular railroad crossing.<sup>17</sup> Thus, the railroad argued that its failure to provide a flagman was not negligent unless the railroad commissioner determined that one was necessary at the crossing where the accident occurred.<sup>18</sup> In this case, the railroad commissioner had not ordered the railroad to provide a flagman at this crossing.<sup>19</sup>

Responding to this argument, the Court reviewed a number of railroad crossing cases,<sup>20</sup> and determined that all of them supported the principle that the duty of reasonable care might require railroad companies to do more than merely "comply with all statutory requirements in the manner of signals, flagmen, and other warnings of danger at public crossings."<sup>21</sup> As the Court pointed out, "neither the legislature nor railroad commissioners can arbitrarily determine in advance what shall constitute ordinary care or reasonable prudence in a railroad company at a crossing, in every particular case which may afterwards arise."<sup>22</sup> Furthermore,

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<sup>11</sup> 144 U.S. 408 (1892).

<sup>12</sup> *Id.* at 411.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 410.

<sup>15</sup> *Id.* at 419–20.

<sup>16</sup> *Id.* at 422.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *See id.* at 423–27 (discussing three cases: *Battishill v. Humphrey*, 31 N.W. 894 (Mich. 1887); *Guggenheim v. Lake Shore & M.S. Ry. Co.*, 33 N.W. 161 (Mich. 1887); and *Freeman v. Duluth, S. S. & A. Ry. Co.*, 41 N.W. 872 (Mich. 1889)).

<sup>21</sup> *Ives*, 144 U.S. at 427.

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

“each case must stand upon its own merits, and be decided upon its own facts and circumstances.”<sup>23</sup> Accordingly, the Court upheld the trial court’s jury instruction that statutory compliance did not necessarily equal due care<sup>24</sup> and affirmed the jury verdict for the decedent.<sup>25</sup>

Legal commentators often identify *Ives* as the source of the traditional approach to regulatory compliance.<sup>26</sup> To be sure, there is language in the opinion that is consistent with this approach. For example, the Court in *Ives* agreed with an instruction that advised the jury that it could find that the railroad company was negligent if it failed to adopt safeguards in addition to those required by statute.<sup>27</sup> The Court also declared that the railroad may be found negligent “even though it may have complied literally with the terms of a statute prescribing” safety requirements for railroad crossings.<sup>28</sup>

### B. *The Restatement (Second) of Torts § 288C*

Section 288C of the Second Restatement of Torts, published by the American Law Institute in 1965, also adopted the traditional approach. The black letter text of § 288C declares that “[c]ompliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.”<sup>29</sup>

However, comment (a) to the Restatement (Second) of Torts § 288C contains an important qualification to the general rule set forth in the black letter text of § 288C. Comment (a) declares:

Where a statute, ordinance or regulation is found to define a standard of conduct for the purposes of negligence actions, as stated in §§ 285 and 286, the standard defined is normally a minimum standard, applicable to the ordinary situations contemplated by the legislation. This legislative or administrative minimum does not prevent a finding that a reasonable man would have taken additional precautions where the situation is such as to call for them. Thus the enactment of an automobile speed limit of forty miles an hour does not mean that the driver is free to proceed always at that speed, and he may be required to slow down to fifteen miles an hour, or even to stop, where traffic conditions require it. Likewise the requirement that a hand signal be given by a driver who is

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<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 434.

<sup>26</sup> See, e.g., Rabin, *supra* note 6; Ashley W. Warren, *Compliance with Governmental Regulatory Standards: Is It Enough to Immunize a Defendant from Tort Liability?*, 49 BAYLOR L. REV. 763, 773–74 (1997); Paul Dueffert, Note, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 180–82 (1989).

<sup>27</sup> *Ives*, 144 U.S. at 420.

<sup>28</sup> *Id.* at 420–21.

<sup>29</sup> RESTATEMENT (SECOND) OF TORTS § 288C (1965).

about to make a left turn does not confer immunity upon a driver who makes the signal but is otherwise negligent in making the turn, as by cutting the corner; and where the driver has reason to know that his signal has not been observed, or for some other reason is not sufficient, he may be required to do more, as for example to blow his horn or to refrain from making an immediate turn. Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion; but if for any reason a reasonable man would take additional precautions, the provision does not preclude a finding that the actor should do so.<sup>30</sup>

In other words, a court may determine that compliance with a regulatory or statutory standard constitutes due care as a matter of law when there are no special circumstances that would require the defendant to take additional precautions.<sup>31</sup> Thus, in the absence of special circumstances, compliance with a regulatory standard should constitute reasonable care. Unfortunately, the logic of this interpretation has escaped many courts.<sup>32</sup>

*C. Restatement (Third) of Torts: Liability for Physical Harm § 16*

The Proposed Final Draft of § 16 of the Restatement (Third) of Torts: Liability for Physical Harm, which will replace the Restatement of Torts § 288C if it is adopted by the American Law Institute, has retained the basic approach of the Second Restatement.<sup>33</sup> Section 16 (a) declares that “[a]n actor's compliance with a pertinent statute, while evidence of nonnegligence, does not preclude a finding that the actor is negligent under section 3 for failing to adopt precautions in addition to those mandated by the statute.”<sup>34</sup>

Comment (c) states that a court may properly conclude that precautions beyond those specified in a statute are called for “when the [regulation] does not specifically address the safety problem at issue.”<sup>35</sup> For example, a statute that requires a motorist to signal before turning left is not relevant to the issue of whether he or she is negligent in cutting the corner while making the left turn.<sup>36</sup> In these circumstances, finding the motorist to be negligent, the court would not

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<sup>30</sup> *Id.* § 288C cmt. a.

<sup>31</sup> See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 36, at 233 (5th ed. 1984); Dueffert, *supra* note 26, at 186.

<sup>32</sup> See *supra* note 4.

<sup>33</sup> See also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4(b) (1998). The regulatory compliance provision in the Third Restatement on Products Liability is very similar to § 16.

<sup>34</sup> RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16(a) (Proposed Final Draft 2007).

<sup>35</sup> *Id.* § 16 cmt. c.

<sup>36</sup> *Id.*

question the legislative body's judgment in any way if the motorist's negligent act were not addressed by the statute.<sup>37</sup>

Comment (d) points out that additional precautions also may be necessary despite compliance with a safety regulation when the regulation "undertakes to establish only minimum standards."<sup>38</sup> In requiring additional precautions, a court recognizes that legislators intended to identify only some of the precautions that a reasonable person would take.<sup>39</sup>

Comment (e) adds that additional precautions may be necessary "despite the actor's compliance with the statute . . . if the precaution relates to some unusual situation beyond the generality of situations anticipated by the statute itself."<sup>40</sup> For example, when a statute establishes a highway speed limit of 55 miles per hour, it is obviously related to determining what a safe vehicle speed should be when highway conditions are ordinary.<sup>41</sup> "If adverse weather or heavy traffic makes speeds as high as 55 miles per hour unwise, a finding that the motorist is negligent who drives at 55 miles per hour does not call into question the general judgment rendered by the legislature."<sup>42</sup>

On the other hand, comment (f) declares that "[w]hen the statute directly addresses the particular safety problem before the court, when the regulatory scheme evidently seeks to identify all the precautions called for by the general negligence [standard of reasonable care], and when the particular case involves no unusual circumstances, the court may conclude that the [defendant's] compliance with the statute shows that the [defendant was not negligent]."<sup>43</sup> This is particularly true when the statute is thorough and comprehensive and when applying compliance with the statute as a defense would impose "a uniform liability standard [in order] to simplify litigation and provide parties with appropriate guidance as to what precautions are expected of them."<sup>44</sup> As comment (f) recognizes, in these circumstances, a safety regulation should set the standard of care when the regulation is intended to be more than a minimum and when there are no special circumstances in the case that might call for additional precautions.<sup>45</sup> This approach is analogous to the Restatement (Second) of Torts § 288C comment (a).<sup>46</sup>

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.* § 16 cmt. d.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* § 16 cmt. e.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* § 16 cmt. f.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> Compare *id.*, with RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965).

## III. OVERVIEW OF THE CASE LAW

Although a majority of courts have embraced the traditional approach to regulatory compliance, a significant minority have given greater deference to governmental safety standards in negligence cases. This Part examines: (A) cases that explicitly recognize a strong regulatory compliance defense, (B) cases that expressly apply the provisions of the Restatement (Second) § 288C comment (a), and (C) cases that apply § 288C comment (a) by implication.

*A. Cases Explicitly Holding That Compliance with a Regulatory Standard Constitutes Reasonable Care*

Some courts have held that compliance with a regulatory standard constitutes due care as a matter of law.<sup>47</sup> For example, in *Leach v. Mountain Lake*, the estate of a man who drowned while attempting to save another member of a boating party brought a negligence action against the marina that rented the boat.<sup>48</sup> The boat's passengers included the decedent, a friend, and five children.<sup>49</sup> While they were on the lake, "a strong gust of wind rocked the boat" and caused one of the children to fall into the water.<sup>50</sup> The decedent drowned while attempting to rescue the child.<sup>51</sup>

The decedent's estate alleged, inter alia, that the marina was negligent for failing to equip the boat with "boat hooks, ropes, and a ring life buoy" even though these items were not required by statute.<sup>52</sup> The trial court granted summary judgment for the defendant on this claim because it was reluctant to impose a duty regarding navigational matters that differed from the standard of care that was prescribed by those in charge of navigational policy.<sup>53</sup> The Eighth Circuit agreed,

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<sup>47</sup> *E.g.*, *Alvarado v. J.C. Penny Co.*, 713 F. Supp. 1389, 1392 (D. Kan. 1989); *Jefferson County Sch. Dist. R-1 v. Gilbert*, 725 P.2d 774, 776–779 (Colo. 1986); *Josephson v. Meyers*, 429 A.2d 877, 880–81 (Conn. 1980); *Teichman v. Potashnick Constr., Inc.*, 446 S.W.2d 393, 397–98 (Mo. 1969); *see also Leach v. Mountain Lake*, 120 F.3d 871, 873–74 (8th Cir. 1997); *Sparks v. Am. Mut. Liab. Ins. Co.*, 287 So. 2d 654, 656 (La. Ct. App. 1973); *cf. Bernstein v. Reforzo*, 379 A.2d 181, 186 (Md. Ct. Spec. App. 1977) (finding regulatory and industry standard intact where there were not any special circumstances that required additional care); *Leisy v. N. Pac. Ry. Co.*, 40 N.W.2d 626, 629–30 (Minn. 1950) (stating that "requirements prescribed by statute . . . are specific and minimum requirements, which may satisfy the requirements of due care, but not necessarily so"); *Gigliotti v. N. Y., Chi. & St. Louis R.R. Co.*, 157 N.E.2d 447, 451 (Ohio Ct. App. 1958) (noting that absent extraordinary hazards "there is no basis for requiring extrastatutory warnings"). *Contra Hostetler v. Consol. Rail Corp.*, 123 F.3d 387, 390–92 (6th Cir. 1997); *Sulpher Springs Valley Elec. Coop., Inc. v. Verdugo*, 481 P.2d 511, 518–19 (Ariz. Ct. App. 1971).

<sup>48</sup> *Leach*, 120 F.3d at 872–73.

<sup>49</sup> *Id.* at 882.

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

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 873–74.

<sup>53</sup> *Id.* at 874.

declaring that “duty or ordinary care with respect to the proper equipment of boats imposes no requirements beyond those enumerated in the pertinent statutes and regulations.”<sup>54</sup>

The New Jersey Supreme Court also applied a deferential view toward governmental regulations in *Contey v. New Jersey Bell Telephone Co.*<sup>55</sup> In *Contey*, the plaintiff was injured when she “missed an unmarked turn in the road and struck a utility pole.”<sup>56</sup> The pole stood about “ten inches from the curb line at the beginning of an S-curve in the road.”<sup>57</sup> The plaintiff sued the telephone company, which owned the pole, the electric company, which had obtained “permission to locate its wires on the pole,” and various government entities.<sup>58</sup> The trial court dismissed the plaintiff’s claim against the utility company, and the intermediate appellate court affirmed.<sup>59</sup> The New Jersey Supreme Court upheld the decision of the lower courts.<sup>60</sup>

Although the court agreed that utility companies had a duty to foresee that motorists might leave the traveled portion of the highway, it declared that governmental bodies and highway planners were in the best position to determine how utilities should satisfy that duty.<sup>61</sup> “In this case, the ordinance required that the utility place its poles within eighteen inches of the curb, presumably to facilitate street lighting.”<sup>62</sup> Although this requirement increased the risk of collisions—indeed, “collisions with that [very pole] had occurred twice before”—the court felt that the government entities, not the utility, should be held responsible for creating this condition.<sup>63</sup> Consequently, the court concluded that “[w]hen a public utility has located its poles or structures within public rights-of-way in accordance with the location and design authorized by the public body, the utility, in the absence of countermanding directions from the public body, should have no further duty to protect the motoring public.”<sup>64</sup>

A Colorado court engaged in a similar line of reasoning in *Jefferson County School District R-1 v. Gilbert*.<sup>65</sup> In that case, a kindergarten student and her parents brought suit against a motorist, the school district, and the City of Arvada for injuries that the student sustained from being struck by an automobile while walking home from school.<sup>66</sup> Stop signs at the intersection where the accident occurred required automobiles traveling north or south to stop but permitted east-

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<sup>54</sup> *Id.*

<sup>55</sup> 643 A.2d 1005 (N.J. 1994).

