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## **TOUSSAINT V. MERCK & CO.: OPENING THE DOOR TO THIMEROSAL VACCINE LITIGATION IN CIVIL COURT?**

### INTRODUCTION

In June 2003, a Louisiana federal court decided *Toussaint v. Merck & Co.*,<sup>1</sup> basing its decision on the notion that thimerosal—a mercury-laden preservative used in several childhood vaccines—was not in and of itself a vaccine.<sup>2</sup> This deceptively simple revelation may mark the first crack in the armor that has shielded thimerosal’s manufacturers from civil court claims made on behalf of thousands of children allegedly injured by the product.<sup>3</sup> The decision allowed the parents of a child allegedly afflicted by mercury poisoning-induced autism to proceed with a claim against a thimerosal manufacturer in civil court, rather than funneling the case into the United States Court of Federal Claims’ “Vaccine Court.”<sup>4</sup>

In 1986, Congress enacted the National Childhood Vaccine Injury Compensation Act (the “Vaccine Act”), which established a special division of the United States Court of Federal Claims to handle claims relating to vaccine-induced injury or death.<sup>5</sup> Citing policy concerns, including efficient judicial administration and the social importance of having pharmaceutical companies continue to produce vaccines, Congress also established what is often referred to as the “Vaccine Court.”<sup>6</sup> In order to recover for injury caused by a vaccine, as a matter of law, a party must first file a claim in Vaccine Court

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1. *Toussaint v. Merck & Co.*, No. 02-3411, 2003 U.S. Dist. LEXIS 10581 (E.D. La. June 12, 2003).

2. *See id.* at \*8.

3. *See* Joseph Hennessey, *Poetic Justice for Kids?: A Literary Magazine Should Use Its Windfall to Compensate for Past Wrongs*, LEGAL TIMES, Mar. 31, 2003, at 34 (explaining that current legislation has shielded pharmaceutical companies from liability, but that they may be exposed to civil liability if the legislature does not extend this protection to thimerosal-containing vaccinations).

4. *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*7-8.

5. 42 U.S.C. § 300aa (2003); Michael E. Horwin, Comment, *Ensuring Safe, Effective and Necessary Vaccines for Children*, 37 CAL. W. L. REV. 321, 328 (2001).

6. *See* Elizabeth C. Scott, Note, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 354-55 (2001).

before making a claim in any other court.<sup>7</sup> The Vaccine Act requires Vaccine Court adjudication where the injured party's claim for a vaccine-related injury against a manufacturer or administrator of a vaccine is in excess of \$1000.<sup>8</sup> The Vaccine Court awards limited compensatory damages—funded by a tax on vaccine doses—to vaccine-injured parties.<sup>9</sup> The court presumes causation and recovery limits are predetermined for claims included on the court's "Vaccine Injury Table."<sup>10</sup> The claimant may then either accept the settlement offer or refuse and pursue other tort remedies.<sup>11</sup> However, the Vaccine Act also limits the available tort remedies.<sup>12</sup>

The primary issue presented by *Toussaint* was whether manufacturers of thimerosal could benefit from the protection of the Vaccine Court's jurisdiction.<sup>13</sup> The Vaccine Act's language is unclear as to whether vaccine component manufacturers, like those who manufacture thimerosal, are "vaccine manufacturers" within the meaning of the Act, thereby leaving the matter open for judicial interpretation.<sup>14</sup> The Vaccine Court has asserted its own jurisdiction over all thimerosal-related injury claims and is conducting an investigation into the issue of causation and autism.<sup>15</sup> Federal courts have struggled to determine whether proper jurisdiction lies with them, state courts, or the Vaccine Court.<sup>16</sup> Meanwhile, the number of thimerosal-induced autism claims in both civil courts and the Vaccine Court is skyrocketing.<sup>17</sup>

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7. *Id.* at 355.

8. *See* 42 U.S.C. § 300aa-11(a)(2)(A) (2003).

9. *See* Scott, *supra* note 6, at 356.

10. *See* Elizabeth A. Breen, Note, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 WM. & MARY L. REV. 309, 318-19 (1999).

11. *Blackmon v. Am. Home Prods. Corp.*, 267 F. Supp. 2d 667, 672 (S.D. Tex. 2003).

12. *Id.* at 672 n.5.

13. *See* *Toussaint v. Merck & Co.*, No. 02-3411, 2003 U.S. Dist. LEXIS 10581, at \*6-8 (E.D. La. June 12, 2003).

14. *See id.* at \*6.

15. *See In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or A Similar Neurodevelopment Disorder; Various Petitioners v. Sec'y of Health & Human Servs.*, 2002 U.S. Claims LEXIS 365, at \*2-4 (Fed. Cl. July 3, 2002) (discussing Autism General Order #1) [hereinafter Autism General Order #1].

16. *See* discussion *infra* Part I.B.

17. *See* Autism General Order #1, *supra* note 15, at \*2.

In discussing the court's decision in *Toussaint*, this Comment will examine the jurisdictional issue in the context of the controversy over the causal connection between thimerosal and autism.<sup>18</sup> Part I focuses on the historical backdrop of the *Toussaint* decision and examines the autism epidemic and its possible connection to thimerosal-containing vaccines.<sup>19</sup> Additionally, Part I discusses judicial responses to the jurisdictional questions involving thimerosal-autism litigation in both the Vaccine Court and civil court prior to *Toussaint*, as well as legislative attempts to resolve the jurisdictional issue.<sup>20</sup> Part II discusses the details and implications of the *Toussaint* decision, and Part III covers the post-*Toussaint* judicial response.<sup>21</sup> Part IV includes an analysis of the problems inherent in each jurisdictional outcome, including the competing interests of ensuring the availability of vaccines and protecting children from vaccine-induced injury, and a discussion of the impact on vaccinations in general.<sup>22</sup> Finally, Part V explores possible solutions to these problems and addresses the implications of current trends.<sup>23</sup>

## I. HISTORICAL DEVELOPMENTS

### A. Autism and Thimerosal in Childhood Vaccines

#### 1. Autism and the Autism Epidemic

Autism is a neurological disorder that results in developmental disabilities.<sup>24</sup> Doctors typically diagnose autism symptoms in children between three and five years of age.<sup>25</sup> The symptoms are, for

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18. See discussion *infra* Part I.

19. See discussion *infra* Part I.

20. See discussion *infra* Part I.

21. See discussion *infra* Parts II, III.

22. See discussion *infra* Part IV.

23. See discussion *infra* Part V.

24. See Autism General Order #1, *supra* note 15, at \*1. The medical profession commonly refers to autism and other related disorders collectively as "autism spectrum disorders." *Id.* Unless otherwise noted, statistics or other analyses herein refer only to autism.

