

JUDICIAL REDUNDANCY AND PRE-EMPTING TORT CLAIMS WITH FEDERAL  
REGULATION

CATHERINE RUHLAND

University of Colorado  
Class of 2010

## JUDICIAL REDUNDANCY AND PRE-EMPTING TORT CLAIMS WITH FEDERAL REGULATION

### INTRODUCTION

Tort law has long provided a remedy for plaintiffs who have suffered injury or loss from inadequate products. A common law doctrine, tort has traditionally been reserved for state law without federal interference. However, in the October 2007 term, the Supreme Court granted certification on and heard an unprecedented six cases concerning common law torts.<sup>1</sup> In October 2008, the Supreme Court granted certification on two additional cases.<sup>2</sup> All eight of these cases involve a conflict between state common law and statutes and regulations recently promulgated by the federal government. The defendants in each of these cases have requested that the Supreme Court find a conflict between the federal laws and the state laws. In the event of finding such conflicts, the defendants ask that the Supreme Court pre-empt state law with the federal regulations and statutes, effectively replacing state common law with federal statutory and regulatory laws.

Several critics have expressed concern about the Court's surprising activism in hearing and deciding federal pre-emption cases, especially in light of a "traditional presumption against preemption."<sup>34</sup> Other critics have been puzzled that a conservative Court, "committed to protecting states' rights," would increase the federal government's reach into traditionally state law territory.<sup>5</sup> This article will examine a third aspect of the Court's recent holdings: namely, the implications of pre-emption in light of the central role and importance of court system in the

---

<sup>1</sup> Daniel E. Troy & Rebecca K. Wood, *The Business of the Court: Federal Preemption at the Supreme Court*, 2007-2008 Cato Sup. Ct. Rev. 257, 257 (2007).

<sup>2</sup> *Wyeth v. Levine*, No. 06-1249 (filed Mar. 12, 2007) (argued Nov. 3, 2008); *Altria Group v. Good*, No. 07-562 (filed Oct. 26, 2007) (argued Oct. 6, 2008).

<sup>3</sup> 2007-08 Cato Sup. Ct. Rev. 257, Troy, *supra* note 1, at 258.

<sup>4</sup> Troy, *supra* note 1, at 258.

<sup>5</sup> Erwin Chemerinsky, *Troubling Trend in Preemption Rulings*, 44 TRIAL 62 (May 2008).

United States. Specifically, the American legal system relies heavily on both redundancy and the adversarial system. First, redundancy ensures that fairness and justice will be achieved, especially where an initial system, such as regulation or a trial court, has failed to achieve the most desirable goal. Redundancy can be found in almost every aspect of the legal system, including the appellate process and regulatory schemes. Second, the American judicial system relies heavily upon the adversarial system. Unlike civil law countries, the United States as a common law country relies on adversaries appealing to an impartial judge in order to achieve the most just result. Often, adversaries will find new facts, invent creative new arguments, or present novel policy goals that might not otherwise be addressed in a civil system. The American judicial system relies heavily on adversaries to expose all relevant evidence and law in a judicial proceeding so that the most just solution may be achieved.

The history of the United States has seen an increasing reliance on the court system as the principle and most efficacious means by which to effectuate laws and achieve justice. For example, the expansion of procedural due process into educational institutions has reflected this trust in the court system as an effective means by which to promulgate laws and receive fair civil judgments.<sup>6</sup> In addition, the Supreme Court has often cited to its “belief in the efficacy of the criminal justice system” when upholding the death penalty.<sup>7</sup> The Supreme Court’s recent holdings have taken cases out of the courts and given more power to the regulations promulgated by the Food and Drug Administration. The Court’s preemption holdings appear to diminish the traditional respect for the judicial process as an effective means for implementing laws and achieving justice.

---

<sup>6</sup> See, e.g. D. Kirp, 28 STAN. L. REV. 841, 843-47 (1976).

<sup>7</sup> William W. Berry, American Procedural Exceptionalism A Deterant or a Catalyst for Death Penalty Abolition? 17 CORNELL J.L. & PUBLIC POL’Y 481, 503 (2008); see also William B. Rubenstein, *The Concept of Equality in Civil Procedure*, 23 Cardozo L. Rev. 1865 (2002) (discussing how procedure is broadly recognized as an effective mechanism to ensure outcome equality and justice).

While historically there has been a “general expansion of tort law, certain theories of liability have faded or disappeared.”<sup>8</sup> There are numerous reasons for this. Some theories of liability vanish because plaintiffs stop bringing such claims in court because of cultural changes or chronically failing arguments.<sup>9</sup> Other causes of actions are preempted by statutory law or judicial decisions, such as has been the case in those published by the Supreme Court’s in recent terms.<sup>10</sup> Kyle Graham, a Deputy District Attorney in California, has developed a framework for analyzing why torts die.<sup>11</sup> This article will use Graham’s framework in order to determine whether the Supreme Court’s recent preemption decisions accurately reflect conclude that it is time for tort actions against medical devices to die.

In the October 2007 term, the Supreme Court heard *Riegel v. Medtronic*, a case about federal pre-emption of state tort law for medical devices.<sup>12</sup> Per Scalia, *Riegel* found that a recent FDA regulation for pre-market approval of a medical device preempts any state common law causes of action.<sup>13</sup> Citing statutory interpretation as well as the benefits of FDA approval, the Supreme Court effectively barred plaintiffs from bringing any negligence, strict liability, or implied warranty claims against manufacturers of medical devices.<sup>14</sup> This article will focus specifically on *Riegel* as a case study to compare the effectiveness of judicial procedure as compared to federal regulation in achieving just and fair outcomes. It will first consider whether the products liability common law concerning medical devices was ready to die under Graham’s analysis. Second, it will consider whether the law post-*Riegel*—without tort—is truly a more effective way to achieve fair results and do justice. Finally, this article will consider the implications of

---

<sup>8</sup> Kyle Graham, *Why Torts Die*, 35 Fla. St. U.L. Rev. 359, 360. (2008).

<sup>9</sup> *Id.*

<sup>10</sup> *See, e.g.* *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

<sup>11</sup> *Id.*

<sup>12</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008).

<sup>13</sup> *Id.* at 1011.

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

*Riegel* for Supreme Court jurisprudence in light of the importance of redundancy and adversaries within the American legal system.<sup>15</sup>

## I. WHY TORTS DIE

While many academics have focused on the rise of new torts, few have analyzed why torts disappear. One academic, Kyle Graham, provides a framework within which to analyze why and how torts die by examining six factors relevant to the tort suits.<sup>16</sup> By examining different torts that have disappeared from common law over the centuries, Graham has correlated the common factors between them. Using these factors as a starting point, this article will specifically examine products liability suits against medical device manufacturers and determine whether that tort was in fact ready to die.

The first factor that Graham identifies as common among torts that have died is a change in the atmosphere surrounding the tort, such as the social and cultural conditions of the time period.<sup>17</sup> Plaintiffs may stop bringing suits because of changes in regimes such as slavery or prohibition.<sup>18</sup> For example, the tort of seduction died most likely because of changes in perceptions about women during the twenties.<sup>19</sup> Cultural atmosphere can also shift due to changes in relationships between governments, people, or people and the government. Changing

---

<sup>15</sup> The Court has also recently decided *Wyeth*, a pre-emption case in which the plaintiff sued a drug manufacturer for failure to warn doctors about the dangers of injection of the drug through the intravenous push method. *Wyeth v. Levine*, No. 061249, 2009 U.S. LEXIS 1774, \*9 (Mar. 4, 2009). While this article will primarily focus on *Riegel*, it will briefly address the implications of *Wyeth* in the context of Supreme Court jurisprudence, procedure and the adversarial system.