<sup>56</sup> *Id.* at 1006.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* at 1010.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 1009–10.

<sup>64</sup> *Id.* at 1010.

<sup>65</sup> 725 P.2d 774 (Colo. 1986).

<sup>66</sup> *Id.* at 774–75.

west traffic to proceed without stopping.<sup>67</sup> In this case, the driver, who was traveling north, stopped at the stop sign at the south side of the intersection, but failed to yield the right-of-way and struck the schoolgirl in the northern crosswalk.<sup>68</sup>

The plaintiffs “contended that the city was negligent in designing, constructing and maintaining the intersection.”<sup>69</sup> In particular, they claimed the intersection was “confusing and dangerous” and that it could have been made safer by additional safety precautions, such as the installation of a traffic signal.<sup>70</sup> The city moved for summary judgment, arguing “that the intersection . . . and crosswalks were designed and maintained in accordance with ‘nationally recognized engineering standards.’”<sup>71</sup> The trial court agreed and granted summary judgment, thereby provoking an appeal from the plaintiffs.<sup>72</sup> The intermediate appellate court affirmed the lower court’s decision and this decision was in turn upheld by the Colorado Supreme Court.<sup>73</sup>

The Colorado Supreme Court noted that the state highway department had adopted the 1971 edition of the Federal Highway Administration’s *Manual on Uniform Traffic Control Devices for Streets and Highways (Manual)* along with its own 1975 supplement to the *Manual*.<sup>74</sup> The *Manual* cautioned against installing traffic signals at intersections except on the basis of an engineering study of the location and identified eight situations that would warrant the installation of a signal.<sup>75</sup> In this case, the state highway department had found no evidence that installation of a traffic signal was justified according to the criteria set forth in the *Manual*.<sup>76</sup> According to the court, “[b]ecause perfect safety is not realistically attainable, local governments are required to achieve only a reasonable level of safety in conformance with section 42-4-503(1) and the national engineering standards set forth in the *Manual*.”<sup>77</sup> Consequently, the Colorado Supreme Court affirmed summary judgment for the city.<sup>78</sup>

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<sup>67</sup> *Id.* at 775.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 779.

<sup>74</sup> *Id.* at 777.

<sup>75</sup> *Id.* at 779.

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

*B. Cases Expressly Applying the Second Restatement's Comment (a) Exception*

A number of courts have expressly relied on comment (a) in their analysis of regulatory compliance issues.<sup>79</sup> For example, in *Beatty v. Trailmaster Products, Inc.*, the plaintiff, whose husband died after being involved in a motor vehicle collision with a Ford Bronco, sued the manufacturer and distributors of a “lift kit” that the Bronco’s owner had used to raise the Bronco’s front bumper from nineteen inches above the ground to approximately twenty-four inches above the ground.<sup>80</sup> The plaintiff alleged that the higher bumper caused the Bronco to ride up onto the hood of her husband’s Honda Civic, crushing the front part of the car, thus pinning his legs in the driver’s side footwell and ultimately causing his death.<sup>81</sup>

The defendants contended that they should not be held liable because the Bronco’s bumper did not exceed the maximum height provided by a state statute.<sup>82</sup> The trial court agreed and granted summary judgment in favor of the defendants.<sup>83</sup> The statute in question established “a maximum bumper height of twenty-eight inches for multipurpose vehicles like the 1982 Bronco.”<sup>84</sup> The defendants asserted that the legislature, when it adopted this maximum bumper height standard, “clearly contemplated possible hazards associated with disparate bumper heights in vehicle collisions.”<sup>85</sup> Furthermore, the defendants alleged that because “the plaintiff ‘failed to produce evidence of any special circumstances or dangers beyond those addressed by the statute, compliance with the statute precludes a finding of defect or negligence’ as a matter of law.”<sup>86</sup>

On appeal, the Maryland Court of Appeals agreed that the state legislature had taken into account the danger posed by mismatched bumper collisions when it adopted the bumper height statute in question.<sup>87</sup> The court also observed that “the statutory scheme contemplate[d] varying bumper heights [among different] classes of vehicles.”<sup>88</sup> Thus, the court concluded, “the legislative scheme plainly contemplates that bumper mismatch between different classes of vehicles is an inevitable occurrence and, as such, sanctioned by the legislature as a matter of public policy.”<sup>89</sup> The Maryland court acknowledged that “compliance with a

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<sup>79</sup> See, e.g., *Ramirez v. Plough, Inc.*, 863 P.2d 167, 172 (Cal. 1993); *Jones v. Hittle Serv., Inc.*, 549 P.2d 1383, 1389 (Kan. 1976); *Beatty v. Trailmaster Prod., Inc.*, 625 A.2d 1005, 1014 (Md. 1993); *Montgomery v. Royal Motel*, 645 P.2d 968, 970 (Nev. 1982) (pointing to statutory enactments as a minimum standard, though additional precautions may be necessary), *withdrawn*, 660 P.2d 114 (Nev. 1983).

<sup>80</sup> *Beatty*, 625 A.2d at 1007–08.

<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at 1008.

<sup>83</sup> *Id.* at 1010.

<sup>84</sup> *Id.* at 1008.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* (quoting the defendant’s motion for summary judgment).

<sup>87</sup> *Id.* at 1013.

<sup>88</sup> *Id.* at 1013–14.

<sup>89</sup> *Id.* at 1014.

statute [would not] preclude a finding of negligence [in cases] where a reasonable person would take extra precautions.”<sup>90</sup> However, the court also pointed out that the Restatement’s comment (a), as well as a number of other cases, had declared 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.”<sup>91</sup> Based on this analysis, and because the court found that there were no special circumstances in the case before it that would prevent the application of the statutory standard as a matter of law, the court affirmed the trial court’s summary judgment in favor of the defendants.<sup>92</sup>

Similarly, the Kansas Supreme Court followed comment (a)’s approach in *Jones v. Hittle Service, Inc.*<sup>93</sup> *Jones* arose out of a propane gas explosion that killed three people.<sup>94</sup> The underground line that supplied liquefied propane gas to one of the plaintiffs’ buildings apparently developed a leak, and the explosion occurred when one of the victims lit a cigarette.<sup>95</sup> The plaintiffs argued that the defendants were negligent because they had not put a sufficient amount of odorant in the gas.<sup>96</sup>

Responding to this argument, the Supreme Court of Kansas noted that the Kansas state fire marshal was statutorily authorized to make rules and regulations for the storage, use, manufacture, and sale of petroleum products and inflammable fluids.<sup>97</sup> Pursuant to this authority, in 1966, the state fire marshal promulgated a regulation that established a standard of one pound of ethyl mercaptan odorant per 10,000 gallons of liquefied petroleum gas.<sup>98</sup> This standard was taken verbatim from the National Fire Protection Association’s Standard No. 58.<sup>99</sup> The parties agreed that the gas supplied by the defendants complied with this standard.<sup>100</sup>

The defendants contended that compliance with the regulatory standard on odorant levels conclusively established that they were not negligent and that the gas was not defective as far as the level of odorization was concerned.<sup>101</sup> Citing the Restatement (Second) of Torts § 288C, the court rejected the proposition that compliance with government safety regulations was a complete defense to negligence.<sup>102</sup> However, relying on comment (a),<sup>103</sup> the court declared that compliance with regulatory standards was “evidence of due care” and “may be

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<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> 549 P.2d 1383 (Kan. 1976).

<sup>94</sup> *Id.* at 1387.

<sup>95</sup> *Id.* at 1387–88.

<sup>96</sup> *Id.* at 1388.

<sup>97</sup> *Id.* at 1389 (citing KAN. STAT. ANN. § 31-207 (1966)).

<sup>98</sup> *Id.* (citing KAN. ADMIN. REGS. § 22-8-2 (1966)).

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *See id.*

conclusive in the absence of a showing of special circumstances.”<sup>104</sup> Furthermore, the court agreed that “a manufacturer should be able to rely on such standards in the absence of actual or constructive notice that they are inadequate.”<sup>105</sup>

Although the plaintiffs’ expert witness argued that the odorant level required by the state regulation was insufficient, he did not support his opinion with any empirical data.<sup>106</sup> The court rejected this unfounded opinion and declared that the regulatory requirement established the appropriate standard of care.<sup>107</sup> Specifically, the court stated:

We do not think a reasonable jury could give credence to plaintiffs’ expert opinion testimony on this issue when set against the universally accepted legislative standard. There were no special circumstances here in the Smiths’ proposed use of the gas which would have put the sellers on notice that more odorant than usual would be required. Neither had there been any industry-wide or individual corporate experience showing that the legislative standard was inadequate.<sup>108</sup>

Accordingly, the Kansas Supreme Court affirmed summary judgment in favor of the defendants.<sup>109</sup>

Finally, in *Ramirez v. Plough, Inc.*,<sup>110</sup> the California Supreme Court relied upon § 288C, comment (a) to make a thoughtful and persuasive argument in favor of greater judicial deference to regulatory decision making. In that case, the plaintiff, a four-month-old child, brought suit against the manufacturer of a children’s aspirin product for failing to include Spanish-language warnings on the bottle.<sup>111</sup> The plaintiff alleged that he contracted Reye’s Syndrome after consuming the defendant’s aspirin.<sup>112</sup> The defendant’s aspirin packages contained a warning in English about the symptoms and risks of Reye’s Syndrome.<sup>113</sup> However, the plaintiff’s mother could not read English, and she was allegedly not aware of the risk of Reye’s Syndrome.<sup>114</sup> The trial court granted summary judgment in the defendant’s favor; however, this decision was reversed by the intermediate appellate court.<sup>115</sup> On appeal, the California Supreme Court reinstated the trial court’s judgment in favor of the defendants.<sup>116</sup>

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<sup>104</sup> *Id.* at 1390.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Id.* at 1390–91.

<sup>108</sup> *Id.* at 1391.

<sup>109</sup> *Id.* at 1396.

<sup>110</sup> 863 P.2d 167 (Cal. 1993).

<sup>111</sup> *Id.* at 169–70.

<sup>112</sup> *Id.* at 170.

<sup>113</sup> *Id.* at 169.

<sup>114</sup> *Id.* at 169–70.

<sup>115</sup> *Id.* at 170.

<sup>116</sup> *Id.* at 178.

In arriving at its decision, the California Supreme Court observed that the Food and Drug Administration (FDA) extensively regulated aspirin and other nonprescription drugs.<sup>117</sup> The court noted that the FDA regulation pertinent to the plaintiff's claims required that manufacturers provide full English labeling for nonprescription drugs, but it did not require labeling in any other language except for drugs "distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English . . . ."<sup>118</sup> The court noted that California's regulations for nonprescription drug labeling had similar requirements.<sup>119</sup>

The defendant argued that "the standard of care for packaging and labeling nonprescription drugs, and in particular the necessity or propriety of foreign-language label and package warnings, has been appropriately fixed by the dense layer of state and federal statutes and regulations that control virtually all aspects of the marketing of its products."<sup>120</sup> In response to this argument, the court observed that compliance with regulatory standards did not ordinarily preclude a finding that a reasonable person would take additional precautions under certain circumstances, the court acknowledged that

there is some room in tort law for a defense of statutory compliance. Where the evidence shows no unusual circumstances, but only the ordinary situation contemplated by the statute or administrative rule, then "the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion . . . ."<sup>121</sup>

The court went on to say that defining the circumstances under which warnings or other information should be provided in a foreign language was "a task for which legislative and administrative bodies are particularly well suited."<sup>122</sup> The court also noted that the California Legislature had "already performed this task in a variety of different contexts, enacting laws to ensure that California residents are not denied important services or exploited because they lack proficiency in English."<sup>123</sup> This, according to the court, suggested that the Legislature and FDA had "deliberately chosen not to require that manufacturers also include warnings in foreign languages."<sup>124</sup> The court concluded by declaring:

To preserve that uniformity and clarity [desired by the FDA in nonprescription drug warnings], to avoid adverse impacts upon the

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<sup>117</sup> *Id.* at 173.

<sup>118</sup> *Id.* (quoting 21 C.F.R. § 201.15(c)(1) (1993)).

<sup>119</sup> *Id.* at 174 (citing CAL. HEALTH & SAFETY CODE § 25900 (1993)).