25. See *Autism and PDD Support Network*, at <http://www.autism-pdd.net> (last visited Dec. 28, 2004).

the most part, permanent.<sup>26</sup> A broad array of symptoms, including learning disabilities, language delay, difficulty with fine and gross motor skills, hypersensitivity to sensory input, and inability to form emotional attachments, characterize the disorder.<sup>27</sup> The distinctive behaviors of autistic children can include hand flapping, shrieking, social withdrawal (including avoidance of eye contact), and “stimming”—a form of self-stimulating behavior that involves staring at a spinning object, such as a wheel on a toy, for extended periods of time.<sup>28</sup> Therapies for autistic children have varying levels of success, but all require enormous expenditures of time, money, and effort on the part of the child’s caregivers.<sup>29</sup> The stress on the family is undeniable: 85% of the married parents of autistic children end up divorced.<sup>30</sup>

Over the past two decades, the incidence of autism in American children has reached epidemic proportions.<sup>31</sup> Speaking before the House Committee on Government Reform, Congressman Dan Burton, a Republican from Indiana, reported that in 1988 autism occurred in the United States at a rate of 1 case per 10,000 people.<sup>32</sup> By the end of 2002, the rate was 1 in 250 and statistics suggested that autism spectrum disorders affected as many as 1.5 million people.<sup>33</sup>

26. See *id.* But see Vin Suprynowicz, *Is Partial Reversal of Autism Possible?*, LAS VEGAS REV. J., Oct. 26, 2003 (suggesting that some individuals have benefited from detoxification to remove mercury from their bodies).

27. Autism General Order #1, *supra* note 15, at \*1 n.2.

28. Mark Benjamin, *UPI Investigates: The Vaccine Conflict*, UNITED PRESS INTERNATIONAL, July 21, 2003.

29. See generally *The Status of Research into Vaccine Safety and Autism: Hearing Before the House Comm. on Gov’t Reform*, 107th Cong. 107-21, 61 (2002) (testimony of James Jeffrey Bradstreet, MD, FAAFP, Clinical Director, The International Child Development Resource Center) (“The cost of education, medical care, and therapies for behavioral and physical symptoms is staggering. Many of our families report having paid \$50,000 per year to care for their child.”).

30. *Id.* at 85.

31. Vin Suprynowicz, *Of Vaccinations, Autism, and “Junk Science,”* LAS VEGAS REV. J., Oct. 5, 2003, at 2E (citing Mark R. Geier, M.D., Ph.D. & David A. Geier, *Thimerosal in Childhood Vaccines, Neurodevelopment Disorders, and Heart Disease in the United States*, 8 J. AM. PHYSICIANS & SURGEONS 1, 6 (2003)).

32. *Vaccines and the Autism Epidemic: Reviewing the Federal Government’s Track Record and Charting a Course for the Future: Hearing Before the House Comm. on Gov’t Reform*, 107th Cong. 107-53 (2002) (testimony of Rep. Dan Burton, Chairman, House Comm. on Gov’t Reform).

33. *Id.*

## 2. *Use of Thimerosal in Childhood Vaccines*

Vaccine manufacturers have used thimerosal as a bactericide in vaccines and other applications since the 1940s.<sup>34</sup> In the 1990s, manufacturers found that by using thimerosal, they could package vaccines in multi-dose vials, thereby lowering production costs and increasing profits.<sup>35</sup> Besides using thimerosal as a preservative in existing childhood vaccinations, the medical profession also approved and routinely administered newly-developed thimerosal-containing vaccines to children during this period.<sup>36</sup> In the 1990s, American children received as many as 40 vaccinations by age two, compared with the three or four vaccines administered to children of the same age in their parents' generation.<sup>37</sup> According to one plaintiff's complaint:

[B]y following a typical immunization schedule during the first 18 months of life, American infants have been exposed to 237.5 mcg (micrograms) of mercury from the thimerosal in vaccine products . . . . This exposure results in a mercury body burden in the typical 18 month-old child that exceeds federal exposure guidelines by more than 30 times the permissible limit.<sup>38</sup>

Pharmaceutical companies widely used thimerosal in childhood vaccines for at least a decade until the American Academy of Pediatrics and the U.S. Public Health Service called into question the safety of the mercury-based preservative.<sup>39</sup> The Food and Drug Administration ("FDA") encouraged manufacturers to discontinue the use of thimerosal because of concerns about "reducing exposure

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34. Margaret Cronin Fisk, *Suits Target Mercury-Laden Vaccinations, Parents Say Son Went from Normal to Autistic After Getting the Vaccine*, THE RECORDER (San Francisco), Mar. 26, 2002.

35. Case v. Merck & Co., No. 02-1779, 2003 U.S. Dist. LEXIS 770, at \*3 (E.D. La. Jan. 17, 2003); see also, Fisk, *supra* note 34.

36. See Benjamin, *supra* note 28.

37. *Id.*

38. *Parents Allege Thimerosal Risk Was Well Known*, 2-5 MEALEY'S LITIG. REP. THIMEROSAL & VACCINES 6 (Nov. 2003) [hereinafter *Parents Allege*].

39. See Sue Reisinger, *Vaccine Lawsuits Against Drug Companies Heat Up*, CORP. LEG. TIMES, Mar. 2003, at 62.

to mercury from all sources.”<sup>40</sup> Vaccine manufacturers agreed to stop using thimerosal in 2001, and they appear to have complied with the FDA’s requests for the most part.<sup>41</sup> Despite widespread concern about autism causation, American children may still be receiving vaccinations containing thimerosal today.<sup>42</sup>

### 3. A Causal Connection?

Beginning in the late 1990s, parents of autistic children began making anecdotal causal connections between their children’s vaccinations and the onset of autism symptoms.<sup>43</sup> These connections began an onslaught of claims charging that childhood vaccinations containing thimerosal caused children to develop autism.<sup>44</sup>

Conflicting early studies both confirmed a possible connection and denied any link between autism and thimerosal; consequently, scientists remain controverted.<sup>45</sup> One study of all children born in Denmark from 1990 to 1996 concluded that “[t]he results do not support a causal relationship between childhood vaccination with

40. *Vaccines and the Autism Epidemic: Reviewing the Federal Government’s Track Record and Charting a Course for the Future: Hearing Before the House Comm. on Gov’t Reform*, 107th Cong. 107-53, 132 (2002) (testimony of Karen Midthun, M.D., Director, Office of Vaccine Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration) (“[A]ll routinely recommended U.S. licensed pediatric vaccines are now available in either thimerosal-free formulations or in formulations that contain only trace amounts of thimerosal.”).

41. See Fisk, *supra* note 34 (noting that Lyn Redwood, President of Safe Minds, a group of parents of autistic children, stated that vaccines sold in the U.S. no longer contain thimerosal, but that pharmaceutical companies still use thimerosal in vaccines sold or donated to other countries); Reisinger, *supra* note 39, at 11.