<sup>16</sup> Kyle Graham, *Why Torts Die*, 35 FLA. ST. U.L. REV. 359, 359 (2008). A tort “dies” when it either pre-empted by a statute, overturned by judges, or falls out of use and therefore no longer remains a cause of action. Examples of “dead” torts include alienation of affections, champerty, bad faith denial of contract, mishandling of dead bodies, personal injury suits by employees, and insult.

<sup>17</sup> *Id.* at 361.

<sup>18</sup> *Id.* at 379.

<sup>19</sup> *Id.* at 364.

cultures often reflect the number of suits that various plaintiffs will bring. However, existence of a changing atmosphere does not absolutely indicate that a tort will disappear.<sup>20</sup>

The second factor identified among dying or dead torts is the quality of the argument surrounding a tort.<sup>21</sup> In general terms, a tort is often attacked for being outside the aims of tort law, outside the conceptual boundaries of tort law not within tort jurisprudence, or as an “unwieldy tool for achieving these goals.”<sup>22</sup> Arguments that a tort should not exist often focus on factors such as proximate cause. For example, defendants in a modern law suit suing gun distributors for negligence often argue that “criminal misuse of a firearm . . . is an intervening, or an independent superseding cause, which the manufacturer of a non-defective weapon has no duty to anticipate.”<sup>23</sup> The proximate cause argument in fact prevailed and killed this particular tort when Congress passed the Protection of Lawful Commerce in Arms Act in 2005.<sup>24</sup> Other arguments that have successfully killed torts include systematic overcompensation or under-compensation of plaintiffs.<sup>25</sup> Underlying societal dismay for overcompensation is a belief that the plaintiff “no longer implicates a cognizable right or interest.”<sup>26</sup> The arguments factor as to why torts die can also speak to the focus of the prevailing jurisprudence of the day. For example, if jurisprudence focused on finding the most cost effective solutions to plaintiff injuries, judges may find for defendants more often where defendants can most effectively shift the costs.

Third, the audiences such as courts, legislatures, juries, and even plaintiffs themselves might cause a tort to die. For example, plaintiffs might be unwilling to bring suit because of court costs or legal fees. Even if a plaintiff does bring suit, juries might be unwilling to render

---

<sup>20</sup> *Id.* at 380.

<sup>21</sup> *Id.* at 361.

<sup>22</sup> *Id.* at 381.

<sup>23</sup> H.R. REP. NO. 109-124, at 7-8 (2005) (footnotes omitted).

<sup>24</sup> Protection of Lawful Commerce in Arms Act, Pub. L. No. 109-92, 119 Stat. 2095 (2005); Graham, *supra* note 5, at 381.

<sup>25</sup> Graham, *supra* note 5, at 382.

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

worthwhile verdicts for plaintiffs because of a dislike of large verdicts. Finally, judges may be reluctant to either render verdicts or publish opinions favoring plaintiffs because of general disfavor for large recoveries or suing large companies.<sup>27</sup> While overlapping somewhat with the atmosphere factor, the jurisprudence of the Supreme Court for the purposes of this article is particularly important. In modern times, the general public has expressed disapproval for large verdicts for plaintiffs. In addition to general public sentiment, the Supreme Court currently favors conservative opinions.

Fourth, a tort's survival may depend on to what extent defendants have unified. If the tort has a strong and unified opposition, such as that found in the gun industry, potential defendants may prevent a tort from being a successful cause of action.<sup>28</sup> Here, defendant's lobbying power plays a pivotal role, especially when plaintiffs are unidentified or lack unity.<sup>29</sup> Because medical devices require a large investment into research and development and because the approval process may be expensive, manufacturers are large and easily identifiable. On the other hand, potential plaintiffs in suits against medical device manufacturers are disparate and spread out. Because the general population does not know in advance that they might need medical devices, it is hard to form plaintiff advocacy groups.

Fifth, the availability of non-tort alternatives to the tort may affect whether plaintiffs decide to bring suit in the first place.<sup>30</sup> For example, workers' compensation brought about an alternative regime for employees specifically tailored for their cause of action with near guarantee of recovery.<sup>31</sup> Compared with workers' compensation, traditional suits in courts became a costly and burdensome prospect with possibility of no recovery. Both plaintiffs and

---

<sup>27</sup> *Id.* at 385.

<sup>28</sup> *Id.* at 386.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 387.

defendants preferred the workers compensation system over judicial rulings, eventually leading to the death of tort suits brought by employees.<sup>32</sup> Furthermore, even though plaintiffs may still decide to use the alternative tort action, doing so will forego their right to workers compensation which in general guarantees a remedy.

Sixth, the inherent structure of the tort itself may lead to its own demise.<sup>33</sup> For example, if a tort has no limits on recovery and vague standards, it may be criticized for being unreliable.<sup>34</sup> Also, a tort may involve “procedural or substantive hurdles that make recovery almost impossible.”<sup>35</sup> Long, difficult discovery processes or expensive expert witnesses may deter plaintiffs from bringing cases.<sup>36</sup>

These six factors provide a well-grounded starting point for determining whether suits against medical device manufacturers were really ready to disappear as causes of actions. While the algebra may not be precise, such an analysis will help shed light on whether or not the Supreme Court may be shifting jurisprudential regimes in the years to come. By analyzing whether or not products liability suits against manufacturers of medical devices was a tort waiting to disappear, we can better understand the jurisprudence of the Supreme Court: whether their decision in *Riegel* merely reflects the inevitable death of that tort or whether *Riegel* will hail in a new era of jurisprudence that does not follow traditional patterns of disappearing torts.

## II. FDA REGULATIONS AND PREEMPTION

In 1976, Congress passed the Medical Device Amendments (“MDA”) and gave regulatory authority over medical devices to the FDA.<sup>37</sup> Under the MDA, the FDA may preempt any state

---

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* at 388.

<sup>34</sup> *Id.* at 388.

<sup>35</sup> *Id.* at 388.

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

<sup>37</sup> Christen L. Young, *Agency Preemption Inputs in Riegel v. Medtronic*, 118 YALE L.J. POCKET PART 22, 23 (2008); 21 U.S.C. § 301 (1976).

law “requirement” that “relates to the safety or effectiveness” of a medical device.<sup>38</sup> Although such law had been in effect for more than thirty years, the Court determined for the first time in *Riegel* that tort common law constituted a “requirement” under the MDA.<sup>39</sup> Because the Court determined that common law was a requirement, federal regulation pre-empted it. In light of the Supreme Court’s historical reluctance to find preemption, *Riegel* represents a departure and perhaps a new era in Supreme Court jurisprudence. The following sections will analyze the rise of common law tort against medical device manufacturers as well as the cultural context of this tort in the modern era in order to determine whether the tort was in fact ready to die.