<sup>120</sup> *Id.* at 172–73.

<sup>121</sup> *Id.* at 172 (quoting RESTATEMENT (SECOND) OF TORTS § 288C cmt. a (1965)).

<sup>122</sup> *Id.* at 174.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at 175.

warning requirements mandated by the federal regulatory scheme, and in deference to the superior technical and procedural lawmaking resources of legislative and administrative bodies, we adopt the legislative/regulatory standard of care that mandates nonprescription drug package warnings in English only.<sup>125</sup>

*C. Cases Implicitly Applying the Second Restatement's Comment (a) Exception*

Other courts have followed the reasoning of § 288C comment (a) without actually mentioning it by name.<sup>126</sup> For example, in *Josephson v. Meyers*, the plaintiff was injured when she was struck by an automobile while attempting to cross a four-lane parkway after exiting a school bus.<sup>127</sup> She alleged that the operator of the school bus was negligent in discharging the plaintiff on the north side of the parkway where she had to cross four lanes of traffic, when he could have discharged her on the south side of the parkway and avoided this risk.<sup>128</sup> The trial court's charge to the jury removed this theory of negligence from its consideration.<sup>129</sup> This decision was affirmed on appeal.<sup>130</sup>

In support of its decision to affirm the trial court's jury instructions, the Connecticut Supreme Court pointed out that the school bus operator complied with the requirements of a state statute entitled "Operators' Duties on Stopping Bus."<sup>131</sup> After making this observation, the Court declared, "Although it is true that compliance with a statute does not necessarily preclude a finding of negligence, where the facts are similar to those contemplated by the statute and no special circumstances or dangers are present, a defendant satisfies his duty of care by complying with the statute."<sup>132</sup>

The court went on to note that the statutory scheme entitled "Operators' Duties on Stopping Bus" specifically contemplated that "students [leaving] a school bus may have to cross the road in order to get home."<sup>133</sup> Moreover, according to the court, the plaintiff had failed to offer any evidence to prove that, "at the time of the accident there were any unusual circumstances which would [have required the driver] to deviate from his assigned route."<sup>134</sup> Therefore, the

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<sup>125</sup> *Id.* at 177.

<sup>126</sup> *See, e.g.*, *Josephson v. Meyers*, 429 A.2d 877, 880–881 (Conn. 1980); *Leisy v. N. Pac. Ry. Co.*, 40 N.W.2d 626, 629–30 (Minn. 1950); *Contey v. N.J. Bell Tel. Co.*, 643 A.2d 1005, 1009–1010 (N.J. 1994); *Gigliotti v. N.Y., Chi. & St. Louis R.R. Co.*, 157 N.E.2d 447, 451 (Ohio Ct. App. 1958).

<sup>127</sup> *Josephson*, 429 A.2d at 878–79.

<sup>128</sup> *Id.* at 879–80.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 883.

<sup>131</sup> *Id.* at 880 n.4 (citing CONN. GEN. STAT. § 14-277 (1980)).

<sup>132</sup> *Id.* at 880–81.

<sup>133</sup> *Id.* at 881.

<sup>134</sup> *Id.*

court concluded, compliance with the statutory requirements was sufficient to satisfy the school bus operator's duty of care, and the trial court was correct in taking this issue away from the jury.<sup>135</sup>

In railroad crossing cases, various courts have held that a railroad satisfies its duty of reasonable care when it complies with regulatory requirements relating to warning devices and other safety precautions at railroad crossings.<sup>136</sup> These cases have declared that additional protective measures are required only if a crossing is "extra-hazardous," that is, more dangerous than an ordinary crossing.<sup>137</sup>

*Gigliotti v. New York, Chicago & St. Louis Railroad Co.* illustrates this principle.<sup>138</sup> In *Gigliotti*, the plaintiff was injured when his automobile struck a diesel locomotive train at an intersection.<sup>139</sup> The jury awarded damages to the plaintiff and the railroad company appealed.<sup>140</sup> The accident occurred at 4:00 a.m. at a crossing that serviced a municipal waterworks plant.<sup>141</sup> The locomotive engineer "stopped at the plant entrance" and after looking 2000 feet down the highway and "seeing no traffic," proceeded into the intersection at a slow rate of speed.<sup>142</sup> The plaintiff, traveling at a speed "of from 40 to 43 miles an hour," did not see the locomotive until it was too late to avoid colliding with it.<sup>143</sup>

The plaintiff alleged that the railroad company was negligent because it failed to "post a watchman at the highway crossing [to] warn approaching traffic" that a train was about to cross the intersection.<sup>144</sup> The court, however, rejected this claim of negligence:

Under specification of negligence . . . , it does not appear that any statute or order of the Public Utilities Commission of this state required a watchman or any other warning than that of the crossbuck sign (which was in proper place) for the crossing in question; and, in the absence of such requirement, "there is *ordinarily* \* \* \* no duty on a railroad to provide extrastatutory warnings at a grade crossing, where no order of the Public Utility Commission has provided for such warnings, if a driver in the exercise of ordinary care should be able to avoid colliding with a

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<sup>135</sup> *Id.*

<sup>136</sup> *E.g.*, *Leisy v. N. Pac. Ry. Co.*, 40 N.W.2d 626, 629–30 (Minn. 1950); *Gigliotti v. N. Y., Chi. & St. Louis R.R. Co.*, 157 N.E.2d 447, 451 (Ohio Ct. App. 1958).

<sup>137</sup> *E.g.*, *Hostetler v. Consol. Rail Corp.*, 123 F.3d 387, 392 (6th Cir. 1997); *Leisy*, 40 N.W.2d at 630 (Minn. 1950); *Hood v. N.Y., Chi. & St. Louis R.R. Co.*, 144 N.E.2d 104 (Ohio 1957) (using term "extremely hazardous"); *Gigliotti*, 157 N.E.2d at 451 (using term "more than ordinarily hazardous").

<sup>138</sup> *Gigliotti*, 157 N.E.2d at 447.

<sup>139</sup> *Id.* at 449.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 450.

<sup>142</sup> *Id.*

<sup>143</sup> *Id.*

<sup>144</sup> *Id.* at 451.

train that is being operated over the crossing in compliance with statutory requirements.<sup>145</sup>

In this case, the court determined that the crossing at the time of the accident “possessed no features which would make it more than ordinarily hazardous, and, under such circumstances, there was no basis” for claiming that the railroad had a duty under general negligence principles to provide additional warnings.<sup>146</sup> Consequently, the court reversed the lower court’s decision and held in favor of the railroad.<sup>147</sup>

The Supreme Court of Minnesota reached a similar conclusion in *Leisy v. Northern Pacific Railway Co.*<sup>148</sup> In that case, the plaintiff and his daughter were injured when their automobile struck the defendant’s train at a crossing.<sup>149</sup> The crossing was located in “a sparsely settled woods and lake region, [and] cross-buck signs” were clearly visible at least 400 feet from the tracks.<sup>150</sup> At trial, the judge refused to instruct the jury that it might take into account “the failure of the defendant to have a flagman at the crossing or to maintain gates, automatic signaling devices,” or other warning devices at the crossing “for the protection of persons approaching the tracks on the road.”<sup>151</sup> The jury reached a verdict in the railroad company’s favor.<sup>152</sup>

On appeal, the Minnesota Supreme Court acknowledged that there is no hard and fast rule in railroad crossing cases for determining whether statutory requirements constitute due care or whether additional precautions are required.<sup>153</sup> Furthermore, the court declared, where the evidence permits conflicting inferences of fact as to whether or not reasonable care required a railroad to take additional precautions, the question is one of fact for the jury.<sup>154</sup> However, the court added, “where the evidence permits only the inference that such additional precautions were not necessary in the exercise of due care, the question is one of law for the court, and in such a case the question should not be submitted to the jury.”<sup>155</sup> In this case, the court concluded that compliance with statutory safety standards constituted due care as a matter of law:

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<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 454.

<sup>148</sup> 40 N.W.2d 626 (Minn. 1950).

<sup>149</sup> *Id.* at 627.

<sup>150</sup> *Id.* at 627–28.

<sup>151</sup> *Id.* at 629.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.* (“Requirements prescribed by statute, or by administrative order under statutory authorization, are specific and minimum requirements, which may satisfy the requirements of due care, but not necessarily so; and where they do not, the actor must take such additional precautions as due care may require.”).

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

Due care did not require that defendant exercise any precautions at the crossing in addition to those prescribed by statute. In the country, where but a few persons pass over the tracks each day and where there are no interferences with hearing and sight, compliance with statutory requirements suffices. Extra or additional care must be exercised at what are called “extrahazardous,” or “peculiarly” and “unusually” dangerous crossings. Here, the evidence not only did not permit an inference of fact that the crossing was extrahazardous or peculiarly and unusually dangerous so as to require that precautions additional to the statutory *minima* be exercised, but, on the contrary, compelled as a matter of law decision that the crossing was not such.<sup>156</sup>

Accordingly, the Minnesota Supreme Court upheld the lower court’s judgment for the defendant.<sup>157</sup>

#### IV. POLICY ARGUMENTS FOR A STRONGER REGULATORY COMPLIANCE DEFENSE

For years, legal scholars have debated the proper relationship between government safety standards and tort law. Those who believe that courts should give greater deference to government safety standards generally make the following arguments: (1) legislatures and administrative agencies have greater expertise than courts in determining appropriate levels of public safety; (2) under our constitutional structure, the legislative and executive branches of government, and not the courts, are supposed to make important safety and risk allocation decisions; (3) because modern safety regulations typically embody optimal rather than minimum standards, superimposing tort law standards on top of existing regulatory requirements produces only minimal safety gains and often imposes great costs upon the regulated activity and upon society at large; (4) greater deference to government safety standards in negligence cases will promote fairness and uniform enforcement; and (5) providing a safe harbor for those who comply with government safety regulations offsets the tendency of tort law to overdeter activities that are socially useful but inherently risky. Each of these arguments will be discussed below in more detail.

##### A. *The Institutional Competence Argument*

The first, and most powerful, argument for greater judicial deference to regulatory standards is that legislative bodies and regulatory agencies are better equipped than courts to formulate effective safety standards.<sup>158</sup> This argument

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<sup>156</sup> *Id.* at 629–30 (citations omitted).

<sup>157</sup> *Id.* at 630.

<sup>158</sup> See Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 334–35 (1985).

relies on the fact that legislatures and administrative agencies usually employ professional staffs with the educational qualifications, training, and experience to understand the technical and economic aspects of safety regulation.<sup>159</sup>

Furthermore, when necessary, these staff members can also obtain assistance by commissioning studies or by soliciting advice from outside experts.<sup>160</sup> In addition, public hearings give the staff additional access to information and opinion. These hearings permit government officials, industry representatives, consumer groups, and ordinary members of the public to express their desires and concerns about proposed regulations. With the benefit of this input, legislators and administrators are better able to take into account a wide variety of interests when they formulate safety standards.<sup>161</sup>

Just as federal administrative agencies are usually well-equipped to develop state of the art safety standards, state and local agencies also have the capacity to formulate optimal standards. Even when they lack the resources and expertise of their federal counterparts, state and local regulators can look to national or consensus safety standards developed by testing laboratories such as Underwriters' Laboratories, professional associations such as the American Society for Mechanical Engineers or the Institute of Electrical and Electronics Engineers, nonprofit membership organizations such as National Fire Protection Association (NFPA), the American Society for Testing and Materials, and other standards-writing organizations such as the American National Standards Institute (ANSI).<sup>162</sup> For the most part, these national or consensus standards are optimal or state-of-the-art, not minimum, safety standards.<sup>163</sup>

In contrast, courts are not well suited to evaluate safety regulations, particularly if they involve technical issues or economic trade-offs.<sup>164</sup> In the first place, judges, and especially juries, seldom have the educational background and training to understand and evaluate technical or scientific data.<sup>165</sup> Second, because courts do not have independent investigative powers, they must rely on whatever information litigants choose to provide. Since, parties to a lawsuit have no

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<sup>159</sup> For example, the FDA's Center for Drug Evaluation and Research (CDER) has a staff of more than 1700 physicians, toxicologists, pharmacologists, epidemiologists, chemists, and statisticians to ensure the safety of prescription drugs, biologics and medical devices. See Daniel Carpenter & A. Mark Fendrick, *Accelerating Approval Times for New Drugs in the U.S.*, 15 REG. AFF. J. 411, 411-17 (2004), available at <http://people.hmhc.harvard.edu/~dcarpent/acceleration-raj.pdf>.

<sup>160</sup> See Warren, *supra* note 26, at 804-05; Steven L. Holley, Note, *The Relationship Between Federal Standards and Litigation in the Control of Automobile Design*, 57 N.Y.U. L. REV. 804, 819 (1982).

<sup>161</sup> See Huber, *supra* note 158, at 331.