42. See Vin Suprynowicz, *Autistic Because They Can’t Excrete the Mercury?*, LAS VEGAS REV. J., Oct. 12, 2003, at 2E (noting that the 2003 Physician’s Desk Reference, as well as some vaccine package inserts indicate that several childhood vaccinations contain thimerosal, and pointing out that a vaccine manufacturer’s explanation that its package inserts do not “accurately reflect what is being marketed” constitutes a criminal offense) [hereinafter *Autistic Because They Can’t Excrete the Mercury?*]; see also Fran Lo Biondo, *Vaccine Recommended as Experts Predict New Strain*, THE DAILY J. (Vineland, NJ), Oct. 9, 2003, at 1B (reporting that people who should not get flu shots include those allergic to thimerosal, implying that the current influenza vaccines contain thimerosal).

43. See Fisk, *supra* note 34, at 10.

44. See Reisinger, *supra* note 39, at 11.

45. Cf. *Autistic Because They Can’t Excrete the Mercury?*, *supra* note 42, at 2E (describing a study suggesting a causal connection between thimerosal and autism where certain individuals lack a genetic ability to excrete mercury). See generally *Childhood Immunization: No Relationship Found Between Thimerosal and Autism*, DRUG WEEK, Oct. 17, 2003, at 99 (describing a study finding no causal connection between thimerosal containing vaccines and autism) [hereinafter *Childhood Immunization*].

thimerosal-containing vaccines and development of autistic-spectrum disorders.”<sup>46</sup> Autism advocacy groups have challenged the Danish study, contending that the study distorted data in significant ways, and that an analysis of the study published in the *Journal of the American Medical Association* failed to disclose that a vaccine manufacturer employed the study’s authors.<sup>47</sup> Another study finding no link between thimerosal and autism, conducted by the Centers for Disease Control, has been challenged by United States Representative Dave Weldon.<sup>48</sup> In a letter to the agency’s director, Representative Weldon stated: “[R]ather than seeking to understand whether or not some children were exposed to harmful levels of mercury in childhood vaccines in the 1990s, there may have been a selective use of the data to make the associations in the earliest study disappear.”<sup>49</sup>

*B. Judicial Response to the Thimerosal-Autism Jurisdictional Issue*

Federal and state courts, as well as the Vaccine Court, are debating whether the Vaccine Court has jurisdiction to adjudicate cases concerning thimerosal-containing vaccinations.<sup>50</sup> The Vaccine Court held in *Leroy v. Secretary of Department of Health & Human Services* that it had jurisdiction over these cases because they were “vaccine-related” under the Vaccine Act’s language.<sup>51</sup> In anticipation of adjudicating thousands of pending claims, the Vaccine Court is conducting an extensive investigation into thimerosal-induced autism claims.<sup>52</sup>

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46. *Childhood Immunization*, *supra* note 45, at 99.

47. *See Advocacy Group Says Danish Study Contained Significant Errors*, 2-4 MEALEY’S LITIG. REP. THIMEROSAL & VACCINES 14 (Oct. 2003).

48. *See CDC Accused of Manipulating Thimerosal Data*, 2-5 MEALEY’S LITIG. REP. THIMEROSAL & VACCINES 11 (Nov. 2003).

49. *Id.*

50. *See Autism General Order #1*, *supra* note 15, at \*2-3.

51. 2002 U.S. Claims LEXIS 284, at \*6 (Fed. Cl. Oct. 11, 2002).

52. *See Autism General Order #1*, *supra* note 15, at \*2-3.



Decisions of the Vaccine Court are not binding on other federal courts.<sup>53</sup> Nevertheless, most federal district courts considering the issue of jurisdiction have reasoned that thimerosal injuries are “vaccine-related” and consequently have held that the Vaccine Act “clearly” covers thimerosal manufacturers.<sup>54</sup> A few district courts have remanded thimerosal cases to state courts upon finding that the exclusion in the Vaccine Act for injuries attributable to an “adulterant” or “contaminant” contained in a vaccination may be sufficient for a state court to have jurisdiction over these cases.<sup>55</sup> District courts have remanded other cases to state courts because of the lack of a federal question or by reversing a finding of fraudulent joinder.<sup>56</sup> At least one federal district court has delayed its decision on jurisdiction until the Vaccine Court makes a determination on the causal connection between thimerosal and autism.<sup>57</sup> Due to successful removal efforts by defendants, few state courts have considered the issue.<sup>58</sup>

### 1. Vaccine Court Adjudication

In 2002, in *Owens ex rel. Schafer v. American Home Products Corp.*, a Texas federal district court interpreted the Vaccine Act to require Vaccine Court adjudication of claims of thimerosal-induced autism spectrum disorder.<sup>59</sup> This decision led to a flood of thimerosal-induced autism claims in the Vaccine Court.<sup>60</sup>

The Vaccine Court examined the question of its own jurisdiction in *Leroy v. Secretary of Department of Health & Human Services*.<sup>61</sup> Relying heavily on *Owens*, the Vaccine Court asserted jurisdiction over claims involving autism induced by thimerosal-containing

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53. See *Toussaint v. Merck & Co.*, No. 02-3411, 2003 U.S. Dist. LEXIS 10581, at \*5 (E.D. La. June 12, 2003).

54. See discussion *infra* Part I.B.2.

55. See *id.*

56. See *id.*

57. See *Wax v. Aventis Pasteur Inc.*, 240 F. Supp. 2d 191, 195 (E.D.N.Y. 2002).

58. See discussion *infra* Part I.B.2.

59. 203 F. Supp. 2d 748, 756 (S.D. Tex. 2002); Autism General Order #1, *supra* note 15, at \*2.

60. See Autism General Order #1, *supra* note 15, at \*2-3.

61. See 2002 U.S. Claims LEXIS 284 (Fed. Cl. Oct. 11, 2002).

vaccines.<sup>62</sup> As in *Owens*, the court in *Leroy* relied on the interpretation of the term “vaccine-related” under the Vaccine Act to find that the Act covered thimerosal-related claims.<sup>63</sup> The Vaccine Court noted that, at the time of the *Leroy* decision, there were 875 thimerosal-induced autism claims pending in that forum.<sup>64</sup> As of October 2003, there were over 3350 petitions filed in the Vaccine Court on behalf of children claiming that mercury-containing vaccinations caused them to develop autism.<sup>65</sup>

The Vaccine Court’s Vaccine Injury Table does not currently list autism spectrum disorders.<sup>66</sup> The Table lists the injuries for which the Vaccine Act presumes causation.<sup>67</sup> Plaintiffs with injuries that are not listed on the Table must show a causal connection between the vaccine and the injury.<sup>68</sup> Because the Vaccine Court had already decided that it was the appropriate forum for thimerosal-induced autism cases, and because of the flood of cases pending there, the Vaccine Court determined that it was necessary to make a preliminary causation finding that would apply to all of its thimerosal cases.<sup>69</sup>

In response, the Vaccine Court formed an advisory committee comprised of attorneys with thimerosal cases pending in the Vaccine Court, as well as counsel for the Department of Health and Human Services.<sup>70</sup> As part of its scheduling order, the court set for itself a two-year time limit for making a causation determination.<sup>71</sup> The court designated a team of attorneys, referred to as the “Omnibus Autism Proceeding,” to represent the interests of all relevant petitioners

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62. *See id.* at \*20-21.