#### A. *The Cultural Context of Strict Liability Litigation*

In order to understand the demise of tort action against medical devices, one must first understand the origins of the particular cause of action. Products liability litigation for defective products did not begin until the early 1960s.<sup>40</sup> Courts began to recognize strict liability causes of action against manufacturers of defective products in reaction to “developing social and economic phenomena.”<sup>41</sup>

The movement towards strict liability began with Cardozo’s decision in *Macpherson v. Buick Motor* in which he cast “the foundation of liability in moral terms: the defendant was ‘not merely a dealer in automobiles.’<sup>42</sup> It was a manufacturer of automobiles. It was responsible for the finished product.”<sup>43</sup> Cardozo’s decision recognized the increasing complexity in technology, the rise of mass production, and the accompanying disarming of the consumer.<sup>44</sup>

---

<sup>38</sup> 21 U.S.C. § 360k(a) (2006).

<sup>39</sup> *Riegel*, 128 S. Ct. at 1007.

<sup>40</sup> MARSHALL S. SHAPO, TORT LAW AND CULTURE 87 (2003).

<sup>41</sup> Shapo, *supra* note 29, at 87.

<sup>42</sup> 111 N.E. 1050, 1055 (NY 1916))

<sup>43</sup> Shapo, *supra* note 29, at 88 (quoting *Macpherson v. Buick Motors*, 111 N.E. 1050, 1055 (NY 1916))

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

The landmark decision of *Greenman v. Yuba Power Products* abolished privity of contract requirements in California Courts and adopted a strict liability standard.<sup>45</sup> A 1970 report by President Nixon revealed that an estimated twenty million Americans were “injured each year as a result of incidents connected with consumer products.”<sup>46</sup> In comparing a manufacturer without fault and a completely innocent consumer, the manufacturer should absorb the cost, especially because of the disappointment of consumer expectations.<sup>47</sup> Hence, it is not surprising that during this time, period Congress also passed a number of consumer protection acts, including Cigarette Labeling and Advertising, Child Protection and toy Safety Act, and the Poison Prevention Packaging Act.<sup>48</sup>

The decision in *Yuba* recognized the “extension of distributional chains” and the “change in the order of magnitude of product complexity from boots and shoes to Buicks.”<sup>49</sup> Traditional contract causes of actions could no longer protect consumers because of the increasing distance between manufacturers and consumers.<sup>50</sup> Judge Traynor, writing for the majority in *Yuba*, focused on morality, attributing fault to the party that possessed the “knowledge, manufacture, and marketing.”<sup>51</sup> Borrowing the notion of implied warranty of merchantability from contract law, Judge Traynor explained that

it should not be controlling whether plaintiff selected the machine because of the statements in the brochure, or because of the machine’s own appearance of excellence that belied the defect lurking beneath the surface, or because he merely assumed that it would safely do the jobs it was built to do.<sup>52</sup>

---

<sup>45</sup> 377 P.2d 897 (Ca. S. Ct., 1963).

<sup>46</sup> Sandra F. Gavin, *Stealth Tort Reform*, 42 VAL. U. L. R.EV. 431, 434 (2007).

<sup>47</sup> Shapo, *supra* note 29, at 193.

<sup>48</sup> See Pub. L. 89-92, 79 Stat. 282 (1965); Pub. L. 91-113, 83 Stat. 187 (1969); Pub. L. 91-601, 84 Stat. 1670 (1970).

<sup>49</sup> Shapo, *supra* note 29, at 89.

<sup>50</sup> Gavin, *supra* note 33, at 435.

<sup>51</sup> Shapo, *supra* note 29, at 88.

<sup>52</sup> *Yuba*, 377 P.2d at 901.

Judge Traynor's analysis reflected a societal reaction to increasingly complex technology; increasing technology shifts knowledge and control of any given product away from the consumer and concentrates it into the hands of producers. Ultimately, strict liability arose in order to provide more protection to consumers where traditional causes of actions such as contract and negligence were no longer adequate in a changing economic and technological structure.<sup>53</sup>

B. *FDA Regulations under the MDA.*

In order to fully understand *Riegel*'s implications, one must first position the case within the historical context of FDA regulation of medical devices. Only a couple of years after the courts recognized strict liability causes of actions, Congress passed the MDA in reaction a series of cases involving the Dalkon shield, which caused “thousands of women to suffer toxic shock, infertility, and pelvic infections due to a design defect.”<sup>54</sup> The 1976 MDA allowed the FDA for the first time to “review the safety of medical devices before their entry into the market” in order to prevent future cases such as the Dalkon shield.<sup>55</sup>

The MDA provides for three classes of medical devices that it distinguishes based upon its potential effect on the human body.<sup>56</sup> Class III devices include pacemakers, replacement heart valves, and other devices intended to sustain or save human life or which present “potential unreasonable risk of illness or injury.”<sup>57</sup> While all medical devices are subject to FDA regulation

---

<sup>53</sup> Gavin, *supra* note 33, at 436.

<sup>54</sup> Robert A. Gerberry, *Medtronic v. Lohr: State Lawsuits May Proceed Against Medical Device Manufacturers*, 11 J.L. & HEALTH 221, 223 (1997).

<sup>55</sup> 11 J.L. & Health 221, Gerberry, *supra* note 41, at 223; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996).

<sup>56</sup> 21 U.S.C. 360c(a)(1) (2006).

<sup>57</sup> 21 U.S.C. 360c(a)(1)(c)(ii) (2006); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 914. (1994).

and control, Class III medical devices receive special scrutiny because of their riskiness and importance in saving human life.<sup>58</sup>

Class III devices, such as the heart valve pump in *Riegel*, must meet the Pre-Market Approval (PMA) standard.<sup>59</sup> Among other requirements, the PMA standard mandates that the manufacturer provide the FDA with “all information . . . concerning . . . whether or not such a device is safe and effective.”<sup>60</sup> However, some manufacturers may avoid this requirement by showing that their device is “substantially equivalent” to another device on the market.<sup>61</sup> By showing substantial equivalence, a manufacturer may receive FDA approval in less time and with less scrutiny. The PMA process “requires the device to be tested by a panel of experts for safety and effectiveness,” whereas “premarket notification demands only raw data to support the assertion that the device is ‘substantially equivalent’ to another device.”<sup>62</sup> In 1990, Congress enacted the Safe Medical Devices Act (“SMDA”) in order to reduce the number of manufacturers who avoided Pre-Market Approval through the “substantially equivalent” doctrine.<sup>63</sup>

### C. *Riegel v. Medtronic, Inc. and FDA Regulations*

*Riegel* was not the first time that the question of preemption had been before the Supreme Court. In *Medtronic v. Lohr*, the Supreme Court addressed preemption of state laws by FDA approval under the “substantially equivalent” doctrine.<sup>64</sup> In *Lohr*, the plaintiff sued the manufacturer of a pacemaker that had failed and injured her.<sup>65</sup> Although the Court did find

---

<sup>58</sup> 11 J.L. & Health Gerberry, *supra* note 41, at 224.

<sup>59</sup> 21 U.S.C. 360c(a)(1)(C) (2006).

<sup>60</sup> 21 U.S.C. 360e(c)(1)(A) (2006).