<sup>162</sup> See Robert W. Hamilton, *Prospects for the Nongovernmental Development of Regulatory Standards*, 32 AM. U. L. REV. 455, 461 (1983).

<sup>163</sup> *Id.* at 462-64. See also *infra* Part V.A (discussing consensus standards in the Life Safety Code).

<sup>164</sup> See Huber, *supra* note 158, at 334-35.

<sup>165</sup> See *id.* at 319-20.

incentive to disclose anything that does not support their position, courts are forced to evaluate safety standards on the basis of limited information.<sup>166</sup> Finally, because the litigation process is case specific in nature, courts tend to focus on the narrow issues before them and ignore the broader economic or social concerns that may be involved in setting safety standards.<sup>167</sup>

The silicone breast implant litigation and the Bendectin cases illustrate some of the problems that bedevil courts and juries when they try to resolve safety issues entirely on their own. In the silicone breast implant controversy, for example, juries awarded damages to plaintiffs despite the fact that no epidemiological studies or literature reviews found any causal connection between implants and connective tissue or autoimmune disease in patients.<sup>168</sup> In her book, *Science on Trial*, Marcia Angell details how courts failed in the breast implant cases to exclude “junk science,” and how jurors in these cases failed to understand basic concepts of scientific causation.<sup>169</sup> Similarly, in a group of cases involving the prescription drug Bendectin, courts allowed plaintiffs’ expert witnesses to base their testimonies on what is now commonly recognized as junk science when orthodox epidemiological studies failed to support their causation claims.<sup>170</sup>

### *B. The Separation of Powers Argument*

Another argument for greater judicial deference to government safety regulations is based on the constitutional principle of separation of powers. In the United States, legislative bodies and administrative agencies are supposed to formulate regulatory policy. Courts have a very limited role in this process: they can interpret statutory language, they can invalidate legislation or administrative regulations when those violate constitutional or statutory provisions, and they can review the decisions of administrative agencies when authorized to do so by state or federal administrative procedure acts. But when courts reject a safety standard

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<sup>166</sup> See James A. Henderson, Jr., *Judicial Review of Manufacturers’ Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1532–33 (1973).

<sup>167</sup> See W. KIP VISCUSI, REFORMING PRODUCTS LIABILITY 8–9 (1991) (“Unfortunately, the courts are not regulatory agencies and do not have the expertise to set safety levels, especially since they must act within the narrow perspective of a particular case.”). In holding that the Medical Device Amendments preempted common-law tort claims, the United States Supreme Court recently declared that “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.” *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008).

<sup>168</sup> See Rabin, *supra* note 6, at 2061–62.

<sup>169</sup> MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 111–125 (1996).

<sup>170</sup> JOSEPH SANDERS, BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION 91–116 (1998). See generally MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION (1996) (discussing the lack of epidemiological studies to link birth defects to Bendectin).

that has been formulated by a government agency, they assume the power to make risk-allocation decisions that have been entrusted to other branches of government.<sup>171</sup> In effect, litigants who urge courts to impose a higher standard of care on an activity seek to challenge legislative or administrative policy decisions without going through the procedures set forth in federal or state administrative procedure acts.<sup>172</sup> In contrast, a strong regulatory compliance defense will promote the proper constitutional balance of power by protecting legislative and administrative decisions against encroachment by the judiciary.

### C. *The Regulatory Efficiency Argument*

A third argument for a stronger regulatory compliance defense posits that a public risk-management regime that incorporates both administrative and tort-based safety standards is likely to be inefficient. Under the current regulatory regime, most activities are subject to two sources of regulation and two sets of regulatory standards.<sup>173</sup> Legislative and administrative regulations establish a “floor” of required conduct in the sense that those who violate these standards will be subject to fines or criminal penalties, while tort law imposes a standard of care that is equal to or higher than the governmental standard.<sup>174</sup> If the standard of care established by government regulation is in fact a minimum standard, there may be a significant difference between it and the standard of care mandated by tort law. In those circumstances, the accident cost reduction savings that result from enforcement of more rigorous tort law standards may be worth the increased expense of maintaining a dual system of regulation. However, if there is no significant difference between the standard of care required by regulation and that required by tort law, superimposing tort-based safety standards on top of existing government regulation is not likely to be cost-effective because the additional reduction in accident costs attributable to marginally higher tort law standards will not exceed the costs of implementing them.<sup>175</sup>

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<sup>171</sup> See Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147, 2153 (2000).

<sup>172</sup> See Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2178 (2000).

<sup>173</sup> See Dueffert, *supra* note 26, at 177.

<sup>174</sup> *Id.* at 176.

<sup>175</sup> See Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1257–66 (1996). This logic also supports a ban on punitive damages when a defendant has complied with applicable safety standards if these standards are optimal or close to optimal. The arguments against punitive damages are discussed *infra* at Part VI.D.

#### D. *The Uniformity Argument*

According to this argument, a strong regulatory compliance defense will promote a fairer and more uniform application of government safety standards.<sup>176</sup> Without a strong policy of judicial deference to regulatory standards, some defendants who comply with applicable safety standards will nevertheless be found negligent, while others will escape liability. This lack of uniform treatment is unfair to litigants and undermines the deterrent effect of tort law.

Furthermore, because jury verdicts in negligence cases can be highly unpredictable, without the safe harbor provided by a strong regulatory compliance defense, individuals and business entities who comply with applicable safety standards can have no assurance *ex ante* that a lay jury will not conclude that they should have taken additional precautions. This is demoralizing to those who seek to “play by the rules” and undermines respect for the legal system. On the other hand, a strong regulatory compliance defense will provide more predictability for those who engage in socially useful, risky activities. In addition, these individuals and businesses might have an additional incentive to comply with regulatory standards if they know that compliance will relieve them of tort liability.<sup>177</sup>

#### E. *The Overdeterrence Argument*

The final rationale for a more robust regulatory compliance defense assumes that vague or inconsistent tort standards place an excessive burden on activities that are socially useful but inherently risky.<sup>178</sup> Faced with the prospect of substantial damage awards (including punitive damages in some cases), businesses either devote excessive resources to safety, and devote correspondingly fewer resources to more productive alternative uses, or they shift their resources into activities where there is less exposure to tort liability.<sup>179</sup> In some cases, fear of massive litigation costs may overdeter even when adverse damage awards are unlikely.<sup>180</sup> The experience of the pharmaceutical industry illustrates how the fear of tort liability can lead to overdeterrence.<sup>181</sup> For example, in the 1970s, many

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<sup>176</sup> See *e.g.*, Warren, *supra* note 26, at 805–06 (discussing and rejecting the uniformity argument).

<sup>177</sup> See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 483 (1997).

<sup>178</sup> See Warren, *supra* note 26, at 780 (noting that a “manufacturer must face often unpredictable liability for negligence in manufacturing, design, or behavior”).

<sup>179</sup> See 2 ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY: APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 86–89 (Reporters’ Study 1991). *But see* Rabin, *supra* note 6, at 2077–78 (arguing that there is no recent empirical evidence available to support overdeterrence claims with respect to pharmaceuticals).

<sup>180</sup> Rabin, *supra* note 6, at 2075.

<sup>181</sup> See Howard A. Denemark, *Improving Litigation Against Drug Manufacturers for Failure To Warn Against Possible Side Effects: Keeping Dubious Lawsuits from Driving Good Drugs off the Market*, 40 CASE W. RES. L. REV. 413, 415 (1990); Charles J. Walsh &

pharmaceutical companies stopped producing vaccines for childhood diseases.<sup>182</sup> The few remaining companies that continued to produce vaccines were forced to charge much higher prices for their products because they needed to set aside money as a reserve against potential damage awards.<sup>183</sup> The Bendectin litigation provides another example of overdeterrence. The manufacturer of Bendectin stopped producing the antinausea drug after defense costs exceeded \$100 million, causing liability insurers to deny insurance.<sup>184</sup> Insurers were justifiably concerned about massive tort liability even though FDA studies had concluded that the drug was safe and should not be withdrawn from the market.<sup>185</sup>

The prospect of tort liability also caused a sharp decrease in the production of general aviation aircraft in the 1980s.<sup>186</sup> In the late 1970s, twenty-nine manufacturers produced 14,000 light piston airplanes per year, but by 1993, only nine manufacturers were left, and they produced only a total of 900 aircraft.<sup>187</sup> The industry did not recover until Congress enacted the General Aviation Revitalization Act (GARA)<sup>188</sup> in 1994 to provide airplane manufacturers with some protection against tort liability.<sup>189</sup> This legislation has enabled the general aviation industry to rebound during the past decade.<sup>190</sup>

As the history of general aviation shows, government regulations can provide an important “safe harbor” for business enterprises when courts recognize regulatory compliance as a defense.<sup>191</sup> Instead of having to predict what tort law standard a court will adopt in the future, a business entity will know in advance that it will not be held liable in a subsequent tort action if it complies with

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Marc S. Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 FOOD DRUG COSM. L.J. 171, 177 (1986).

<sup>182</sup> Huber, *supra* note 158, at 287–90.

<sup>183</sup> Tim Moore, Comment, *Comment K Immunity to Strict Liability: Should All Prescription Drugs Be Protected?*, 26 Hous. L. REV. 707, 718 (1989).

<sup>184</sup> Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167, 2171–72 (2000).

<sup>185</sup> Richard A. Epstein, *Products Liability as an Insurance Market*, 14 J. LEGAL STUD. 645, 648 (1985).

<sup>186</sup> Timothy S. McCallister, *A “Tail” of Liability Reform: General Aviation Revitalization Act of 1994 & the General Aviation Industry in the United States*, 23 TRANSP. L.J. 301, 305–07 (1995).

<sup>187</sup> Victor E. Schwartz & Leah Lorber, *The General Aviation Revitalization Act: How Rational Civil Justice Reform Revitalized an Industry*, 67 J. AIR L. & COM. 1269, 1273–74 (2002).

<sup>188</sup> 49 U.S.C. § 40101 (2006).

<sup>189</sup> DAVID G. OWEN, PRODUCTS LIABILITY LAW § 14.5 (2005) (describing the provisions of GARA).

<sup>190</sup> See Schwartz & Lorber, *supra* note 187, at 1283–84.

<sup>191</sup> Ausness, *supra* note 175, at 1218.

applicable government safety standards that are prospective in nature and where there are no special circumstances in the case.<sup>192</sup>

*F. Arguments Against a Strong Regulatory Compliance Defense*

Notwithstanding the arguments discussed above, some legal commentators object to a broad rule that would recognize compliance with government standards as a defense to tort liability.<sup>193</sup> For example, some critics claim that government safety regulations are often inadequate and cite as examples of regulatory failure the former federal fabric flammability standard,<sup>194</sup> and the FDA's licensing of dangerous drugs.<sup>195</sup> In their view, tort liability is necessary to protect public safety because government standards are often minimal in nature.<sup>196</sup>

There is probably no way to prove conclusively whether this argument is valid or not. Much of the evidence on this issue is anecdotal and decades old. Moreover, examples of one agency's failures do not prove that all, or even most, government standards are inadequate. On the other hand, many safety standards reflect consensus or national standards or are adopted by an agency after formal rulemaking procedures. At the federal level, these include safety standards promulgated by the Consumer Product Safety Commission (CPSC), OSHA, the FDA, the Nuclear Regulatory Commission, and the FAA.<sup>197</sup> State and local building codes, electrical and plumbing codes, and fire protection standards are also likely to be state-of-the-art when they are developed by national professional standard-setting organizations. Finally, it is important to distinguish between the adequacy of safety standards and the effectiveness of their enforcement. We believe that concerns about inadequate enforcement are not relevant to the issue of whether courts should recognize a strong regulatory compliance defense. The defense is only available to those who actually comply with applicable safety standards. If the defendant complied with these standards, it should not matter that others have not.

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<sup>192</sup> Even if a strong regulatory compliance defense does not discourage potential plaintiffs from bringing lawsuits, it may induce them to settle prior to trial. See Warren, *supra* note 26, at 798.

<sup>193</sup> See, e.g., Teresa Moran Schwartz, *Punitive Damages and Regulated Products*, 42 AM. U. L. REV. 1335, 1340–41 (1993); Warren, *supra* note 26, at 807.

<sup>194</sup> See David C. Campbell & John F. Vargo, *The Flammable Fabrics Act and Strict Liability in Tort*, 9 IND. L. REV. 395, 403 (1976) (declaring “that some plaintiff’s experts have demonstrated that ordinary toilet tissue will pass the . . . test”).

<sup>195</sup> See Schwartz, *supra* note 193, at 1347–52 (discussing eleven instances in which the FDA licensed dangerous pharmaceutical products); Daniel W. Sigelman, *Turning the Tables on Drug Companies*, 30 TRIAL, Mar. 1994, at 72, 72 (citing various examples of FDA failure to discover drug-related risks during the licensing process).