63. *See id.*

64. *Id.* at \*3.

65. *Ongoing Studies Remain a Point of Dispute in Autism Proceeding*, 2-5 MEALEY’S LITIG. REP. THIMEROSAL & VACCINES 10 (Nov. 2003).

66. *See* Vaccine Injury Table, 42 C.F.R. § 100.3 (2003).

67. *Leroy v. Sec’y of Dep’t of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284, at \*12 n.6 (Fed. Cl. Oct. 11, 2002).

68. *Id.*

69. *See* Autism General Order #1, *supra* note 15, at \*2.

70. *See id.* The Vaccine Act provides that plaintiffs adjudicating claims in the Vaccine Court must bring their claims against the Secretary of the Department of Health and Human Services. 42 U.S.C. 300aa-11(a)(1) (2003).

71. *See* Autism General Order #1, *supra* note 15, at \*2-3.

during the investigation.<sup>72</sup> Assuming there is sufficient evidence to prove causation generally, the court will create an “Autism Master File” containing the relevant evidence for parties to use in proving or disproving causation in individual cases.<sup>73</sup>

Some have criticized the Vaccine Court because, even in cases where the court presumes causation (i.e., where the Vaccine Injury Table already lists an injury), the court remains far from fulfilling its purpose of providing a streamlined means of recovery for the injured.<sup>74</sup> Petitioners have described their cases as highly adversarial proceedings that have dragged on for years.<sup>75</sup> The goal of Congress in passing the Vaccine Act was to provide an efficient and less adversarial means of recovery for vaccine-injured parties, while limiting the liability of vaccine manufacturers, in order to avoid discouraging vaccine production and development.<sup>76</sup> According to testimony given before Congress, this goal has not been met, even in the so-called “easy” cases where the court presumes causation.<sup>77</sup> Thus, even if the Autism Omnibus Proceeding results in a finding that there is a causal connection between thimerosal-containing vaccines and autism, families suffering from the injury may still be unable to recover without undergoing a lengthy and difficult claim process.<sup>78</sup>

## 2. *Civil Court Adjudication*

The Vaccine Court is not alone in being inundated with thimerosal-induced autism cases; litigation on this issue is flooding the civil court system as well.<sup>79</sup> However, most federal courts have

72. *Id.* at \*4.

73. *See id.*

74. *See, e.g., The National Vaccine Injury Compensation Program: Is it Working as Congress Intended?: Hearing Before the House Comm. on Gov't Reform*, 107th Cong. 107-44 (2001) (statement of Rep. Dan Burton, Chairman, House Comm. on Gov't Reform) [hereinafter *Burton Testimony I*].

75. *Id.* at 140.

76. *See Leroy v. Sec'y of Dep't of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284, at \*10-11, 13 n.7 (Fed. Cl. Oct. 11, 2002).

77. *See Burton Testimony I, supra* note 74.

78. *See id.*

79. *See* Petition for Permission to Appeal from the United States District Court for the Eastern District of Louisiana Civil Action No. 02-3422 at 7, *Davis v. Merck & Co., Inc.* (5th Cir. 2003) (No. 03-

determined that thimerosal cases are within the Vaccine Court's jurisdiction.<sup>80</sup> In 2002, the court in *Bertrand v. Aventis Pasteur Laboratories, Inc.* stated that “[i]t appears that every federal court to have ruled on the issue has held that injuries resulting from Thimerosal contained in vaccines are vaccine-related under the meaning of the Act.”<sup>81</sup>

Plaintiffs in some cases have argued that the Vaccine Court has no jurisdiction over thimerosal cases because of the “adulterant/contaminant” exception under the Vaccine Act.<sup>82</sup> The Vaccine Act provides that a vaccine-related injury “does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.”<sup>83</sup> Plaintiffs argue that because pharmaceutical companies add thimerosal to vaccines, it falls under this exception; thus, claims of thimerosal injury are not subject to the Vaccine Court's jurisdiction.<sup>84</sup> However, since the plain language meanings of “adulterant” and “contaminant” have connotations of impurity and inferiority, courts have held that thimerosal's use as a preservative does not fit these characterizations, since thimerosal is actually meant to improve the vaccine's purity.<sup>85</sup> Most courts have rejected the argument that the Vaccine Act does not apply to thimerosal cases because of the adulterant/contaminant exception.<sup>86</sup>

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00034) (noting that as of July 2003, there were “approximately twenty similar civil actions pending in the United States District Courts in the State of Louisiana and . . . over two hundred such actions pending throughout the United States”).

80. See *Bertrand v. Aventis Pasteur Labs., Inc.*, 226 F. Supp. 2d 1206, 1213 (D. Ariz. 2002).

81. *Id.*

82. See, e.g., *Liu v. Aventis Pasteur, Inc.*, 219 F. Supp. 2d 762, 766 (W.D. Tex. 2002); *Bertrand*, 226 F. Supp. 2d at 1213.

83. 42 U.S.C. § 300aa-33(5) (2003).

84. See *Leroy v. Sec'y of Dep't of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284, at \*17 (Fed. Cl. Oct. 11, 2002).

85. See *id.* at \*17-18.

86. See, e.g., *Liu*, 219 F. Supp. 2d at 762; *Bertrand*, 226 F. Supp. at 1213. *But see* *Garcia v. Aventis Pasteur, Inc.*, 2002 U.S. Dist. LEXIS 15122 (W.D. Wash. Apr. 22, 2002) (holding that the adulterant/contaminant issue is unsettled and holding that the state court was competent to decide that issue on remand).