<sup>61</sup> 21 U.S.C. 360e(b)(1)(B) (2006); 21 C.F.R. 807.81(a)(1) (2007)

<sup>62</sup> Gerberry, *supra* note 41, at 225.

<sup>63</sup> Gerberry, *supra* note 41, at 225; Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511; 21 C.F.R. § 807 (1995).

<sup>64</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

<sup>65</sup> *Id.*

federal pre-emption of state failure to warn and negligent manufacturing torts, the Court in *Lohr* found no federal preemption for claims concerning negligent design because the scope of preemption is restricted by a presumption against preemption and Congressional intent.<sup>66</sup> The Court in *Lohr* was concerned with invading the police power of the states and intruding upon state sovereignty.<sup>67</sup>

While the Supreme Court left open the issue of preemption in *Lohr*, a number of lower courts interpreted *Lohr* to mean that PMA preempted state tort claims.<sup>68</sup> The Supreme Court did not rule on whether PMA devices preempted state law causes of action until *Riegel*.<sup>69</sup> *Riegel* arose out of the Second Circuit when a cardiac patient sued the manufacturer of a balloon catheter asserting strict liability, breach of implied warranty, and negligence.<sup>70</sup> Medtronic, manufacturer of the balloon catheter, had received pre-market approval from the FDA.<sup>71</sup> The District Court dismissed the case due to federal preemption, and the Second Circuit affirmed.<sup>72</sup>

The MDA expressly pre-empts “state requirements “different from, or in addition to, any requirement applicable . . . to the device”” under federal law.”<sup>73</sup> The decision in *Riegel* turned upon whether tort duties constitute “requirements” under the MDA, an issue purely of statutory interpretation.<sup>74</sup> This analysis in *Riegel* departs steeply from prior pre-emption analyses in which “the purpose of Congress is the ultimate touchstone of pre-emption” and the Court “starts

---

<sup>66</sup> *Id.* at 485.

<sup>67</sup> *Id.* at 488.

<sup>68</sup> *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2005).

<sup>69</sup> 2007-08 Cat Sup. Ct. Rev. 257, 268

<sup>69</sup> Troy, *supra* note 1, at 268.

<sup>70</sup> *Riegel v. Medtronic*, 128 S. Ct. 999, 1006 (2008).

<sup>71</sup> *Id.* at 1005.

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

<sup>73</sup> *Id.* at 1006 (quoting 21 U.S.C. §360(k)(a)(1)).

<sup>74</sup> *Id.* at 1007.

with the assumption that ‘the historic police powers of the States [a]re not to be superseded . . . unless that was the clear and manifest purpose of Congress.’<sup>75</sup>

Justice Scalia, writing for the majority, approached the issue first as a matter of statutory interpretation.<sup>76</sup> Since the MDA preempts state requirements that are “different from, or in addition to, any requirement applicable” under federal law, Scalia began his analysis by determining whether premarket approval is in fact a federal requirement.<sup>77</sup> In order to conclude that PMA preempts state law, Scalia had to carefully distinguish *Riegel* from the holding in *Lohr*, which found no preemption under the substantial equivalence doctrine.<sup>78</sup> Under the MDA, the Food and Drug Administration may grant pre-market approval only if it finds that there is a “reasonable assurance” of the device’s “safety and effectiveness” by weighing “any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”<sup>79</sup> PMA analysis and approval involves careful examination of the safety “specific to individual devices.”<sup>80</sup> By contrast, the FDA approval in *Lohr* through substantial equivalence focused on equivalence, not on safety.<sup>81</sup> Thus, Scalia concluded that the substantial equivalence doctrine and PMA are fundamentally different forms of FDA approval: “premarket approval . . . imposes ‘requirements’ under the MDA as we interpreted it in *Lohr*.”<sup>82</sup>

After interpreting the meaning of the federal requirement, Scalia then analyzed the meaning of “any requirement” under state law.<sup>83</sup> Here, however, the state law at issue comprised of almost exclusively common law causes of action. However, since “common law liability is

---

<sup>75</sup> *Id.* at 1013 (Ginsberg, J., dissenting) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

<sup>76</sup> *Id.* at 1006.

<sup>77</sup> *Id.* at 1006.

<sup>78</sup> *Id.* at 1007.

<sup>79</sup> *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1004 (2008) (citing 21 U.S.C. § 360e(d), c(a)(2)(C)).

<sup>80</sup> *Id.* at 1007.

<sup>81</sup> *Id.* at 1007.

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

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

‘premised on the existence of a legal duty,’” a common-law duty is a state requirement.<sup>84</sup> Two prior Supreme Court decisions in which the Court had found common law actions to be pre-empted by a provision of the Federal Insecticide, Fungicide, and Roudenticide Act and by the Public Health Cigarette Smoking Act respectively helped justify the opinion.<sup>85</sup>

In determining that FDA approval pre-empted state law causes of action, Scalia examined the FDA procedure in detail. The Court took careful note that the FDA approves the labeling in detail and also examines all of the reports and information concerning the device that the manufacturer provides to it.<sup>86</sup> The Court emphasized all the points at which the FDA could deny approval: immediately after review, when changes are submitted after approval, and anytime at which the FDA receives newly reported data or existing information concerning the device.<sup>87</sup>

In defense of pre-emption, Scalia also noted that state statutes and regulations may bring about better results in the long run because they are formulated carefully with cost-benefit analyses and other considerations, whereas a jury “sees only the cost of a more dangerous design, and is not concerned with its benefits.”<sup>88</sup> In other words, Scalia attacked the procedure of tort law. Furthermore, general “tort duties of care, unlike fire codes or restrictions on trade practices, ‘directly regulate’ the device itself, including its design.”<sup>89</sup> Scalia indicated a mistrust of juries and the judicial process in emphasizing that a single state jury should not have the same power as “the state administrative or legislative lawmaking processes.”<sup>90</sup>

Scalia’s departure from traditional preemption interpretation paves the road for a new preemption jurisprudence. Scalia’s landmark opinion destroyed a very active cause of action in

---

<sup>84</sup> *Id.* at 1008 (quoting *Cipollone* at 522).

<sup>85</sup> *Id.* at 1007 (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)).

<sup>86</sup> *Id.*

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

<sup>88</sup> *Id.* at 1008.

<sup>89</sup> *Id.* at 1010.

<sup>90</sup> *Id.* at 1008.

tort law. The following sections will analyze whether or not it was in fact time for this cause of action to disappear.

D. *Was it Time for Claims against Medical Device Manufacturers to Die?*

The Supreme Court decision in *Riegel* has been met with much criticism.<sup>91</sup> While many have criticized tort for its large recoveries and litigious plaintiffs, analyzing whether or not law suits against drug manufacturers are ready to disappear may cast light on a different foundation for the criticism in *Riegel*. Such an analysis spotlights some of the underlying concerns of Americans and perhaps even a change in direction of the Supreme Court, although it may be too early to tell. First, analyzing the culture in which this tort has evolved reveals that perhaps the tort was ready to die in light of a consumer population that favors stronger controls over manufacturers. On the other hand, strict liability torts appear to have a broad audience, especially in today's mass media world. Moreover, the arguments made about tort recovery for defective medical devices span a both extremes: some advocate that tort recoveries are too high, and others advocate consumer empowerment. Fourth, the medical devices manufacturers, the defendants, are highly unified, which may give them lobbying power or more credibility. However, the last of Graham's factors, alternatives, may play the most important role here, as the immediate alternative to the strict liability tort for medical devices is the FDA. Finally, because part of the reasoning in *Riegel* rested upon an economic rationalism analysis of preemption, this article will analyze all of the factors concerning dying torts within an economic framework.