<sup>196</sup> Warren, *supra* note 26, at 807.

<sup>197</sup> For a brief description of federal regulatory statutes, see Ausness, *supra* note 175, at 1214–17.

A second argument suggests that systemic problems in the regulatory process virtually ensure that government regulation will not be wholly effective. One problem is lack of adequate resources. Government regulators are said to be chronically underfunded and, therefore, lack the necessary resources to do their job properly.<sup>198</sup> Underfunding was particularly common in the 1980s and early 1990s. As one commentator declared, “[t]he systematic hostility to regulation that characterized the last few presidential administrations effectively gutted many agencies of resources and sapped their political will.”<sup>199</sup> Another commentator has described how budgetary cutbacks hampered the FDA and the CPSC during this period.<sup>200</sup> While adequate funding is always a problem, it appears that federal agencies have more resources now than they did in the 1980s.<sup>201</sup> Furthermore, in our opinion, when underfunding exists, it is more likely to adversely affect enforcement efforts than the development of safety standards.

Agencies are also allegedly dependent upon industry sources for essential information about risks and safety technology.<sup>202</sup> As a result, the argument goes, safety standards promulgated by these agencies tend to represent only the industry’s view about acceptable levels of safety.<sup>203</sup> It is no doubt true that some regulatory agencies rely heavily on regulated industries for technical information. However, these agencies also employ professional staffs who can evaluate and verify this information and who often have the ability to obtain additional information from independent sources when necessary.<sup>204</sup>

Another argument against the adoption of a strong regulatory compliance defense is based on the phenomenon known as agency capture, where special interests exercise so much influence over an agency that its safety regulations benefit the regulated industry instead of the public.<sup>205</sup> The risk of agency capture is exacerbated by the “revolving door” between regulatory agencies and private

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<sup>198</sup> See Vincent R. Johnson, *Liberating Progress and the Free Market from the Specter of Tort Liability*, 83 NW. U. L. REV. 1026, 1048–49 (1989).

<sup>199</sup> Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspectives on Tort Reform*, 72 N.C. L. REV. 1129, 1181 (1994).

<sup>200</sup> Schwartz, *supra* note 9, at 1157–58.

<sup>201</sup> For example, the FDA has received additional funding from the Prescription Drug User Fee Act, 21 U.S.C. §§ 379(g)–(h) (2006).

<sup>202</sup> See Schwartz, *supra* note 9, at 1147 (“Industry often controls indispensable data about the nature and extent of the safety problem that an agency is attempting to address, as well as information about the technology and costs of reducing or eliminating the risk.”).

<sup>203</sup> Carl Tobias, *Great Expectations and Mismatched Compensation: Government Sponsored Public Participation in Proceedings of the Consumer Product Safety Commission*, 64 WASH. U. L. Q. 1101, 1103 (1986).

<sup>204</sup> For example, the FDA can call upon the Centers for Disease Control, the National Academy of Sciences, the Federation of American Societies for Experimental Biology, and other scientific organizations to assist it with compiling and reviewing research submitted to it by drug companies. See Noah, *supra* note 171, at 2161.

<sup>205</sup> See Andrew E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 87 (2005); Anita Johnson, *Products Liability “Reform”: A Hazard to Consumers*, 56 N.C. L. REV. 677, 687 (1978).

employers which encourage agency personnel to promote the interests of regulated industries in order to enhance their prospects of future employment in the private sector.<sup>206</sup> Furthermore, even if a regulatory agency is not captured by special interests, it may be pressured to lower safety standards by politicians in the legislative or executive branch.<sup>207</sup>

However, we are skeptical of the claim that regulated parties could acquire sufficient influence over a regulatory agency to dictate its regulatory program. Obviously, regulated businesses will seek to put their views before the agency, just as they do before legislative bodies and the general public. Nevertheless, no matter how much influence particular businesses have with a regulatory agency, competitors, consumer groups, and other governmental entities can counteract this and are in a position to closely scrutinize agency behavior for signs of improper behavior.<sup>208</sup> Indeed, a regulated business probably has less influence over a legislative body or a regulatory agency than a plaintiff's expert witness has over jurors in a trial.

Another concern with a strong regulatory compliance defense is that regulatory standards often become obsolete with the passage of time.<sup>209</sup> This occurs because agencies are not always able to respond quickly to new information or advances in safety technology due to inadequate resources.<sup>210</sup> For example, lack of resources contributed to National Highway Traffic Safety Administration's failure to revise many motor vehicle safety standards in the 1970s.<sup>211</sup> In other cases, updating obsolete standards is delayed by the rulemaking process itself. For example, it took the CPSC many years to adopt a new safety standard for walk-behind power lawn mowers.<sup>212</sup>

We acknowledge that the issue of obsolete standards is a legitimate one. In many areas, safety standards issued by agencies lag behind technological developments, particularly when existing standards must be changed by lengthy rulemaking proceedings. However, we believe that ignoring regulatory compliance simply because *some* safety standards may be obsolete, throws the baby out with the bathwater. In our opinion, a better way to deal with the obsolescence problem is to allow the plaintiff to raise the issue before the court when the defendant seeks to assert regulatory compliance as a defense instead of rejecting the defense out of hand.

Several other arguments have been made that are not directed against the regulatory compliance defense as such, but instead rest on the notion that tort law has certain advantages over government regulation and, therefore, tort liability should not be cut back by "tort reform" measures such as the regulatory

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<sup>206</sup> See Johnson, *supra* note 198, at 1051–52.

<sup>207</sup> VISCUSI, *supra* note 167, at 39.

<sup>208</sup> See Noah, *supra* note 171, at 2154–55.

<sup>209</sup> See Schwartz, *supra* note 9, at 1150–51.

<sup>210</sup> *Id.* at 1151–52.

<sup>211</sup> *Id.* at 1152.

<sup>212</sup> See *Southland Mower Co. v. Consumer Prod. Safety Comm'n*, 619 F.2d 499, 503 (5th Cir. 1980).

compliance defense. Thus, as Professor Robert Rabin points out, tort litigation provides a means of exposing corporate wrongdoing.<sup>213</sup> For example, even though breast implants were not ever scientifically linked to any major disease, pretrial discovery revealed to the public that manufacturers of these products were “anything but scrupulous in their concern for product safety or for marketing their product in an honest fashion.”<sup>214</sup>

Professor Rabin also observes that tort law, unlike government regulation, provides a mechanism for compensating accident victims.<sup>215</sup> According to this argument, regulatory agencies typically employ risk-benefit analysis to determine an acceptable level of safety.<sup>216</sup> By protecting individuals and businesses from tort liability when they comply with government safety standards, a robust regulatory compliance would place tort law in an efficiency-based straightjacket that ignores other objectives, such as risk-spreading, that courts have traditionally invoked to justify liability.<sup>217</sup>

Professor Rabin is undoubtedly correct that tort law, provides educational and risk-spreading benefits that would be lost or reduced if a strong regulatory compliance defense were adopted. However, the savings from the reduction of unnecessary tort litigation associated with a strong regulatory compliance defense greatly outweigh the educational benefits that the present tort law system provides. Moreover, as Professor Lars Noah points out, even if courts adopt a strong regulatory compliance defense, plaintiffs will still have a strong incentive to look for evidence of noncompliance, nondisclosure or fraud in order to defeat the regulatory compliance defense if the defendant attempts to assert it.<sup>218</sup> As far as the “compensation gap” argument is concerned, risk-spreading may be a persuasive rationale for imposing liability without fault in the law of products liability, but it is less important in negligence law where the standard of care, based on the Learned Hand formula, focuses on achieving an efficient level of safety rather than spreading accident costs.<sup>219</sup>

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<sup>213</sup> Rabin, *supra* note 6 at 2068–70; *see also* Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. HEALTH CARE L. & POL’Y 27, 58 (2007) (concluding that tort litigation provides the public with information about dangerous pharmaceutical products).

<sup>214</sup> Rabin, *supra* note 6, at 2068.

<sup>215</sup> *Id.* at 2070–74.

<sup>216</sup> *See id.* at 2070–71.

<sup>217</sup> *Id.* at 2071.

<sup>218</sup> Noah, *supra* note 171, at 2161–62.

<sup>219</sup> We would also point out that defendants in negligence cases often have less risk-spreading ability than product manufacturers. *See infra* Part V.B. (discussing how many nursing homes have been forced out of business because they were unable to obtain liability insurance at reasonable rates).

## V. NURSING HOME REGULATION: A CASE STUDY

A fire at the NHC nursing home facility in Nashville, Tennessee caused sixteen deaths and a number of injuries, mostly from smoke inhalation. Thirty-two plaintiffs filed lawsuits against NHC, seeking damages for injuries sustained in the fire. In each case, the plaintiffs claimed NHC was negligent because it had failed to retrofit the Nashville facility with sprinklers in each resident's room. Although NHC had complied with all applicable safety regulations, it was forced to defend against these claims in court. We believe the NHC experience illustrates the need for a stronger regulatory compliance defense than the Third Restatement provides.

A. *The Nursing Home Safety Regulations*

The fire safety aspects of nursing home facilities are regulated by various federal, state, and local governmental agencies. Title IV of the Omnibus Budget Reconciliation Act of 1987 (OBRA),<sup>220</sup> known as the Nursing Home Reform Act, is the principal source of federal oversight.<sup>221</sup> The federal statute is supplemented by extensive regulations.<sup>222</sup> Federal law regulates many aspects of nursing home safety, including fire protection. For example, a provision of OBRA, entitled "Life Safety Code," declares that "[a] skilled nursing facility must meet such provisions of such edition (as specified by the Secretary in the regulations) of the Life Safety Code of the National Fire Protection Association as are applicable to nursing homes."<sup>223</sup> In addition, a federal regulation, states that "[e]xcept as otherwise provided in this section . . . the facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association."<sup>224</sup>

The State of Tennessee and the Metropolitan Government of Nashville also regulate nursing home safety. In Tennessee, the state's Division of Health Care Facilities is responsible for determining whether nursing home facilities comply with applicable federal and state building and life safety regulations, including fire safety regulations.<sup>225</sup> To carry out this task, the Division of Health Care Facilities

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<sup>220</sup> 42 U.S.C. §§ 1395i-3, 1396r (2006).

<sup>221</sup> See Jennifer Gimler Brady, *Long-Term Care Under Fire: A Case for Rational Enforcement*, 18 J. CONTEMP. HEALTH L. & POL'Y 1 11-17 (2001) (discussing OBRA); Charles Grassley, Essay, *The Resurrection of Nursing Home Reform: A Historical Account of the Recent Revival of the Quality of Care Standards for Long-Term Care Facilities Established in the Omnibus Reconciliation Act of 1987*, 7 ELDER L.J. 267, 270-274 (1999).

<sup>222</sup> 42 C.F.R. §§ 483.200-485.729 (2007).

<sup>223</sup> 42 U.S.C. § 1395i-3(d)(2)(B).

<sup>224</sup> 42 C.F.R. § 483.70(a)(1).

<sup>225</sup> See TENN. CODE ANN. §§ 68-11-201 to 1500 (2006); TENN. COMP. R. & REGS. 1200-8-11.01 to .14 (2007); Defendant's Reply to Plaintiffs' Response in Opp. to Defendant's Motion for Partial Summ. J. on Punitive Damages at 30, *In re NHC-Nashville Fire Litigation*, No. 03-MDI (Davidson County Ct., Tenn. Oct. 9, 2006) (on file with authors) [hereinafter NHC's Reply]; Affidavit of Katy Gammon ¶ 5-6, *In re NHC-*

conducts annual surveys of each Tennessee nursing home facility and makes a compliance determination based on those surveys.<sup>226</sup> The regulations enforced in the surveys are contained in various editions of the Life Safety Code.<sup>227</sup>

The Life Safety Code is a product of the NFPA, an advocate of fire prevention and an authoritative source on fire safety.<sup>228</sup> The mission of the NFPA and its approximately 80,000 members is to “reduce the worldwide burden of fire and other hazards on the quality of life by providing and advocating consensus codes and standards, research, training, and education.”<sup>229</sup> As part of this mission, the NFPA drafts and publishes the Life Safety Code. The NFPA generally publishes a new edition of the Life Safety Code every three years. Each edition includes requirements that are specifically applicable only to health care facilities like nursing homes. Those requirements are divided in two distinct sets: those applicable to nursing homes under construction and those applicable to existing nursing homes. The NFPA studies, develops, revises, and updates safety standards for each new edition of the Life Safety Code. In that way, the requirements in each edition of the Life Safety Code reflect the NFPA’s most recent determination about what fire safety features are needed to provide an appropriate level of fire safety in existing nursing homes.