Some federal courts have remanded previously removed thimerosal-autism cases back to state courts.<sup>87</sup> These federal courts have rejected the proposition that the claims present a federal question since state courts are competent to interpret the Vaccine Act, and the Act itself contemplates the possibility of civil court action in thimerosal cases.<sup>88</sup>

Where defendants have argued for federal court jurisdiction on the basis of fraudulent joinder, courts have been reluctant to find jurisdiction.<sup>89</sup> The court in *Shadie v. Aventis Pasteur, Inc.* stated that “the majority of federal courts that have considered a motion to remand in cases involving a failure to exhaust the Vaccine Court process have granted the motion, rejecting similar fraudulent joinder arguments.”<sup>90</sup>

Because of successful removal efforts by vaccine defendants seeking Vaccine Court jurisdiction, state courts have heard few thimerosal-induced autism cases.<sup>91</sup> In May 2003, the Pennsylvania Court of Common Pleas dismissed with prejudice a class action thimerosal claim in *Ashton v. Aventis Pasteur, Inc.*<sup>92</sup> In *Ashton*, the court held that the claim fell under the jurisdiction of the Vaccine Court.<sup>93</sup> The court expressly rejected the argument that thimerosal manufacturers are not vaccine manufacturers, holding that thimerosal is “interchangeable with the vaccine” for the purpose of determining jurisdiction under the Vaccine Act and, therefore, thimerosal manufacturers are subject to the Vaccine Act.<sup>94</sup> In its analysis, the court relied heavily on the Vaccine Court’s decision in *Leroy*, reasoning that that court’s inclusion of vaccine constituents (such as thimerosal) in the definition of the term “vaccine” leads to the

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87. See, e.g., *Doherty v. Aventis Pasteur, Inc.*, 2002 U.S. Dist. LEXIS 9596 (N.D. Cal. May 15, 2002).

88. See, e.g., *Shadie v. Aventis Pasteur, Inc.*, 254 F. Supp. 2d 509, 517, 521 (M.D. Pa. 2003).

89. See, e.g., *id.*

90. 254 F. Supp. 2d 509, 519 (M.D. Pa. 2003) (referring to, among others, *Bertand*, 226 F. Supp. 2d 1206, *Garcia*, 2002 U.S. Dist. LEXIS 15122, and *Doherty*, 2002 U.S. Dist. LEXIS 9596).

91. See *Utility Defendants Get Cases Remanded to State; ‘Desperate’ Removal Seen*, 1-7 MEALEY’S LITIG. REP. THIMEROSAL & VACCINES 5 (Jan. 2003) [hereinafter ‘*Desperate’ Removal Seen*].

92. 2003 WL 21361355, at \*1 (Pa. Com. Pl. May 22, 2003), *aff’d*, 851 A.2d 908 (Pa. Super. 2004).

93. See *id.*

94. *Id.* at \*6.

conclusion that the terms “vaccine” and “thimerosal” are interchangeable.<sup>95</sup>

### C. Legislative Response to the Thimerosal-Autism Jurisdictional Issue

Congress has attempted to resolve the issue of jurisdiction over claims against thimerosal manufacturers in favor of Vaccine Court adjudication.<sup>96</sup> The Homeland Security Act, passed in November 2002, included a rider containing an amendment to the Vaccine Act.<sup>97</sup> The amendment modified the Vaccine Act to provide that thimerosal manufacturers were expressly to be included in the Act’s definition of “vaccine manufacturers.”<sup>98</sup> The rider inspired a significant outcry among vaccine injury plaintiffs and was controversial in that, initially, no one appeared to be willing to admit having sponsored that portion of the legislation.<sup>99</sup> Congress quickly repealed the amendment without prejudice in February 2003.<sup>100</sup> However, that legislation contained a provision directing certain legislative committees to revisit the issue within six months.<sup>101</sup>

The sponsor of the eleventh-hour thimerosal rider to the Homeland Security Act, Senator Bill Frist, has twice attempted to reintroduce legislation to amend the Vaccine Act’s definition of vaccine manufacturer to include thimerosal manufacturers.<sup>102</sup> His efforts have provoked advocacy groups, led by parents of children believed to have thimerosal-induced autism, to engage in vigorous grass-roots

95. See *id.* Interestingly, *Toussaint* relied on the *Leroy* decision in reaching the opposite result—that the terms are not interchangeable. See *Toussaint v. Merck & Co.*, No. 02-3411, 2003 U.S. Dist. LEXIS 10581, at \*4, 8 (E.D. La. June 12, 2003).

96. See *Frist Do Us No Harm: Angry Parents of Vaccine-Injured, Mercury-Poisoned Children Jam Fax Machines Before Frist’s Legislation Goes Back to Markup this Wednesday*, PR NEWSWIRE, Apr. 8, 2003. [hereinafter *Frist Do Us No Harm*].

97. 6 U.S.C. §§ 101-557 (2002); see *Frist Do Us No Harm*, *supra* note 96; Susan Warner, *Vaccine Clause Angers Parents of Autistic; Amendment Buried in Homeland Security Law Restricts Right to Sue Makers of Drug Preservative*, WASH. POST, Dec. 9, 2002, at A3.

98. See *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*7.

99. See Hennessey, *supra* note 3, at 1.

100. *Thimerosal Rider Repealed; Will Return Within 6 Months*, 1-8 MEALEY’S LITIG. REP. THIMEROSAL & VACCINES 1 (Feb. 2003) [hereinafter *Thimerosal Rider Repealed*].

101. *Id.*

102. See *Frist Do Us No Harm*, *supra* note 96.

campaigns to prevent the reintroduction of Frist's proposed legislation.<sup>103</sup>

## II. *TOUSSAINT V. MERCK & CO.*

### A. *Factual Summary*

The *Toussaint* case involved several claims by the parents of Allen Toussaint, who allegedly suffered "toxic neurological effects of mercury poisoning 'as a result of the mercury in the thimerosal-containing vaccinations [he] received during [his] developmental years.'"<sup>104</sup> His parents sought to recover damages on their son's behalf from Eli Lilly & Company ("Eli Lilly"), the distributor and a former thimerosal manufacturer.<sup>105</sup> The parents brought a claim against Eli Lilly in tort "under the *Louisiana Products Liability Act* for inadequate warning, and for the negligent and/or fraudulent misrepresentation."<sup>106</sup> The lower court dismissed the claims against the other defendants for lack of jurisdiction.<sup>107</sup> Eli Lilly sought to dismiss the case against them arguing that the plaintiffs had not exhausted their remedies under the Vaccine Act because Eli Lilly was a "manufacturer" under the Act, and it was subject to Vaccine Court protection.<sup>108</sup>

The court in *Toussaint* agreed with the Vaccine Court and the majority of federal courts that claims for thimerosal-related injuries are "vaccine-related" and subject to the Vaccine Act.<sup>109</sup> The court also joined the majority of courts in rejecting the notion that

103. See Vin Suprynowicz, *The Eli Lilly Protection Act*, LAS VEGAS REV. J., Oct. 19, 2003.

104. *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*2.

105. See *id.* at \*3. The parents' claims, independent of their child's, are not subject to Vaccine Court jurisdiction because the Vaccine Court reaches only those "qualified to file a petition" or their representative(s), for injuries sustained from the qualified party's vaccination. The parents sought recovery for emotional distress, loss of income, loss of consortium, hedonic damages, and punitive damages. *Id.* at \*3.

106. *Id.*

107. *Id.* at \*4 n.3.