1. Culture: Is it time to shift risk?

Shapo has described product defect as a cultural barometer.<sup>92</sup> For some products, such as cars, courts impose a minimum level of safety that the manufacturer is required to provide.

---

<sup>91</sup> See, Terry Carter, *The Pre-emption Prescription*, ABA JOURNAL, Nov. 2008, at 42.

<sup>92</sup> Shapo, *supra* note 29, at 211.

These minimum levels of safety are now deeply woven into the cultural fabric, and every consumer expects the minimum levels.<sup>93</sup> At first blush, it would seem that medical devices must have a minimum level of safety because cultural norms dictate that they must. However, as expressed in the Restatement (Second) of Torts, “there are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use.”<sup>94</sup> Unlike cars, Class III medical devices are intended for saving lives or help curing the most dangerous diseases. Furthermore, while car manufacturing technology may change slowly over time, medical technology has seen a number of startling advances that both consumers and manufacturers would like to get to the market as soon as possible.<sup>95</sup> Consumers continue to expect “a steady stream of new miracles.”<sup>96</sup> In addition to the insatiable demand for new medical technology, consumers also expect quality and lack of defects. Thus, there is a tension among consumers over whether losses from injuries should be spread out over the masses through tort, or suffered by only an unlucky few.<sup>97</sup> Furthermore, our modern intuitions

Products liability cases have reflected changes in cultural attitudes over time, especially cultural attitudes towards risk.<sup>98</sup> Certain risks that used to be a standard part of life are now considered worthy of multi-million dollar jury verdicts.<sup>99</sup> For example, as Shapo explains, “had there been mechanized roof sweepers in 1889 . . . no one would even have thought of bringing this suit then.”<sup>100</sup> However, such a case is unremarkable today.<sup>101</sup> This change reflects a

---

<sup>93</sup> Shapo, *supra* note 29, at 219.

<sup>94</sup> RESTATEMENT (SECOND) OF TORTS §402(A) Cmt K.

<sup>95</sup> SUSAN Bartlett.... FOOTE, *MANAGING THE MEDICAL ARMS RACE: INNOVATION AND PUBLIC POLICY IN THE MEDICAL DEVICE INDUSTRY*. At p. 4 Berkeley: University of California Press, (1992.), available at <http://ark.cdlib.org/ark:/13030/ft5489n9wd/>

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

<sup>97</sup> Shapo, *supra* note 29, at 223.

<sup>98</sup> Shapo, *supra* note 29, at 232

<sup>99</sup> See *Austin v. Lincoln Equip. Assoc.*, 888 F.2d 934, 937 (1st Cir. 1989)

<sup>100</sup> Shapo, *supra* note 29, at 232.

<sup>101</sup> See *Austin*, 888 F.2d at 937.

changing societal attitude concerning the relationship between consumers and manufacturers. Examining the rise in the number of causes of actions and lawsuits generally reveals that though technological innovations may improve life, they “must also meet rising standard.”<sup>102</sup> One explanation for the reason why the technological boom has led to a change in cultural attitudes towards risk is that “technology can conquer risk from nature.”<sup>103</sup> However, there are limits on technological capabilities because “technology cannot wholly eliminate risk.”<sup>104</sup> Tort law stands at the precipice of conquering risk without being entirely able to eliminate it. Not surprisingly then, “evidence seems to indicate that the current malpractice crisis is indeed most acute in the cities where medicine is most sophisticated.”<sup>105</sup> While reducing overall risk and potentially saving more lives, technology seems to decrease society’s tolerance for risk, and thus brings with it a flood of lawsuits.

Understanding how society perceives risk in terms of medical devices, the next issue to arise is how society wants to apportion risk. The rise of strict liability lawsuits in the 1960s shifted risk from consumers to manufacturers. The Medical Amendments Act then attempted to reduce the risk transferred to consumers in the first place by regulating medical devices in order to make them less risky. Thus, the key question is whether or not societal attitudes are ready to place risk abatement entirely in the hands of the FDA without recourse for consumers. America, for its part, is highly divided on the issue.<sup>106</sup>

## 2. Audiences: Who is the Supreme Court?

---

<sup>102</sup> Shapo, *supra* note 29, at 232.

<sup>103</sup> Mark F. Grady, *Why Are People Negligent? Technology, Nondurable Precautions, and the Medical Malpractice Explosion*, 82 Nw. U.L. REV. 293, 294 (1988).

<sup>104</sup> 82 Nw. U.L. Rev. 293, Grady, *supra* note 87, at 294.

<sup>105</sup> 82 Nw. U.L. Rev. 293, Grady, *supra* note 87, at 299

<sup>106</sup> See, Kenneth Chang “, *When Medical Devices Fail in the Body*”, N.Y. TIMES, Aug. 7, 2001 (documenting the failures of the FDA and the pain and suffering caused to plaintiffs); *But see* George W. Gekas, “*Lawsuits Endanger New Medical Advances*”, N.Y. TIMES, July 15, 1997 (costly lawsuits have slowed medical innovation and have driven several medical device suppliers out of business).

The rise of two new justices, Chief Justice Roberts and Justice Alito has created uncertainty within the Court regarding pre-emption.<sup>107</sup> The outcome of *Riegel* rested largely on the jurisprudence of the Justices sitting on the Court at the time. Both Justice Scalia and Justice Thomas are known champions of preemption, especially in light of their opinion in *Bates v. Dow Agrosciences* in which they held that Federal approval of Insecticide preempted common law causes of action.<sup>108</sup> Before his tenure on the Supreme Court, Chief Justices Roberts submitted briefs to the Court in a case similar to *Riegel* arguing for preemption of common law causes of action.<sup>109</sup> Justice Alito, sitting on the Third Circuit, took part in a decision finding preemption under the MDA for common law claims against a manufacturer of an inflatable penile prosthesis.<sup>110</sup> With four justices already expressing clear opinion on the issue, the *Riegel* decision does appear less surprising.

### 3. Arguments: Costs & Stifling Innovation

Just Scalia found statutory interpretation the most persuasive argument in *Riegel*. Looking deeper into the issue, however, arguments exist that may have either been disregarded in favor of statutory interpretation or may have been the underlying guidance of the opinion. However, such arguments have strong counterarguments.

For example, several politicians and scholars have argued that subjecting medical device manufacturers to strict liability claim recoveries will reduce the amount of money that manufacturers can invest in future research, thus harming the social well-being of the country

---

<sup>107</sup> Jacob M. Eckburg, “*Medical Device Preemption: A Reasonable Avenue of Tort Reform?*” 1 SEVENTH CIR. REV. 292, 297 (2006), available at <http://www.kentlaw.edu/7cr/v1-1/eckburg.pdf>.

<sup>108</sup> Eckburg, *supra* note 91, at 299.