Each edition of the Life Safety Code is developed through an open consensus process accredited by ANSI.<sup>230</sup> The individuals primarily responsible for developing the Life Safety Code’s requirements applicable to nursing homes are a group of approximately twenty experts that comprise the NFPA Technical Committee on Health Care Occupancies.<sup>231</sup> The members of this committee have diverse expertise and backgrounds in a variety of health care, fire, and life safety fields, including several members who have a background in code enforcement.<sup>232</sup>

Nashville Fire Litigation, No. 03-DMI (Davidson County Ct., Tenn. July 14, 2004) (on file with authors) [hereinafter Gammon Aff.].

<sup>226</sup> TENN. COMP. R. & REGS. 1200-8-11.05(10).

<sup>227</sup> See NHC’s Reply, *supra* note 225, at 40; Gammon Aff., *supra* note 225, ¶¶ 6, 9–11; Deposition of James C. Chandler, *In re* NHC-Nashville Fire Litigation at 67–70, No. 03-DMI (Davidson County Ct., Tenn. Apr. 14, 2005) (on file with authors) [hereinafter Chandler Dep.]; Deposition of Seth Afotey at 16, *In re* NHC-Nashville Fire Litigation, No. 03-DMI (Davidson County Ct., Tenn. Apr. 20, 2005) (on file with authors).

<sup>228</sup> NHC’s Reply, *supra* note 225, at 39; Carson Aff. ¶ 4; see NFPA 101: LIFE SAFETY CODE (National Fire Protection Agency 2006).

<sup>229</sup> NHC’s Reply, *supra* note 225, at 39; Carson Aff. ¶ 4; National Fire Protection Ass’n, <http://www.nfpa.org> (follow “About Us” hyperlink).

<sup>230</sup> See NHC’s Reply, *supra* note 225, at 40; Carson Aff. ¶¶ 15–21, 23; National Fire Prevention Association, Codes and Standards, available at <http://nfpa.org> (follow “Codes and Standards” hyperlink; then follow “Code Development Process” hyperlink).

<sup>231</sup> See NFPA, COMPLETE LISTING OF NFPA TECHNICAL COMMITTEE MEMBERS, CORRELATING COMMITTEE MEMBERS AND PANEL MEMBERS 222–27 (Rev. Jan. 2008).

<sup>232</sup> *Id.* Of the seventeen members of the NFPA Technical Committee on Health Care Occupancies that worked on the 2000 edition of the Life Safety Code, four members had a background in code enforcement, six members represented entities subject to the code, two members had a background in insurance, one member had a background in the manufacture

The disparate expertise of committee members ensures that varied viewpoints and interests are present in the committee, which produces standards and requirements that represent a carefully considered consensus on fire and life safety issues.<sup>233</sup>

The members of the Technical Committee on Health Care Occupancies use their diverse expertise—along with numerous reports, studies, and suggested provisions submitted by members of the NFPA and the public—to develop each edition of the Life Safety Code’s requirements applicable to health care facilities like nursing homes. Specifically, the members of the Technical Committee work to develop requirements that will, based on their expert determination, provide fire safety in nursing homes consistent with the public interest while avoiding requirements that impose unreasonable hardships or unnecessary interference with the normal use and occupancy of a nursing home or that force closure of a facility due to unnecessary and unreasonable financial obligations.<sup>234</sup> When considering whether to include a provision requiring the installation of a particular fire safety feature in a health care occupancy, the members of the Technical Committee on Health Care Occupancies consider, among other things, the potential life-saving capabilities of the feature, the cost of installing the feature, the interference or inconvenience with health care operations likely to be caused by the feature, and the history of fire accidents, injuries, or deaths in health care facilities with and without the feature.<sup>235</sup>

Once the Technical Committee on Health Care Occupancies prepares a new edition of the Life Safety Code standards applicable to healthcare facilities like nursing homes, the revised edition of the code is submitted to the entire membership of the NFPA who vote to ratify or reject the committee’s recommended draft. Because the requirements in the Life Safety Code are developed through this open consensus process, each edition of the Life Safety Code reflects the collective determination of the diverse experts who comprise the Technical Committee on Health Care Occupancies and the collective wisdom and experience of the entire NFPA membership about what requirements are necessary to provide a reasonable level of safety to life in the event of a fire in a nursing home.<sup>236</sup>

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of fire safety devices, and four members were “special experts” without a connection to any specific facet of the fire and life safety field, but having special expertise on the issue of life and fire safety in health care facilities. NHC’s Reply, *supra* note 225, at 40, Affidavit of Thomas W. Jaeger, P.E., ¶ 8, *In re* NHC-Nashville Fire Litigation, No. 03-DMI (Davidson County Ct., Tenn. Aug. 18, 2006) (on file with authors) [hereinafter Jaeger Aff.]; Carson Aff. ¶ 17–19.

<sup>233</sup> NHC’s Reply, *supra* note 225, at 40; Jaeger Aff., *supra* note 232, ¶ 8; Carson Aff. ¶¶ 17–19.

<sup>234</sup> NHC’s Reply, *supra* note 225, at 41; Jaeger Aff., *supra* note 232, ¶ 21.

<sup>235</sup> NHC’s Reply, *supra* note 225, at 81; Jaeger Aff., *supra* note 232, ¶¶ 29, 338; Carson Aff. ¶ 26–27.

<sup>236</sup> NHC’s Reply, *supra* note 225, at 40; Jaeger Aff., *supra* note 232, ¶ 7.

At least thirty states have incorporated portions of the Life Safety Code into their regulatory or statutory systems.<sup>237</sup> Both the State of Tennessee and the Federal Centers for Medicare & Medicaid Services (CMS) have, as part of their regulatory schemes, adopted different editions of the Life Safety Code's requirements applicable to nursing homes. Despite some perceived problems with enforcement, the Life Safety Code has significantly improved nursing home safety since CMS first adopted the Code's requirements in 1967. The fire loss history for all nursing homes in the United States since that time can be used as a measure of the effectiveness of the Life Safety Code's requirements because, due to participation in Medicare or Medicaid programs, the overwhelming majority of nursing homes in the United States (at least 98%) are required to comply with the Life Safety Code, as adopted by the CMS.<sup>238</sup>

Since CMS first adopted the Life Safety Code, the number of deaths at nursing homes throughout the country has dropped dramatically. For example, in the five years from 1966 through 1970, there were an average of 15.2 deaths in nursing homes every year that were cause by multiple-death nursing home fires.<sup>239</sup> In contrast, for the five-year period prior to 2003, there were no multiple-death nursing home fires in the entire United States. In fact, for the entire twenty-year period prior to 2003—during which various editions of the Life Safety Code were being enforced as part of CMS regulation of nursing homes across the country—there was only an average of approximately one death per year at nursing homes throughout the entire country caused by multiple-death fires.<sup>240</sup> This is an impressive fire safety record considering the fact that during the twenty years prior to 2003, there were approximately 17,000,000 nursing home residents across the country. This fire history shows the remarkable effectiveness of CMS' adoption and regulation of nursing homes throughout the United States pursuant to the Life Safety Code's requirements and strongly suggests that the Life Safety Code provides a reasonable standard of fire safety for nursing homes.

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<sup>237</sup> See News Release, National Fire Protection Agency, State of Vermont Adopts 2003 Editions of NFPA1, Uniform Fire Code and NFPA 101, Life Safety Code (Nov. 15, 2005), available at <http://www.nfpa.org> (follow "Press Room" hyperlink; then follow "2005" hyperlink).

<sup>238</sup> See NHC's Reply, *supra* note 225, at 43; Jaeger Aff., *supra* note 232, ¶ 20.

<sup>239</sup> For these purposes, a "multiple-death nursing home fire" is a fire at a nursing home resulting in more than two fatalities. This definition is used because sprinklers and other fire protection features in nursing homes cannot be expected to prevent fatal fire injuries inflicted on someone very close to the starting point of a fire, such as those in the room of a fire's origin. NHC's Reply, *supra* note 225, at 38; Jaeger Aff., *supra* note 232, ¶ 21; Carson Aff. ¶ 11.

<sup>240</sup> NHC's Reply, *supra* note 225, at 43; Jaeger Aff., *supra* note 232, ¶¶ 15–16, 21–22; Carson Aff. ¶ 11.

*B. The Effect of Tort Liability on the Nursing Home Industry*

Notwithstanding the fact that nursing homes are subject to a comprehensive regulatory regime, the nursing home industry has been subjected to an increasing number of tort claims in recent years.<sup>241</sup> Nursing homes are now sued at a rate of 14.5 lawsuits per thousand beds, a rate which doubled in 5 years' time.<sup>242</sup> The size of the average damage award or settlement has increased as well. According to one account, the average claim paid has risen to \$200,000.<sup>243</sup> This increased liability exposure has also caused nursing home insurance premiums to increase substantially.<sup>244</sup> Insurance premiums rose by 150% nationally between 1998 and 2000.<sup>245</sup> Nursing homes in some areas of the country have experienced even greater increases in their insurance premiums. For example, insurance premiums have risen 300% for some Pennsylvania nursing homes.<sup>246</sup> The situation is even worse in California and Florida, states with the largest and second-largest populations of elderly persons.<sup>247</sup> In California, the price of insurance rose from \$125 per bed for \$1 million in coverage in 2000 to \$1100 per bed in 2002.<sup>248</sup> The cost of liability insurance in Florida is even higher, having risen to \$7000 per bed.<sup>249</sup> Furthermore, losses from tort claims have caused at least ten liability insurers to leave Florida or stop underwriting new business altogether in that state.<sup>250</sup> For similar reasons, nursing homes in Texas are also beginning to experience problems with the cost and availability of insurance coverage.<sup>251</sup>

The rising cost of insuring against tort liability threatens the financial solvency of the nursing home industry.<sup>252</sup> For example, in a recent twelve-month period, "more than 1,600 of the nation's 17,000 nursing homes . . . filed for bankruptcy,"<sup>253</sup> and other nursing home operators have been forced to sell their

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<sup>241</sup> See Marshall B. Kapp, *Resident Safety and Medical Errors in Nursing Homes: Reporting and Disclosure in a Culture of Mutual Mistrust*, 24 J. LEGAL MED. 51, 68–69 (2003).

<sup>242</sup> Richard H. Tilghman IV, Note, *Rethinking Constitutional Limitations on Punitive Damages: Providing Economically Efficient Incentives to Prevent Nursing Home Abuse*, 54 DEPAUL L. REV. 1007, 1011 (2005).

<sup>243</sup> *Id.*

<sup>244</sup> Kapp, *supra* note 241, at 70.

<sup>245</sup> See R. Patrick Bedell, Note, *The Next Frontier in Tort Reform: Promoting the Financial Solvency of Nursing Homes*, 11 ELDER L.J. 361, 369 (2003).

<sup>246</sup> Tilghman IV, *supra* note 242, at 1011–12.

<sup>247</sup> See Terrance J. Shanahan, Comment, *Statutory Limits on Punitive Damages in Nursing Home Negligence Tort Actions: Preventing the Collapse of the Private Nursing Home*, 4 J. HEALTH CARE L. & POL'Y 373, 379 (2001).

<sup>248</sup> Bedell, *supra* note 245, at 369.

<sup>249</sup> *Id.* at 369.

<sup>250</sup> *Id.* at 368.

<sup>251</sup> Shanahan, *supra* note 247, at 383–84.

<sup>252</sup> See Bedell, *supra* note 245, at 368–69.

<sup>253</sup> *Id.* at 367–68.

properties because of rising liability costs.<sup>254</sup> Not only does excessive tort liability have a negative impact on nursing home owners, it also harms nursing home residents and the public by forcing nursing homes to raise their fees.<sup>255</sup> Obviously, nursing home patients bear some of these higher costs, but because Medicaid pays for more than half of the cost of nursing home care in the United States,<sup>256</sup> taxpayers also feel the effects of increased damage awards and liability insurance premiums.

### C. *The NHC Nursing Home Fire*

At 10:17 p.m. on September 25, 2003, a fire alarm sounded at the nursing home facility in Nashville, Tennessee. The fire originated and was contained within one resident's room, but due to the fire department's forty-five-minute delay in extinguishing the fire, it generated a tremendous amount of smoke. All of the 217 residents living in the facility had to be evacuated. Twenty-two of these residents suffered from smoke inhalation and injuries during their evacuations and at least sixteen residents died as a result of smoke inhalation.

#### 1. *The Life Safety Code's Sprinkler Regulations*

Following the fire, thirty-two plaintiffs filed lawsuits against NHC, seeking damages for injuries sustained in the fire. Each of these lawsuits claimed that NHC was negligent because it failed to install sprinklers in the Nashville facility. Although NHC had installed numerous fire safety features in its Nashville building, at the time of the fire none of the applicable federal, state, and local safety regulations required the installation of sprinklers. In fact, just months prior to the fire, inspectors for the State of Tennessee has found the NHC Nashville facility to be in compliance with all requirements of the Life Safety Code.<sup>257</sup> Accordingly, a critical issue in the claims filed against NHC was whether NHC could be held liable under principles of common-law negligence for not installing sprinklers in its facility when those sprinklers were not required under any applicable building or fire safety regulation and when the facility had been found to be in full compliance with the applicable provisions of the Life Safety Code just months prior to the fire.