108. See *id.* at \*5-6, 8.

109. *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*4 (citing *Leroy v. Sec'y of Dep't of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284 (Fed. Cl. Oct. 11, 2002)).

thimerosal fell under the “adulterant/contaminant” exception.<sup>110</sup> Nevertheless, the court still found that the Vaccine Act did not cover suits against thimerosal manufacturers.<sup>111</sup>

In explaining its holding, the court noted “[t]he Act requires that before an individual who sustained a ‘vaccine-related injury’ may file a civil lawsuit in state or federal court *against a vaccine manufacturer or administrator* (for damages greater than \$1,000), he must first file a claim in [the Vaccine Court].”<sup>112</sup> The court further explained that the Vaccine Act defines a “manufacturer” as “any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine as set forth in the vaccine Injury Table.”<sup>113</sup> The court looked to the Vaccine Act’s vaccine manufacturer definition in holding that thimerosal manufacturers are not vaccine manufacturers under the Act.<sup>114</sup>

The court also determined that thimerosal is not an adulterant or contaminant, but rather a component of vaccines.<sup>115</sup> However, the court explicitly rejected the notion that the term “thimerosal” is interchangeable with the [term] ‘vaccine’ for purposes of Defendant’s jurisdictional defense.”<sup>116</sup> Therefore, the court held that a strict construction of the language of the Vaccine Act required a finding that “the exclusive jurisdiction of the Vaccine Act (as that Act is presently worded) does not apply to manufacturers, suppliers, and distributors of thimerosal [sic].”<sup>117</sup>

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110. *Id.* at \*8.

111. *Id.*

112. *Id.* at \*5 (citing 42 U.S.C. § 300aa-11(a)(2)(A) (2003)) (emphasis added).

113. *Id.* at \*7 n.7 (citing 42 U.S.C. § 300aa-33(3)).

114. *See id.* at \*8.

115. *Toussaint v. Merck & Co.*, No. 02-3411, 2003 U.S. Dist. LEXIS 10581, at \*8 (E.D. La., June 12, 2003).

116. *Id.*

117. *Id.*



### B. Implications of the Decision

As a result of the decision the plaintiffs did not first have to file a claim on their child's behalf in the Vaccine Court and could instead seek recovery directly from Eli Lilly in civil court.<sup>118</sup> A successful action in civil court would allow the plaintiffs to potentially recover damages in excess of the Vaccine Court's limits on recovery, while bypassing the wait for a causation determination by the Autism Omnibus of the Vaccine Court.<sup>119</sup>

This decision is consistent with other courts' contentions that thimerosal injuries are vaccine-related.<sup>120</sup> The court in *Toussaint* cited *Owens* on this matter with approval.<sup>121</sup> The Vaccine Court also relied on *Owens* in finding its own jurisdiction over these claims.<sup>122</sup> However, the *Toussaint* decision based its finding that the Vaccine Court lacked exclusive jurisdiction primarily on the status of the thimerosal manufacturer as not being a "vaccine manufacturer" under the Vaccine Act.<sup>123</sup> *Toussaint* is significant because it marked the first time a federal court asserted jurisdiction over a thimerosal vaccine claim since the Vaccine Court asserted its own jurisdiction over these cases in *Leroy*.<sup>124</sup>

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118. *See id.* at \*9.

119. *See* Reisinger, *supra* note 39, at 11.

120. *See Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*8.

121. *See id.* at \*8 n.9; *Owens ex rel. Schafer v. Am. Home Prods. Corp.*, 203 F. Supp. 2d 748, 756 (S.D. Tex. 2002).

122. *See Leroy v. Sec'y of Dep't of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284, at \*21 (Fed. Cl. Oct. 11, 2002).

123. *See Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*8 n.9.

124. *See id.* This was not the first time that a federal court had ever applied that distinction. In three separate decisions on the same day in May 2002, a Texas federal district court held that a thimerosal manufacturer was not subject to the Vaccine Act's tort suit ban because it was not a "vaccine manufacturer." However, these cases were decided prior to the Vaccine Court decision in *Leroy*. *See Blackmon v. Am. Home Prods. Corp.*, 267 F. Supp. 2d 667 (S.D. Tex. 2003); *O'Connell v. Am. Home Prods. Corp.*, 2002 U.S. Dist. LEXIS 22046 (S.D. Tex. May 7, 2002); *Owens ex rel. Schafer*, 203 F. Supp. 2d 748. Interestingly, while the court in *Leroy* maintained jurisdiction over all claims for thimerosal containing vaccine induced injury (implicitly including those against thimerosal manufacturers), it relied heavily on these three cases in its analysis. *See Leroy*, 2002 U.S. Claims LEXIS 284, at \*5. The court in *Leroy* did not address the Texas district court's holdings that the Vaccine Act did not protect thimerosal manufacturers. *See id.*

The court in *Toussaint* was also the first federal court to address the thimerosal manufacturers' status under the Vaccine Act since the repeal of the Frist-sponsored amendment to the Vaccine Act contained in the repealed rider to the Homeland Security Act.<sup>125</sup> The rider temporarily redefined "manufacturer" to include a manufacturer of "any component or any ingredient of such vaccine," which would have included thimerosal manufacturers.<sup>126</sup> The court mentioned the rider, noting that it would have allowed the defendant relief had the amendment not been repealed, but it declined to draw any conclusions as to legislative intent saying it "does not glean the intent of the Congress which enacted the Vaccine Act from the subsequent actions of another Congress (whether in amending the definition of 'manufacturer' or in repealing the amendment)."<sup>127</sup>

### III. RECENT DEVELOPMENTS

In August 2003, the Fifth Circuit Court of Appeals affirmed *Toussaint* in a one-sentence decision denying a petition for an interlocutory appeal by Eli Lilly.<sup>128</sup> A month later, the same court remanded two other thimerosal cases to Mississippi state courts, reversing the district court's finding that the plaintiffs in both cases had fraudulently joined defendants to defeat federal court diversity jurisdiction and holding instead that state courts were competent to decide whether the Vaccine Act protected the thimerosal manufacturers.<sup>129</sup>

The following month, in October 2003, the Fifth Circuit denied another appeal—again by Eli Lilly along with other thimerosal manufacturers—of the district court's holding in *Davis v. Merck & Co.* that a thimerosal manufacturer is not a vaccine manufacturer

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125. See Reisinger, *supra* note 39, at 11.

126. *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*7 (emphasis omitted).

127. See *id.* at \*7.

128. *5th Circuit Denies Eli Lilly's Thimerosal Appeal*, 2-3 MEALEY'S LITIG. REP. THIMEROSAL & VACCINES 2 (Sept. 2003).