<sup>109</sup> See Brief Supporting Petitioner/Cross Respondent, *Medtronic v. Lohr*, 518 U.S. 470 (1996) (Chief Justice Roberts for Medtronic arguing preemption);

<sup>110</sup> *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995) (per curiam) (oral arguments heard by Judge Alito, Judge Nygaard and Judge Cowen)

overall.<sup>111</sup> On the other hand, fear of such suits may encourage medical device manufacturers to devote more time to research and development to ensure that there are no design defects.<sup>112</sup>

A similar argument that has been made against strict liability for tort law is that it strict liability stifles innovation because “custom constitutes the benchmark against which defendants’ conduct is evaluated.”<sup>113</sup> In many jurisdictions, failure to conform to custom may be admissible evidence “of the presence of a defect in its product.”<sup>114</sup> Such a rule ultimately discourages innovation and big technological leaps because it would be more likely to expose a manufacturer to liability. However, California and several other jurisdictions have adopted a strict liability regime in which “evidence of the manufacturer’s compliance with the relevant industrial custom is irrelevant and consequently inadmissible.”<sup>115</sup> Such a regime will not discourage technological innovation in the form of moving beyond industrial custom or standards. Thus, other common law solutions to tort reform are available, and the federal pre-emption found by the Supreme Court was not necessary to fix this problem.

#### 4. The role of the defendant medical device manufacturers

Unlike many defendants in other areas of tort law, the manufacturers of medical devices are very large and easily identifiable corporations.<sup>116</sup> As such, they have the ability to exert control through their significant political lobbying power. Because more than twenty percent of the FDA’s \$2.1 billion 2008 budget was generated by user fees, there has been some concern that

---

<sup>111</sup> George W. Gekas, “*Lawsuits Endanger New Medical Advances*”, N.Y. TIMES, July 15, 1997 (costly lawsuits have slowed medical innovation and have driven several medical device suppliers out of business).

<sup>112</sup> Under *Lohr v. Medtronic*, manufacturers of medical devices are now only liable for design defects and are not responsible for negligent manufacturing.

<sup>113</sup> Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 286 (2008).

<sup>114</sup> *Id.* at 299.

<sup>115</sup> *Id.* at 300.

<sup>116</sup> Medical Product Outsourcing, *The Top 30 Medical Device Companies*, available at <http://www.mpo-mag.com/articles/2006/07/top-medical-device-companies-report>

manufacturers “have, in effect, become more customers or clients than regulated entities.”<sup>117</sup> Medical device manufacturers can exploit this weakness and pressure approvals. In some surveys, over twenty percent of FDA researchers have said that they “have been pressured to approve drugs despite reservations about safety and effectiveness.”<sup>118</sup> Before *Riegel*, the tort system could act as a secondary mechanism to ensure safety to consumers where the FDA might fall short in its regulations. *Riegel* has effectively removed this safeguard.

#### 5. Alternatives: the role of the FDA

In order to uncover the procedural aspects of why the tort in *Riegel* died, it is important to examine another tort that has not truly died, but rather has been shifted procedurally. Like negligence against manufacturers, employers’ liability had been around for less than a century before it was replaced by workers’ compensation.<sup>119</sup>

Prior to employer liability, there was an implicit assumption that “an employee should be grateful for the opportunity for gainful employment” and assumed any risk that comes with that employment.<sup>120</sup> After the decision in *Farwell*, an employer became responsible for the negligence of his individual employees, creating a duty on the part of employers.<sup>121</sup>

Employer liability “was widely thought to go to the heart not only of tort law but also of the relationship between capital and labor in the production and exchange of goods and services.”<sup>122</sup> Similarly, strict liability suits against medical device manufacturers are a mechanism by which distant consumers can connect back with manufacturers of important products. However, while both strict liability for manufacturers and negligence suits against

---

<sup>117</sup> Terry Carter, *The Pre-emption Prescription*, ABA JOURNAL, Nov. 2008, at 45.

<sup>118</sup> *Id.*

<sup>119</sup> Richard A. Epstein, *The Historical Origins and Economic Structure of Workers’ Compensation*, 16 GA. L. REV. 775, 777 (1982); See also *Farwell v. Boston & Worcester R.R.*, 45 Mass. (4 Met.) 49 (1842).

<sup>120</sup> Epstein, *supra* note 101, at 777.

<sup>121</sup> *Id.*

<sup>122</sup> Epstein, *supra* note 101, at 775.

employers have followed changing relationships over time, products liability law is fundamentally different because it involves changing technology. Furthermore, products liability is also a tort of strict liability rather than negligence.

Some academics have made the argument that “negligence law is fundamentally a creature of technology” because it is “the common law’s response to technology.”<sup>123</sup> Therefore, tort may be understood as following technological advances and innovations and providing remedies for plaintiffs until new systems can better respond to the technology itself. Under this theory, since no one can effectively anticipate new technologies and the potential risks they might encompass, tort law must provide a grounds for general recovery until an alternative system can take its place. Thus, rather than representing a fundamental change in tort law, *Riegel* only represents the next evolutionary step for ensuring safety among medical devices. Under this analysis, *Riegel* does not represent a tort that has died but rather represents a technology that is ready to move into the regulatory field and away from the field of courtrooms and torts. In fact, Scalia’s opinion appears to reflect this mentality. By focusing on the nuances of the FDA’s approval procedure, Scalia effectively argued that it is time for a new regulatory regime for medical devices.

However, Scalia’s argument that the FDA can regulate medical technology better has been met with much criticism. Traditionally, the FDA “has viewed lawsuits brought by persons injured by a drug as a valuable complement of the agency’s regulatory efforts” because “private litigation can provide an additional layer of protection against unsafe drugs.”<sup>124</sup> The FDA’s

---

<sup>123</sup> Grady, *supra* note 87, at 293.

<sup>124</sup> FDA Career Staff Objected to Agency Preemption Policies. United States House of Representatives Committee on Oversight and Government Reform Majority Staff Report October 2008 at 3.

website itself tells consumers to “stop and remember that all drugs have risks.”<sup>125</sup> FDA approval does not mean that the drug in question has no risks or minimal risks. Rather, FDA approval is a determination that the drug’s benefits outweigh the risks for the intended use.<sup>126</sup> As mentioned before, American concerns appear focused on risk abatement in general, which may go beyond just minimizing risks. Even if the FDA is actually correct in all of its determinations of all of the costs and benefits, its determination may still not be satisfactory to the American public because it will necessarily carry risk with it that will statistically affect a number of the population.

Furthermore, FDA approval only reflects a limited universe of testing and knowledge. Since obtaining approval necessarily means that the drug has not been widely used by consumers, there are inevitably aspects of the drug or combinations with other drugs that have not been tested. While in an ideal world the FDA could supply a pre-tort analysis of cost and benefits which would provide a prima facie case of no liability, the FDA cannot know of all of the potential harms that the drug may cause.

In addition, Scalia’s hypothesis that the FDA can properly balance cost and benefits hinges upon perfect information between the FDA and the drug manufacturer. In trials, adverse parties seek information from the opposing side that is favorable to their case through discovery. Information damaging to the party that possesses it will come out through this process of judicial enforcement of the discovery requests of the opposing counsel.<sup>127</sup> By contrast, the FDA approval process is heavily one-sided. Drug manufacturers seeking approval from the FDA have little or no incentive to hand over to the FDA information that would be potentially damaging to

---

<sup>125</sup> United States Food and Drug Administration, Stop-Learn-Go, *available at* [http://www.fda.gov/cder/consumerinfo/stop\\_learn\\_go.htm](http://www.fda.gov/cder/consumerinfo/stop_learn_go.htm) (last visited Jan. 24, 2009).