It is important to reiterate that no edition of the Life Safety Code adopted by the NFPA prior to the fire at the NHC Nashville facility contained any provision that would require sprinklers to be installed in existing nursing homes of the same

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<sup>254</sup> Tilghman IV, *supra* note 242, at 1011.

<sup>255</sup> See Bedell, *supra* note 245, at 378.

<sup>256</sup> Kapp, *supra* note 241, at 55.

<sup>257</sup> NHC's Reply, *supra* note 225, at 31; Gammon Aff., *supra* note 225, ¶ 7; Deposition of Katy Gammon at 29–30, *In re* NHC-Nashville Fire Litigation, No. 03-DMI (Davidson County Ct., Tenn. Dec. 14–15, 2004) (on file with authors) [hereinafter Gammon Dep. II]; Chandler Dep., *supra* note 227, at 58.

construction type as the NHC Nashville facility.<sup>258</sup> The lack of a requirement mandating sprinklers in existing nursing homes was not an oversight on part of the NFPA. Instead, the Technical Committee on Health Care Occupancies expressly considered and rejected proposals for such a requirement during its process of developing each of the 1991, 1994, 1997, and 2000 editions of the Life Safety Code.<sup>259</sup> On each occasion, the Technical Committee rejected the proposals because the good fire safety history at nursing homes and other health care facilities, along with the fire safety provided by the requirements already included in the Life Safety Code, did not justify the additional burden and cost that would be caused by mandating the installation of sprinklers in existing nursing homes.<sup>260</sup> In other words, experts on fire safety, on at least four separate occasions prior to the fire at the NHC Nashville facility concluded that, although sprinklers might provide some additional level of fire safety, the safety features already required by the Life Safety Code provided a reasonable and appropriate level of fire safety and the risk posed by the lack of sprinklers in existing nursing homes was not substantial enough to justify the burden of installing sprinklers in those facilities.<sup>261</sup>

At the time of the Nashville fire, approximately 25% or about 4200 of the nursing homes in the United States did not have sprinklers in resident rooms.<sup>262</sup> Based on a 2002 study, the aggregate cost of installing automatic fire sprinklers in existing nursing homes was conservatively estimated at approximately \$1 billion. This cost was one of the factors the Technical Committee on Health Care Occupancies considered when deciding not to adopt a requirement in the Life Safety Code mandating the installation of sprinklers in all existing nursing homes.

## 2. *The Litigation Experience*

The plaintiffs and NHC agreed to mediate the various cases filed in connection with the Nashville fire. Prior to the mediation, some of the authors, as NHC's counsel, researched comment (a) to § 288C of the Second Restatement and hired another of the authors as an academic expert in the regulatory compliance field in order to formulate the argument for a strong regulatory compliance defense. Together, we drafted a partial summary judgment motion on the issue. We expected the plaintiffs to discount the argument and respond that, under the traditional approach, the regulations should be seen as "minimum standards." Still, we hoped that the regulatory compliance argument would give the plaintiffs' lawyers pause and that, once studied, the court could be persuaded to adopt the kind of tort reform suggested by a strong regulatory compliance defense.

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<sup>258</sup> See TENN. CODE ANN. § 68-11-235 (2006).

<sup>259</sup> NHC's Reply, *supra* note 225, at 81; Jaeger Aff., *supra* note 232, ¶¶ 29–30; Carson Aff. ¶¶ 26–28.

<sup>260</sup> NHC's Reply, *supra* note 225, at 81; Jaeger Aff., *supra* note 232, ¶¶ 29, 33; Carson Aff. ¶¶ 26–27.

<sup>261</sup> NHC's Reply, *supra* note 225, at 81; Jaeger Aff., *supra* note 232, ¶¶ 29, 33; Carson Aff. ¶¶ 26–27.

<sup>262</sup> NHC's Reply, *supra* note 225, at 79; Jaeger Aff., *supra* note 232, ¶ 31.

The briefing was filed in advance of the mediation and was available for the benefit of the mediator and the plaintiffs' lawyers. The strong regulatory compliance argument, along with the comparative fault arguments, were effectively used in settlement negotiations. The cases ultimately were resolved before the court ruled on the motion for partial summary judgment on the defendant's regulatory compliance defense.

*D. The Nashville Fire Litigation and the Role of Regulatory Compliance*

The following characteristics of the nursing home industry are relevant to the regulatory compliance issue. First, nursing homes are subject to a rigorous and comprehensive regulatory regime. Second, the agencies that regulate nursing homes must make trade-offs between safety and other considerations. Finally, the nursing home industry has very high social utility but is also vulnerable to excessive tort liability.

*1. "Optimal" Safety Standards*

Tort liability imposes significant economic costs, with few offsetting benefits, when the regulatory regime is already adequate. We believe this to be the case with nursing home regulation. As described above, the Life Safety Code's safety standards are developed by NFPA through an open consensus process so that they reflect the opinion of the members of the Technical Committee on Health Care Occupancies and the entire NFPA membership.<sup>263</sup> Furthermore, these safety standards are reviewed by the NFPA every three years with each new edition of the Life Safety Code. These safety standards applied to NHC's Nashville facility as well as other nursing homes in Tennessee. Representing the collective expertise of the NFPA members, these standards could hardly be called "minimal." Rather, they are about as close to "optimal" or "state of the art" as it is possible to get. Therefore, from the perspective of regulatory efficiency, it is doubtful that tort liability is capable of providing any significant degree of incremental safety beyond that which can already be achieved by enforcement of the Life Safety Code. Unfortunately, in this case, there was a very real possibility that lay juries would have ignored existing safety standards and, in effect, imposed higher safety standards on NHC if the lawsuits filed against it had gone to trial.

This risk of tort liability imposes a financial hardship on nursing homes either by inducing them to spend additional money to achieve minimal increases in safety or by forcing them to pay large damage awards if juries conclude that they were negligent for not installing safety features beyond those required by the applicable codes. In addition, when juries impose tort liability upon businesses that have complied with existing safety regulations, they force them to reduce expenditures for other purposes. In the nursing home context, this means that nursing home owners must spend money to achieve marginal increases in fire safety instead of

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<sup>263</sup> See *infra* notes 225–240 and accompanying text.

devoting more resources toward improving the quality of life of nursing home residents.

## 2. *Regulatory Trade-offs*

Agencies that formulate administrative regulations frequently must balance safety goals against other considerations.<sup>264</sup> The drafters of the Life Safety Code made these sorts of trade-offs when they formulated sprinkler requirements for existing nursing home facilities. On several occasions, NFPA's Technical Committee on Health Care Occupancies considered whether it should require existing nursing homes to install sprinkler systems. Each time, it decided that the safety features already required by the Life Safety Code appeared to provide a reasonable level of fire safety, and therefore, that the risk posed by the lack of sprinklers in existing nursing homes was not substantial enough to justify the burden of installing sprinklers in those facilities.<sup>265</sup> Trade-offs, such as the decision to exempt existing nursing homes from the obligation to install sprinklers, are a necessary and legitimate part of the regulatory process. However, the integrity of these regulatory trade-offs will be seriously compromised if juries are permitted to ignore them in tort cases. A robust regulatory compliance defense will help to prevent this from happening.

## 3. *The Effect of Tort Liability on Socially Useful Enterprises*

Nursing homes have high social utility. However, as we have seen, the financial health of nursing homes and other socially desirable enterprises is threatened by the prospect of excessive tort liability. In the Nashville fire litigation, for example, even though these cases were eventually settled, the settlement awards and litigation expenses were substantial. In addition, the tort liability problem is exacerbated by the risk of punitive damages. For example, many plaintiffs in the Nashville fire litigation sought millions of dollars in punitive damages. Had the plaintiffs prevailed in their request at trial, the financial effects of multiple punitive damage awards would have been devastating. Furthermore, even though these cases did not go to trial, the prospect of punitive damage liability increased the pressure on NHC to settle and may have even influenced the size of the settlement awards. Again, this experience indicated that courts should reject the traditional regulatory compliance analysis in favor of a rule that protects nursing home and other socially useful enterprises from the risk of being wiped out by tort claims.

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<sup>264</sup> See Noah, *supra* note 171, at 2163.

<sup>265</sup> Within days after the fire, NHC committed to retrofit all of its facilities with sprinklers and also agreed to support legislation requiring that sprinklers be retrofitted. Tennessee's legislature subsequently enacted such legislation. See TENN. CODE ANN. § 68-11-235 (2006).

## VI. REVISING THE TRADITIONAL REGULATORY COMPLIANCE DOCTRINE

We have concluded that courts in negligence cases should give considerably more weight to standards of care that are embodied in modern statutes, ordinances, and administrative regulations. The NHC nursing home fire litigation provides some insight into how a more robust regulatory compliance defense should be formulated. In particular, the NHC experience suggests that if a regulatory compliance defense is to be useful, a defendant must be able to assert the defense early in the litigation process. A regulatory compliance defense that takes the form of an evidentiary presumption or a jury instruction makes its appearance too late in the proceedings to do the defendant much good.

*A. A Proposed Alternative to the Third Restatement § 16*

We suggest the following alternative to the Restatement (Third) of Torts: Liability for Physical Harm § 16:

- (1) An actor is not negligent if the actor complies with a pertinent statute, ordinance, or administrative regulation that is designed to protect against the type of accident that occurred and if the victim is within the class of persons the statute, ordinance, or administrative regulation is designed to protect. If the court finds that these conditions are satisfied, it shall rule as a matter of law that the actor's compliance with the statute, ordinance or administrative regulation constitutes reasonable care.
- (2) In any action for personal injury or damage to property against an actor who has been issued or granted a license or permit by a federal, state, or local government entity or administrative agency, unless the victim can show by clear and convincing evidence that the license or permit was issued or granted as the result of fraud, the court shall rule that the license or permit holder has complied with all safety standards and requirements specified for the issuance of the permit or license.
- (3) Whenever a federal, state, or local government entity or administrative agency has conducted an inspection of the actor's business premises to determine whether the actor is in compliance with a particular regulation or safety standard, unless the victim can show by clear and convincing evidence that the actor was guilty of fraud or fraudulent concealment in connection with the inspection, the court shall rule that the actor was in compliance with the applicable regulation or safety standard at the time of the injury if:
  - (a) the inspector found that the actor was in compliance with the applicable permit requirement or safety standard and the inspection

was conducted no more than one year before the injury occurred, or (b) if the regulatory entity or agency has certified that the actor was in compliance with the permit requirement or safety standard at the time the injury occurred.

*B. Commentary on Proposed Changes*

This proposal is substantially different from the Third Restatement's formulation. Unlike the Restatement, which declares in the black letter text that regulatory compliance is merely evidence of reasonable care,<sup>266</sup> our proposal requires courts to rule as a matter of law that compliance with governmental regulations constitutes reasonable care if it finds that the statute, ordinance, or regulation is designed to protect against the type of accident that occurred and that the victim is within the class of persons the statute, ordinance, or regulation is designed to protect. In addition, unlike the Restatement, our proposal provides that a permit holder will be deemed to be in compliance with all applicable permit requirements or safety standards, thereby preventing plaintiffs from making collateral attacks on the agency's decision to grant the license or permit. Finally, when a regulatory agency has inspected a defendant's business premises to determine whether it is in compliance with a particular regulation or safety standard, the court shall prevent a plaintiff from challenging the agency's finding of compliance if the inspector has concluded that the defendant was in compliance with the applicable requirement or standard and the inspection was conducted no more than one year before the injury occurred or if the regulatory agency certifies that the actor was in compliance with the permit requirement or safety standard at the time the injury occurred.

*1. Government Regulations as Standards of Care*

The Third Restatement's general rule is that regulatory compliance is normally nothing more than evidence of reasonable care.<sup>267</sup> This, of course, means that the question of whether a regulatory standard constitutes reasonable care will usually be left to the jury. Only in comment (f) do the drafters of the Restatement suggest that a court may sometimes take this question away from the jury and rule as a matter of law that compliance with a regulatory safety standard<sup>268</sup> satisfies a defendant's duty of reasonable care. In our opinion, this approach does not provide enough protection to defendants who comply in good faith with meaningful safety regulations. As the Nashville nursing home fire litigation illustrates, it is essential from the defendant's point of view to obtain a definitive ruling on the regulatory compliance issue at an early stage in the proceedings. If the resolution of this issue

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<sup>266</sup> RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16 (Proposed Final Draft 2007).