129. See *id.*

under the Vaccine Act.<sup>130</sup> The District Court for the Eastern District of Louisiana decided *Davis* one month after it decided *Toussaint*.<sup>131</sup>

#### IV. REMAINING PROBLEMS

While the *Toussaint* decision may have provided another forum for plaintiffs seeking recovery from thimerosal manufacturers, problems related to jurisdiction over these claims remain unresolved.<sup>132</sup> The consequences of these problems reach beyond the courts, thus affecting the ability of health and safety initiatives to protect the public from disease.<sup>133</sup>

##### A. Concerns About Uncertainty of Forum

*Toussaint* marked the first time that a federal district court conclusively determined that the Vaccine Act does not protect thimerosal manufacturers since the Vaccine Court asserted its jurisdiction over such claims in *Leroy*.<sup>134</sup> The court in *Toussaint* agreed with the Vaccine Court and the other federal district courts that thimerosal-induced injuries are “vaccine-related,” but it nonetheless found that the Act does not protect thimerosal manufacturers.<sup>135</sup>

While district courts remain conflicted, the only appellate court to address the issue, the Fifth Circuit, has affirmed the *Toussaint* stance that thimerosal manufacturers are not vaccine manufacturers and are therefore not subject to the protection of the Vaccine Act.<sup>136</sup> Whether other circuits will follow the Fifth Circuit remains to be seen.<sup>137</sup>

130. No. 03-00034 (5th Cir. Oct. 2, 2003); see Petition for Permission to Appeal from the United States District Court for the Eastern District of Louisiana Civil Action No. 02-3422, at 7, *Davis v. Merck & Co.*, (5th Cir. Oct. 2, 2003) (No. 03-00034).

131. See Petition for Permission to Appeal from the United States District Court for the Eastern District of Louisiana Civil Action No. 02-3422, at 7, *Davis v. Merck & Co.*, (5th Cir. Oct. 2, 2003) (No. 03-00034); *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*7.

132. See *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*7.

133. See *id.*

134. *Id.* at \*8. But see discussion *supra* Part II.B; *supra* note 126.

135. See *Toussaint*, 2003 U.S. Dist. LEXIS 10581, at \*8.

136. See discussion *supra* Part II.B.

137. See discussion *supra* Part II.B.

The current state of the law leaves plaintiffs with uncertainty in choosing the proper forum in which to file their claims.<sup>138</sup> While the Vaccine Court has asserted its jurisdiction, at least one circuit has affirmed the Vaccine Court's lack of jurisdiction.<sup>139</sup> In addition, given the relatively short statute of limitations currently in force for Vaccine Court claims, some plaintiffs who believe they have run out of time in exhausting their available remedies may yet be able to recover.<sup>140</sup> The uncertainty created by the conflicting assertions of jurisdiction may increase the legal costs for families already financially strapped by their child's medical needs.<sup>141</sup>

### B. Concerns About Vaccine Court Adjudication

Although the Vaccine Court has not reached a definitive finding on the causation issue, thimerosal-induced autism claims in both civil courts and the Vaccine Court are skyrocketing.<sup>142</sup> The Vaccine Court, although insisting such cases are within its jurisdiction, has not made a causation determination, thereby delaying any action on these claims.<sup>143</sup>

Even if the Vaccine Court finds a causal connection between thimerosal and autism, the forum has not proven to be the "streamlined" means for recovery envisioned by the Vaccine Act.<sup>144</sup> Families have reported a highly adversarial system with cases involving recognized "table injuries" dragging on as long as eight years.<sup>145</sup> Because of the inefficiency and adversarial nature of the Vaccine Court, it seems unlikely that families struggling to manage

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138. Reisinger, *supra* note 39.

139. *See* discussion *supra* Part II.B.

140. *See Ongoing Studies Remain a Point of Dispute in Autism Proceeding*, 2-5 MEALEY'S LITIG. REP. THIMEROSAL & VACCINES 10 (Nov. 2003) (indicating that the statute of limitations for filing a claim tolls 36 months after a doctor first makes a diagnosis of autism).

141. *See* Burton Testimony I, *supra* note 74 (citing the expense and burden of adjudicating these claims while caring for autistic children).

142. *See* Autism General Order #1, *supra* note 15, at \*2.

143. *See id.*

144. *See* Burton Testimony I, *supra* note 74. The Chairman also contended that the Vaccine Court pressured parents who prevailed in their claims to prevent the opinions from being published, thereby preventing future claimants from using the cases as precedent. *See id.* at 142.

145. *See id.* at 142-44.

their autistic children's care will find much relief from the Vaccine Act, even if the Autism Omnibus affirms a causal connection between thimerosal-containing vaccinations and autism.<sup>146</sup>

### C. Concerns About Civil Court Adjudication

The decision in *Toussaint* opens the door to what one commentator described as “the truth-ascertaining process of civil litigation.”<sup>147</sup> But that same decision may lead some vaccine manufacturers to conclude that the Vaccine Act has failed in its mission to protect them from unlimited exposure to liability.<sup>148</sup> These manufacturers may reconsider the economic feasibility of producing vaccines at all, which is a central policy concern underlying the Vaccine Act.<sup>149</sup> This kind of exposure could lead pharmaceutical companies to either stop producing vaccines or to produce them only at extremely high costs.<sup>150</sup> The childhood vaccine shortage that occurred in the early part of this century was “largely the result of the liability crisis of the 1980s that drove most companies out of the market.”<sup>151</sup> The removal of thimerosal from vaccines also contributed to that shortage since pharmaceutical manufacturers must produce preservative-free vaccines in single-dose vials, a more complex and time-consuming process.<sup>152</sup> Only four companies continue to manufacture childhood vaccines in the United States.<sup>153</sup> Industry representatives caution that protecting the Vaccine Act is vital because the loss of any one manufacturer could result in a lengthy vaccine shortage.<sup>154</sup> At the same time, the pharmaceutical industry is adamantly opposed to the government's entry into the vaccine production field, even to

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146. *See id.*

147. Hennessey, *supra* note 3, at 1.

148. *See* Scott, *supra* note 6, at 2.

149. *See id.*

150. *See Protecting Our Kids: What is Causing the Current Shortage in Childhood Vaccines?: Hearing Before the Senate Governmental Affairs Comm.*, 107th Cong. 107-559, at 46 (2002) (testimony of Wayne Pisano, Executive Vice President, Aventis Pasteur North America, for the Pharmaceutical Research and Manufacturers of America (“PhRMA”)) [hereinafter Pisano Testimony].

151. *Id.* at 43.

152. *Id.* at 47.

153. *Id.* at 43.