<sup>126</sup> United States Food and Drug Administration, Is it Really FDA Approved?, *available at* <http://www.fda.gov/consumer/updates/approvals093008.html#biologics> (last visited Jan. 24, 2009).

<sup>127</sup> Specifically, the adversarial system aids in bringing out all of the relevant information in a suit. In pursuing their own self-interest in the case, adversaries will put in a significant amount of effort in obtaining information from the opposing side. An impartial judge, on the other hand, while pursuing justice, may not be as motivated as an adversarial party in attempting to bring out all of the relevant information.

obtaining approval.<sup>128</sup> That is, not only does the FDA, which is a governmental entity and not truly an adverse party, have little incentive to gain access to adverse knowledge of the drug manufacturer, but there is no adversary in the FDA approval process who would attempt to bring out potentially damaging information.

The adversarial system and redundant mechanisms for achieving the same goal are an important part of the American legal system. *Riegel* abandoned the redundant mechanisms as well as the adversarial system, two important themes in American law, in favor of a regulatory system. By pre-empting state common law torts, the Supreme Court has removed the safety net of consumer-initiated lawsuits. While lawsuits focus only on an individual or group of individuals harmed by the product, in our common law system they also create precedent for future products. Thus, tort suits constitute a redundant mechanism in the legal system for regulating medical devices because manufacturers will pay attention to the precedent set by ongoing lawsuits and adjust their manufacturing guidelines and policies in order to limit their own future liability.

Furthermore, under Graham's dying tort analysis, products liability suits against medical device manufacturers are not yet ready to die. Therefore, there must be another factor missing from the analysis that casts light upon why the Supreme Court, with only one dissent, determined that pre-emption was necessary within *Riegel*. The following sections examine the importance of procedure in America, specifically the adversarial and the redundant systems, in order to

---

<sup>128</sup> In fact, "virtually every major pharmaceutical company has been accused of hiding or manipulating information that questions the safety or effectiveness of its most profitable drugs." Terry Carter, *The Pre-emption Prescription*, ABA JOURNAL, Nov. 2008, at 46. In addition, in a recent survey, "more than 20 percent of the FDA's researchers and physicians say they have been pressured to approve drugs despite reservations about safety and effectiveness." *Id.* at 45. In addition, the FDA relies heavily on "user fees," which are the fees generated from drug manufacturers applying for approval. *Id.* The dependence on user fees generated by drug manufacturers has caused the FDA to rely on the drug manufacturers for its revenue, reducing furthermore the incentive to find negative data about any given drug. *See Id.*

determine if there has been a fundamental change in ideology concerning this procedure that may be the key to understanding why the Supreme Court has taken such an interest in pre-emption recently.

### III. IMPORTANCE OF PROCEDURE IN AMERICA

The American system of justice places heavy emphasis on the importance of procedure, and several theorists have put forth the idea of legitimization through procedure: “the political administrative system procures legitimacy for its decisions through procedures as such.”<sup>129</sup> In effect, the power of the government to enforce substantive law is affirmed through sound procedural process. Furthermore, the “basis of legitimacy of modern law has changed, that a consensus on values has been lost and either has been or will have to be replaced to an increasing extent by a consensus on the rationality of procedures.”<sup>130</sup> While it is difficult to pinpoint an ultimate goal for FDA approval and regulation, the American ideal is that sufficient procedure can ultimately produce a just result. In the pre-*Riegel* world, this meant that loopholes, mistakes, or even intentional wrongdoing in the FDA regulation process could be corrected by consumers through the American courts and strict liability causes of action.

There are two procedural aspects of the American legal system that have helped to promote fairness, reasonableness, and justice by engaging debate between different interests. First, the American government is full of redundancies. For example, the House and the Senate in the federal government are both law making bodies and act in concert in order to most effectively promulgate legislation. Having two houses is technically redundant but the existence of both fosters debate and may ultimately create a better end product. Other less obvious examples also exist: both the Federal Trade Commission and the Department of Justice are

---

<sup>129</sup> Klaus F. Rohl, *Procedural Justice: Introduction and Overview*, in *PROCEDURAL JUSTICE* 1, 18. (Klaus F. Rohl & Stefan Machura, eds., 1997).

<sup>130</sup> Rohl, *supra* note 108, at 20.

empowered with the same antitrust regulation capabilities.<sup>131</sup> Second, the effectiveness of American procedure rests upon the adversarial system. Under the theory of the adversarial system, parties with competing interests will most effectively achieve a sound and just result by playing out all arguments and examining all aspects of any given controversy.<sup>132</sup>

For example, the current state of capital punishment law reflects the centrality of procedure in the criminal justice system and in American ideology. An examination of this area of law may elucidate the importance of procedure in the American government and thus cast light upon the role of tort law within the American legal system. Although in the criminal system due process is mandated by the Fifth and Fourteenth Amendments, the due process requirements of the criminal system reflect a larger ideology within the American legal system that believes that the adversary system and redundant mechanisms are the most effective way to achieve justice.

For example, mandatory death sentences are unconstitutional because they allow too little discretion in sentencing, and hence are procedurally unfair.<sup>133</sup> On the other hand, juries and judges cannot be allocated too much discretion in determining death penalty cases.<sup>134</sup> In between these two extremes, state legislatures and the Supreme Court have devised a complex network of laws all ultimately aimed towards preventing arbitrary and capricious action.<sup>135</sup> In other words, current law focuses on creating and guaranteeing procedural fairness in order to achieve justice. While due process is certainly not required for civil actions, the advances in the

---

<sup>131</sup> See William E. Kovacic, *Procurement Reform and the Choice of Forum in Bid Protest Disputes*, 9 ADMIN. L. J. AM. U. 461, 493 (1995) (discussing the existence of a number of redundant public administrative agencies in the Federal government).

<sup>132</sup> Neil Vidmar, *Procedural Justice and Alternative Dispute Resolution*, in PROCEDURAL JUSTICE 130 (Klaus F. Rohl & Stefan Machura, eds.).

<sup>133</sup> *S v Makwanyane* 1995 BCLR 1 at 7 (CC) (S. Afr.).

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

<sup>135</sup> 21A AM. JUR. 2D *Criminal Law* § 963 (1998).

criminal system, which are promulgated by the same courts that hear civil cases, reflect an underlying philosophical belief in justice through proper procedure.

Specifically, in light of its other international roles, America's antithetical position to the rest of the world concerning the death penalty indicates more than just pure disagreement about human rights. Rather, in America, the ideal that fair procedure can achieve justice has attached itself firmly to laws concerning the death penalty. Thus, abolition of the death penalty carries with it the renunciation of the ideal of procedural fairness as a guarantee of justice. In other words, by following public opinion, the Supreme Court has avoided addressing morality and human rights arguments in favor of acknowledging and implicitly asserting that it is possible to achieve justice through procedural mechanisms. Thus, the United States stands alone among Western countries not only for its resistance to abolishing the death penalty, but also in its commitment to discovering from within a procedural mechanism through which justice can be administered with capital punishment.