<sup>267</sup> *See id.*

<sup>268</sup> *Id.* § 16 cmt. f.

is left until the trial, the cost of litigation for both parties will be greater and the settlement negotiations will be more protracted and difficult. In addition, a ruling in the defendant's favor early in the litigation will also remove the threat of punitive damages.

In order to achieve this objective, however, a defendant must be able to invoke the regulatory compliance defense sometime before, during, or immediately after discovery by means of a motion to dismiss or a motion for summary judgment. However, for a defendant to raise a regulatory compliance defense at this stage of the proceedings, the defense must not be too fact specific. As mentioned earlier, the Restatement's version of the regulatory compliance defense is so open-ended that it would be difficult for a defendant to successfully invoke it prior to trial. In contrast, our proposal limits factual issues to whether the statute, ordinance, or regulation was designed to protect against the type of accident that occurred and if the victim was within the class of persons the statute, ordinance or regulation was designed to protect. In most instances, a court should be able to resolve these questions by examining the statute, ordinance, or regulation in question, as well as other documents, and by reviewing affidavits of government officials and expert witnesses obtained during discovery.

## 2. *Disputes About Compliance*

In the Nashville nursing home fire case, when NHC revealed that it would assert a regulatory compliance defense in a motion for partial summary judgment, some of the plaintiffs' attorneys responded that summary judgment on this issue should not be granted because NHC did not comply with all of the requirements of the Life Safety Code.<sup>269</sup> If plaintiffs were allowed to allege noncompliance without any substantial factual support, they could prevent defendants from invoking the regulatory compliance defense early in the litigation process. The compliance issue would then be treated as one of fact to be resolved by the jury at trial. To prevent plaintiffs from taking advantage of this tactic, our proposal limits their ability to defeat motions for summary judgment by alleging lack of compliance with regulatory requirements. This makes it easier for a court to rule on the regulatory compliance issue as a matter of law instead of leaving the question of regulatory compliance to the jury.

A similar rationale applies to situations where an employee of a regulatory agency has inspected the defendant's business premises to determine whether it is in compliance with applicable safety standards. Under our proposal, absent fraud, a determination by the agency that the defendant is in compliance, when made during an inspection of the defendant's business premises, shall be conclusive and, therefore immune from collateral attack by plaintiffs in a tort action.

Finally, our proposal contains a very narrow "fraud exception" to the regulatory compliance defense. There is no fraud exception to the safety standards themselves. We believe that the likelihood of fraud is nonexistent when safety

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<sup>269</sup> See NHC's Reply, *supra* note 225, at 101.

standards are formulated and approved by national standard-setting organizations in proceedings that are open and transparent. On the other hand, plaintiffs may allege fraud in connection with the issuance of licenses or in connection with inspections by employees of administrative agencies. However, in such cases, allegations of fraud must be specific and must be supported by clear and convincing evidence. This standard will prevent a plaintiff from defending against a motion for summary judgment by making generalized and unsupported claims of fraud. We believe that a clear and convincing evidentiary standard is appropriate because this is the prevailing standard in civil fraud cases.<sup>270</sup>

### C. Other Issues

#### 1. Regulatory Compliance and Negligence Per Se

Under the common-law doctrine of negligence per se, the court adopts the provisions of a statute or administrative regulation as the standard of care in a negligence case.<sup>271</sup> Thus, the unexcused violation of a relevant safety statute or administrative regulation constitutes negligence as a matter of law.<sup>272</sup> In § 14, the drafters of the Third Restatement codify the negligence per se doctrine as follows: “An actor is negligent if, without excuse, the actor violates a statute that is designed to protect against the type of accident the actor’s conduct causes, and if the accident victim is within the class of persons the statute is designed to protect.”<sup>273</sup>

One might ask whether our proposal treats the doctrine of negligence per se and the regulatory compliance defense similarly. Both § 16 of the Third Restatement, which deals with regulatory compliance, and § 14, which is concerned with negligence per se, rely on statutes and regulations to provide guidance as to the applicable standard of care. However, under the Third Restatement, the procedural effect of violation of a statute is quite different from that of compliance with a statute. As comment (c) to § 14 points out, an unexcused violation of a statute or regulation is not merely evidence of negligence, it is conclusive on the standard of care issue.<sup>274</sup> On the other hand, § 16 of the Restatement declares that compliance with a statute is merely evidence of reasonable care.<sup>275</sup> The rationale for this disparate treatment is that statutory standards are minimal rather than optimal; therefore, violation of such standards is obviously negligent, while compliance does not necessarily constitute reasonable

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<sup>270</sup> See *Rodriguez v. Suzuki Motor Corp.*, 936 S.W.2d 104, 110 (Mo. 1996); *Riley Hill Gen. Contractor v. Tandy Corp.*, 737 P.2d 595, 605 (Or. 1987).

<sup>271</sup> See *Costa*, *supra* note 205, at 54.

<sup>272</sup> See *Noah*, *supra* note 171, at 2151.

<sup>273</sup> RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 14 (Proposed Final Draft 2007).

<sup>274</sup> *Id.* § 14 cmt. c.

<sup>275</sup> *Id.* § 16.

care.<sup>276</sup> In contrast, our proposal treats these doctrines similarly in the sense that it requires courts to defer to legislative and administrative safety standards when determining the applicable standard of care.

## 2. Punitive Damages

Our proposal deals with the effect of regulatory compliance on a defendant's liability for compensatory damages and does not expressly address the effect of such compliance on punitive damage awards. Unlike compensatory damages, which are intended to compensate a plaintiff for injuries suffered because of the defendant's tortious conduct, punitive damages are intended to punish a defendant for serious wrongdoing and to deter others from acting in a similar manner.<sup>277</sup>

There are several reasons why we failed to discuss the issue of punitive damages earlier. First, under our proposal, compliance with government safety standards, in most cases, conclusively establishes that a defendant has exercised reasonable care and, therefore is not negligent. Since punitive damages cannot be awarded unless the defendant is held liable for compensatory damages, it follows that under our proposal compliance with government safety standards would protect a defendant from liability for punitive as well as compensatory damages.

Second, our proposal is based on the principle that government safety standards should determine the duty of reasonable care in common-law negligence actions. Compliance with government safety standards and liability for punitive damages, however, involves consideration of factors other than reasonable care.<sup>278</sup> We felt that injecting such issues as malice or reckless indifference to the rights of others into our proposal would only confuse matters. That having been said, we are aware that a number of states have concluded that compliance with government safety standards, while not sufficient to protect against liability for compensatory damages, will preclude liability for punitive damages, at least in some cases.<sup>279</sup> Consequently, we will briefly consider why punitive damages are inappropriate when a defendant has complied in good faith with applicable safety standards.

First of all, even if safety standards are not optimal, good faith compliance with them would still be inconsistent with the type of intent that is necessary to impose punitive damages.<sup>280</sup> Under this rationale, regulatory compliance would protect a defendant from liability except when agency approval has been obtained by fraud or some other illegal conduct. Furthermore, since punitive damages are quasi-criminal in nature, there are additional policy considerations that may proscribe an award of punitive damages when defendants have complied with

<sup>276</sup> See Rabin, *supra* note 6, at 2051.

<sup>277</sup> See Warren, *supra* note 26, at 809.

<sup>278</sup> See OWEN, *supra* note 189, § 18.6, at 1204-05.

<sup>279</sup> *E.g.*, 42 U.S.C. §§ 300aa-22(b), 300aa-23(d) (2006) (childhood vaccines); ARIZ. REV. STAT. ANN. § 12-701 (2003); MICH. COMP. LAWS SERV. § 600.2946(5) (LexisNexis 2000); N.J. STAT. ANN. § 2A:58C-5c (West 2000); OHIO REV. CODE ANN § 2307.80(C)(1) (LexisNexis 2001); OR. REV. STAT. § 30.927 (2005); UTAH CODE ANN. § 78-18-2 (2002).

<sup>280</sup> See *Stone Man, Inc. v. Green*, 435 S.E.2d 205, 206 (Ga. 1993).

applicable government safety standards. One such concern is that imposing punitive damages on individuals and businesses that have followed the law undermines confidence in the competence of regulatory agencies and arguably creates problems with enforcement. If faithful adherence to safety standards duly promulgated by a regulatory agency results in quasi-criminal punishment, there is less incentive to obey these standards in the first place.

A related issue is lack of notice to a defendant when prescribed conduct is defined by vague liability formulas instead of specific rules set forth by a regulatory agency. Common-law liability standards employ such terms as “malice,” ill will,” “fraud,” and “oppression” or call for the assessment of punitive damages for conduct that is “wanton,” “reckless,” or involves “conscious disregard or indifference toward the interests of others.”<sup>281</sup> Unfortunately, these words and phrases provide little guidance to regulated parties as to what conduct will be sanctioned and what conduct will not.<sup>282</sup> For example, an administrative regulation that declares that sprinkler systems are required in new construction but not in existing nursing homes provides a clear standard for nursing home operators to follow. On the other hand, if compliance with this standard does not provide a safe harbor against punitive damages, owners of existing nursing homes will be left to speculate on whether a jury will consider its failure to install sprinkler systems to be “wanton,” “reckless,” or “malicious.”<sup>283</sup>

A third concern with punitive damages is that of disproportionate punishment. This is a problem that affects punitive damages generally. Recently the United States Supreme Court has begun to scrutinize punitive damage awards in terms of constitutional due process principles to determine when they are excessive.<sup>284</sup> Although this form of federal oversight may put a damper on excessively high punitive damage awards, this is still a matter of concern, especially when the defendant has complied with applicable safety standards. Since a defendant who has complied in good faith with government safety standards is usually much less

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<sup>281</sup> Richard C. Ausness, *Retribution and Deterrence: The Role of Punitive Damages in Product Liability Litigation*, 74 KY. L.J. 1, 46 (1985–86) (citations omitted).

<sup>282</sup> See OWEN, *supra* note 189, § 18.5, at 1185.

<sup>283</sup> Ausness, *supra* note 281, at 46. In addition to the notice problem described above, there is an equal protection problem because different juries may disagree as to whether punitive damages are warranted under these various formulations. Thus, the same conduct may result in punitive damages in one case, but not in another.

<sup>284</sup> *E.g.* Philip Morris v. Williams, 127 S. Ct. 1057 (2007); State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408 (2003); BMW of N. Am., Inc. v. Gore, 517 U.S. 559 (1996); Pac. Mut. Life Ins. Co. v. Haslip, 499 U.S. 1 (1991). See generally Laura J. Hines, *Due Process Limitations on Punitive Damages: Why State Farm Won't Be the Last Word*, 37 AKRON L. REV. 779 (2004) (discussing emerging case law on punitive damages); A. Benjamin Spencer, *Due Process and Punitive Damages: The Error of Federal Excessiveness Jurisprudence*, 79 S. CAL. L. REV. 1085 (2006) (discussing defects in punitive damage jurisprudence); Garrett T. Charon, Note, *Beyond a Bar of Double-Digit Ratios: State Farm v. Campbell's Impact on Punitive Damage Awards*, 70 BROOK. L. REV. 605 (2005–06) (discussing *Campbell's* single digit ratio requirement).

culpable than other types of defendants, it would seem that any punitive damage award would be disproportionate to the defendant's wrongdoing. Finally, the prospect of overdeterrence militates against awarding punitive damages when a defendant has complied with regulatory safety standards. If the fear of large compensatory awards is sufficient to cause some businesses to skew their safety-related expenditures, it is likely that the threat of punitive damages will result in even greater misallocations of resources.<sup>285</sup>

All of this suggests that a strong argument can be made for developing a regulatory compliance defense that protects those who comply with government safety standards against punitive damages liability. However, for the most part, the case for applying a regulatory compliance defense to punitive damage claims rests on different rationales than we have invoked to support our proposal for a robust regulatory compliance defense against compensatory damage claims.

## VII. CONCLUSION

The NHC case illustrates how good-faith compliance with applicable safety regulations currently provides businesses with insufficient protection against tort liability. This is because the traditional rule that governs compliance with government regulations is too weak. In effect, most courts treat a defendant's compliance with governmental regulations as evidence of due care, but allow the jury to find that a defendant was negligent, notwithstanding his or her compliance with legislative or administrative regulations. The Third Restatement continues this approach.

In contrast, we believe that courts should give more deference to safety regulations that are promulgated by legislative bodies and administrative agencies. Not only are these standards usually optimal rather than minimal in nature, but they often represent important policy choices by the legislative and executive branches of government that should be respected by the courts.

We have proposed an alternative regulatory compliance defense that is more appropriate for activities, such as nursing homes, that are subject to regulation under comprehensive, modern safety standards. Accordingly, we recommend that the current version of the Restatement (Third) of Torts § 16: Liability for Physical Harm be replaced by a regulatory compliance provision that resembles our proposal.

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<sup>285</sup> See Ausness, *supra* note 281, at 86–92 (discussing the excessive deterrent effects of punitive damages in the context of products liability).