154. *See id.* at 51.

alleviate some of the production burden and prevent future shortages.<sup>155</sup>

*D. Concerns About Congressional Action to Clarify Jurisdiction*

While families continue to suffer as they await the Vaccine Court's causation finding, some legislators have been busy trying to immunize thimerosal manufacturers from liability with clandestine efforts to amend the Vaccine Act.<sup>156</sup> The effort to insulate thimerosal manufacturers from liability by way of the Homeland Security Act underscores this issue's importance to pharmaceutical companies.<sup>157</sup> Congress has made it clear that it will address the thimerosal manufacturer protection issue under the Vaccine Act.<sup>158</sup> One Maryland judge described the apparent "desperation" of pharmaceutical companies to avoid having their cases litigated in civil court.<sup>159</sup>

*E. Concerns About Conflicts of Interest in the Scientific Community*

There are serious concerns about bias and conflict of interest in the studies the Vaccine Court may rely on for the causation determination.<sup>160</sup> In addition, critics accuse the Centers for Disease Control, the federal agency responsible for recommending vaccines to the medical community, of having serious and pervasive conflict of interest problems among members of its vaccine review panels.<sup>161</sup> The conflict of interest accusations include accepting funds from pharmaceutical companies and allowing vaccine patent-holders to sit on committees that recommend approval of the patent-holders' own vaccines.<sup>162</sup>

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155. *See id.* at 49.

156. *See* discussion *supra* Parts I.C, II.B.

157. *See* Hennessey, *supra* note 3, at 1.

158. *See* *Thimerosal Rider Repealed*, *supra* note 100, at 29.

159. *See* *'Desperate' Removal Seen*, *supra* note 91.

160. *See* discussion *supra* Part I.A.3.

161. *See* Benjamin, *supra* note 28.

162. *See id.*

### F. Concerns About the Impact on Vaccination Initiatives

Meanwhile, the controversy surrounding thimerosal and autism has caused undesirable effects on public health.<sup>163</sup> Some parents are foregoing their children's vaccinations and seeking exemptions based on pretextual "religious" reasons so that their children can continue to attend school without being vaccinated.<sup>164</sup> In 2002, approximately 5% of new elementary school students in Michigan submitted waivers to avoid the required shots.<sup>165</sup> The "herd immunity" created by vaccinating a majority of the population is waning, and diseases that vaccines had almost vanquished are resurfacing.<sup>166</sup>

## V. SUGGESTIONS AND PROPOSALS

When Congress enacted the Vaccine Act, it intended to provide an efficient and non-adversarial means of adjudicating the claims of a small but significant number of people injured by vaccinations.<sup>167</sup> Congress wanted to insulate vaccine manufacturers from unlimited liability so they could continue cost-effective vaccine production.<sup>168</sup> However, in terms of helping plaintiffs recover, the Vaccine Court is not meeting the goals Congress intended.<sup>169</sup>

The traditional civil court system may handle thimerosal-induced injury claims more efficiently than the Vaccine Court.<sup>170</sup> Vaccine Court adjudication of thimerosal claims would not further the goal of encouraging vaccine production, since pharmaceutical manufacturers have produced vaccines without thimerosal for a number of years

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163. See Mike Wowk & Tenisha Mercer, *Thousands of Parents Skip Children's Shots; Critics: It Puts Others in Jeopardy*, THE DETROIT NEWS, Oct. 7, 2003, at 1-C.

164. *Id.*

165. *See id.*

166. See Samuel Katz, *Vaccinations: U.S. Must Take Threat from Measles Seriously*, CHARLESTON GAZETTE (West Virginia), Oct. 12, 2003, at 1C (explaining that in England, where vaccination levels have dropped from 92 percent of the population to 84 percent, incidence of measles increased by 300 percent, while reports of measles in the United States are still very low, with only 37 cases in 2002).

167. See *Leroy v. Sec'y of Dep't of Health & Human Servs.*, 2002 U.S. Claims LEXIS 284, at \*10-11 (Fed. Cl. Oct. 11, 2002).

168. *See id.* at \*13 n.7.

169. *See* Burton Testimony I, *supra* note 74.

170. *See* discussion *supra* Part I.B.1.

now.<sup>171</sup> The goal of providing vaccine-injured plaintiffs with a streamlined means of recovery is laudable, but the tort system, while time consuming, does not require plaintiffs to forego their right to prove and plead damages in favor of a predetermined level of compensation.<sup>172</sup> Since Congress is not granting plaintiffs the benefit of rapid claim resolution, why must the plaintiffs continue to bear the burden of the Vaccine Court's limitations on damages?<sup>173</sup>

Even though exposing thimerosal manufacturers to liability would cause some manufacturers to leave the vaccine production market, another manufacturer would likely compensate for any temporary shortfall, especially because of the lack of market competition.<sup>174</sup> Additionally, the current system of liability protection for vaccine manufacturers does not give them an incentive to respond quickly to indications that their products may be causing problems.<sup>175</sup> Although the FDA first proposed removing thimerosal from vaccines in 1982, the pharmaceutical companies did not act until 2001.<sup>176</sup>

### CONCLUSION

Pharmaceutical companies and vaccine-injured plaintiffs are currently litigating the issue of whether the Vaccine Act extends protection to thimerosal manufacturers, a mercury-containing preservative once widely used in childhood vaccinations.<sup>177</sup> The *Toussaint* decision is significant in that it marks the first time, since the Vaccine Court asserted it had jurisdiction over all thimerosal-

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171. See discussion *supra* Part I.A.2.

172. See discussion *supra* Part I.B.1. The Vaccine Court allows plaintiffs to presume causation for Table injuries, but it limits the amount of damages they may recover. See discussion *supra* Part I.B.1.

173. See discussion *supra* Part I.B.1.

174. See Vin Suprynowicz, *Is Partial Reversal of Autism Possible?*, LAS VEGAS REV. J., Oct. 26, 2003 (citing comments of Laura Bono, founder of the Right to Fight Mercury Damage Campaign). *But see* Pisano Testimony, *supra* note 151 (noting it could take more than a year for another manufacturer to "fill the gap").

175. See *Parents Allege*, *supra* note 38; Reisinger, *supra* note 39, at 11.

176. See *id.*

177. See discussion *supra* Part I.B.



related claims in *Leroy*, that a court has determined that the Vaccine Act's tort suit ban does not protect a thimerosal manufacturer.<sup>178</sup>

For claims adjudicated in the Vaccine Court, the Vaccine Act limits the amount that plaintiffs may recover.<sup>179</sup> Vaccine Court adjudication can also subject plaintiffs to extremely adversarial and lengthy proceedings in a forum that limits their rights in exchange for granting them a fast and simple recovery process.<sup>180</sup> The Vaccine Court has fallen short of its goal of protecting plaintiffs while insulating vaccine manufacturers from unlimited liability.<sup>181</sup> Allowing thimerosal-induced autism claims in civil court may be a more expeditious and fair means for injured plaintiffs to recover.<sup>182</sup>

*Beverly Jones Sill*<sup>183</sup>

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178. See discussion *supra* Part II.B.

179. See discussion *supra* Part I.B.1.

180. See discussion *supra* Part I.B.1.

181. See *supra* Part IV.

182. See *supra* Part V.

183. The author wishes to thank her husband, Doug Sill, and her family for their understanding and support, and dedicates this Comment to her nephew, William Brenneman.