More recently, the Supreme Court was presented with the issue of whether execution by lethal injection constitutes cruel and unusual punishment. In *Baze v. Rees*, the Court held that lethal injection is a constitutional form of execution because it does not involve "a deliberate infliction of pain for the sake of pain."<sup>136</sup> In its opinion, the Court analyzed the common procedure used for lethal injection and determined that it does not impose an "objectively intolerable risk" of pain.<sup>137</sup> This analysis at first glance seems to indicate that for moral or ethical reasons the Supreme Court is concerned about the pain of a criminal who is unable to retaliate or complain in any manner. One explanation provided by Justice Scalia was that the

---

<sup>136</sup> *Baze v. Rees*, No. 07-5439, slip op. at 9 (Apr. 16, 2008)

<sup>137</sup> *Id.* at 18.

morality of the Supreme Court Justices does not bear on the judgments rendered.<sup>138</sup> Rather, Scalia described his role on the Supreme Court as a “part of the criminal-law machinery” which invokes images of a fine-tuned, objective mechanism for criminal justice rather than an impassioned moral one.<sup>139</sup> As such, the opinion reflects review of one part of the machinery to ensure that all aspects of the death penalty are procedurally constitutional. Thus, according to Scalia’s perspective, the *Baze* analysis reflects the importance of procedure at all levels of the criminal system. In other words, guaranteeing constitutional and fair procedure, even in the final moments before death, has value in and of itself. Perhaps this sheds light on why the United States stands alone among Western countries in retaining the death penalty: abolition would not only admit past wrongs, but it would also concede that procedure itself, which is fundamental to American ideology and notions of fairness and justice, may be inherently inadequate.

Scalia’s opinion in *Baze* expressed a concern about the “continuing deterioration of the prestige of the federal courts.”<sup>140</sup> The prestige of the federal courts plays an important role in continuing to engender trust by the American people into the federal government.<sup>141</sup> The above analysis demonstrates that the federal courts believe that their procedures can ensure that even the most important decisions, life and death, may be decided fairly. Furthermore, this belief pervades not only criminal law but civil law as well, including the tort system. The rise of torts in the common law represented not only important cultural changes, but also an invested trust in the judicial system to correct wrongs and ultimately bring about justice. *Riegel* represents an

---

<sup>138</sup> Antonin Scalia, *God’s Justice and Ours*, FIRST THINGS: THE JOURNAL OF RELIGION, CULTURE AND PUBLIC LIFE, May 2002 at ¶ 3, [http://www.firstthings.com/article.php3?id\\_article=2022](http://www.firstthings.com/article.php3?id_article=2022)

<sup>139</sup> *Id.* at ¶ 6.

<sup>140</sup> Schultz 90

<sup>141</sup> It is important to acknowledge that this discussion concerns only the federal government. While it is true that some states have abolished the death penalty through legislation, this does not reflect the federal government, and specifically the federal courts’ underlying ideologies, philosophies, or goals.

ideological break from this trust in the judicial system because it removes a cause of action from the courts and places it in the hands of a regulatory agency.

#### IV. RIEGEL IN CONTEXT: A NEW DIRECTION FOR THE SUPREME COURT?

In his opinion in *Riegel*, Scalia spent considerable time endorsing the positive aspects of the FDA approval process over the downfalls of retaining the tort system.<sup>142</sup> In light of the importance of procedure in the American psyche, strict liability causes of action against manufacturers of medical devices are a tort that is not ready to die. Graham's factors that indicate that the *Riegel* tort should die are more readily and easily addressed by reform within the judicial system itself, rather than transferring the entire responsibility of medical device safety to a singular regulatory agency. Removing causes of action from the judicial system and putting them in the hands of the FDA offends two fundamental tenants of American government: redundancy and the adversarial system. First, state causes of action constitute a redundant system by which states may fix loopholes in the federal law and regulation. Removing the state causes of action disables states from implementing their own redundant systems and puts an unprecedented amount of trust in the FDA approval process. Second, placing the safety of medical devices exclusively in the hands of the FDA removes the adversarial aspect of medical device regulation. Medical device approval, unlike tort suits, is more similar to a client relationship than adversaries.<sup>143</sup> A client-like relationship such as this is not conducive to finding the safest and most effective medical devices, especially when there is no recourse against the government and the manufacturers are motivated by profit.

In addition, the conclusion that tort suits against medical device manufacturers is not yet a tort ready to die does not only shed light on the cultural status of our judicial system. Rather, it

---

<sup>142</sup> *Riegel*, 128 S. Ct. at 1008.

<sup>143</sup> Terry Carter, *The Pre-emption Prescription*, ABA JOURNAL, Nov. 2008, at 42.

may point out an inconsistency in the Supreme Court jurisprudence and American federal court jurisprudence in general. While on the one hand, the death penalty stubbornly persists with ever-increasing procedural complexities, the Supreme Court appears to be dismantling other procedures, especially in tort.

Furthermore, the Supreme Court recently handed down a new pre-emption case in which the Court with a five-justice majority opinion that declined to find federal pre-emption of state tort claims on a failure to warn suit against a drug manufacturer.<sup>144</sup> Justice Stevens, writing for the majority, relied on the principle that the “the purpose of Congress is the ultimate touchstone in every pre-emption case.”<sup>145</sup> Justice Stevens also expresses the generally accepted presumption against pre-emption because of the importance of respecting states as independent sovereigns.<sup>146</sup> Thus, Justice Stevens and the majority rely on the traditional pre-emption jurisprudence which supports redundant laws concerning manufacturer regulation as well as supporting the integrity of the adversarial system by allowing states to continue to develop their common law jurisprudence. However, Justice Scalia, joined by Justice Alito and Chief Justice Roberts wrote a dissenting opinion once again concerned with putting manufacturer liability in the hands of juries to decide.<sup>147</sup>

The diverging jurisprudence between *Riegel* and *Wyeth* indicates that the Supreme Court is not yet settled about pre-emption issues. Tort pre-emption not only shifts the procedural process from judicial into regulatory control, it also fundamentally changes procedure from an adversarial process to a government oversight process reminiscent of the continental procedural system. One conclusion from this analysis is that there is a divergence in the United States

---

<sup>144</sup> *Wyeth v. Levine*, No. 061249, 2009 U.S. LEXIS 1774 (Mar. 4, 2009).

<sup>145</sup> *Id.* at \*17 (quoting *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996)).

<sup>146</sup> *Id.* at \*18

<sup>147</sup> *Id.* at \*86 (Scalia, J., dissenting)

between civil and criminal law. That is, the courts are guiding civil law away from the adversary system and towards a regulatory system, whereas criminal law retains the adversarial aspect and focuses more and more on procedure, such as the many procedural requirements surrounding the death penalty and jury trials. On the other hand, procedure may persist within the United States' criminal system because of constitutional requirements that do not exist within the civil system.

At the same time, the decision in *Wyeth* may indicate an upper limit for tort pre-emption. That is, while the Supreme Court has certainly become more active in pre-emption cases it has found an upper bound for the types of tort causes of action it is willing to restrict. However, ultimately in light of these circumstances, only time will tell whether or not preemption decisions indicate a new direction for the Supreme Court in an attempt to move at least civil cases out of the courts and into regulatory regimes.