

# DPT VACCINE CONTROVERSY: AN ASSESSMENT OF THE LIABILITIES OF MANUFACTURERS AND ADMINISTERING PHYSICIANS UNDER SEVERAL LEGAL THEORIES

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## I. INTRODUCTION

During the previous several years, a medico-legal controversy has brewed regarding the vaccine injected into young infants to protect them against the childhood diseases of diphtheria, pertussis or whooping cough, and tetanus.<sup>1</sup> Commonly known by its acronym, DPT, the vaccine first became used in the United States in the 1930s.<sup>2</sup> The proponents of the DPT vaccine attribute the virtual eradication of these diseases<sup>3</sup> at the present time to the long-term efforts of the medical community,<sup>4</sup>

<sup>1</sup> See Tarr, *DPT Vaccine Injuries: Who Should Pay?* 7 NAT'L. L.J. 1 (April 1, 1985). See also Edelson, *What is "Acceptable Risk" for DPT Vaccine?*, Asbury Park Press, March 31, 1985, at F12, col. 2; Russell, *Firm Ceases Making Vaccine*, Washington Post, June 19, 1984, at A5, col.1.

<sup>2</sup> See Houts, *Presenting the Medical Research: Adverse Reactions From DTP Immunization (Part 2)*, 25 TRAUMA 6:19, 6:22 (April 1984). More than 200,000 cases of pertussis were reported annually in the 1930s with approximately 7,500 annual deaths from the disease. Brunell, Chairman, Pertussis Vaccine, Committee on Infectious Disease, 1983-84, 74 PEDIATRICS 303 (1984). See also Hinman & Koplan, *Pertussis and Pertussis Vaccine, Reanalysis of Benefits, Risks, and Costs*, 251 J.A.M.A. 3109 (1984) (discussing history of vaccine); The Fresno Bee, Dec. 1984, at 1, col.1.

<sup>3</sup> At the present time, there are between 1,000 and 3,000 cases of pertussis annually with between five and 20 related deaths. Statement by Dr. William H. Foegen, Director of Center for Disease Control, before the United States Senate Subcommittee on Investigations and General Oversight, Committee on Labor and Human Resources 7 (May 7, 1982) (published by the American Academy of Pediatrics).

<sup>4</sup> See *id.*

backed recently by the federal, state, and municipal governments,<sup>5</sup> toward universal vaccination.<sup>6</sup>

The focus of the controversy is the "P" or pertussis portion of the triple vaccine.<sup>7</sup> Since at least 1948, when Byers and Moll published their study of DPT in the *New England Journal of Medicine*,<sup>8</sup> knowledgeable pediatricians and medical researchers have recognized that the pertussis portion of DPT triggers adverse reactions in certain children ranging from low-grade fever and irritability to severe brain damage and death.<sup>9</sup>

According to the DPT advocates, notwithstanding the ad-

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<sup>5</sup> See Houts, *supra* note 2, at 6:39 (discussing National Immunization Initiative launched by Department of Health, Education and Welfare toward universal immunization); Testimony by Vincent A. Fulginiti, M.D., On Immunization Programs, Before the United States Senate Subcommittee on Investigations and General Oversight, Committee on Labor and Human Resources 1 (May 7, 1982) (published by American Academy of Pediatrics) (discussing various levels of government's attempts to provide guidance in using vaccines). In addition, the federal government expended 21.8 million dollars in 1982 alone in support of immunization programs. Foege, *supra* note 3, at 2-3. Furthermore, legislation in 44 states mandates DPT vaccination prior to public school entry. Hinman, *The Pertussis Vaccine Controversy*, 99 PUB. HEALTH REP. 255, 258 (1984).

<sup>6</sup> See Cody, Baraff, Cherry, Marcy & Manclark, *Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children*, 68 PEDIATRICS 650, 658 (Nov. 5, 1981) [hereinafter *Cody*]. Using published information, Hinman and Koplan, hypothesized that vaccination of 90% of all American children would reduce the incidence of pertussis and reduce costs by 82%. Hinman and Koplan, *supra* note 2, at 3109. They estimated that without an immunization program, overall costs associated with pertussis would multiply 5.7 times. *Id.* Almost 96% of all American children entering school in 1980 received DPT vaccinations. Foege, *supra* note 3, at 3. According to DPT vaccine supporters, the efficacy of DPT is between 63 and 94%. *Id.* at 9. See also Broome, Preblud, Burner, McGowan, Hayes, Harris, Elsea & Frasele, *Epidemiology of Pertussis*, Atlanta, 1977, 98 PEDIATRICS 362 (1981); Hinman, *supra* note 5, at 256.

<sup>7</sup> The "D" and "T" are used with "P" because the "P" acts as an adjuvant to increase immunity to diphtheria and tetanus; however, it has been suggested that the combination may increase reactivity. Mortimer, *Pertussis Immunization: Problems, Perspectives, Prospects*, 15 HOSP. PRAC. 103-07, 111-12, 117-18 (1980).

<sup>8</sup> Byers & Moll, *Encephalopathies Following Prophylactic Pertussis Vaccine*, 14 PEDIATRICS 437 (1948).

<sup>9</sup> See, e.g., Berg, *Neurological Complications of Pertussis Immunizations*, 2 BRIT. MED. J. 24 (1958); Miller, Ross, Alderslade, Bellnar & Rawson, *Pertussis Immunizations and Serious Acute Neurological Illness in Children*, 282 BRIT. MED. J. 1595 (1981); Strom, *Further Experience of Reactions Especially of a Cerebral Nature in Conjunction with Triple Vaccination*, 4 BRIT. MED. J. 320 (1967); Strom, *Is Universal Vaccination Against Pertussis Always Justified?*, 2 BRIT. MED. J. 1184 (1960) (hereinafter Strom, *Universal Vaccination*); Sutherland, *Encephalopathy Following Diphtheria-Pertussis Inoculation*, 28 ARCHIVES OF DISEASE IN CHILDHOOD 149 (1953); Toomey, *Reactions to Pertussis Vaccine*, 139 J.A.M.A. 448 (1948). See also Madsen, *Vaccination Against Whooping Cough*, 101 J.A.M.A. 187 (1933). Symptoms which comprise "pertussis reaction syndrome" are listed in Table III of Appendix.

verse reactions, the benefits of vaccination against whooping cough far outweigh its risks.<sup>10</sup> Although the proponents and critics of DPT sharply disagree on the percentage of children detrimentally affected by the vaccine,<sup>11</sup> there is agreement among most medical groups and researchers that a less reactogenic vaccine needs to be developed.<sup>12</sup> Meanwhile, the supporters of pertussis vaccine fear the incidence of an epidemic as a result of a possible decrease in vaccinations caused by public awareness of the dangers of DPT.<sup>13</sup>

Some critics of DPT contend that the alleged benefits of pertussis vaccination do not outweigh the risks.<sup>14</sup> According to Gordon T. Stewart, M.D. of Glasgow, Scotland, the desirability of pertussis vaccination is highly questionable in the face of serious neurological residua following the administration of pertussis

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<sup>10</sup> Baraff, Cody & Cherry, *DPT-Associated Reactions: An Analysis by Injection Site, Manufacturer, Prior Reactions, and Dose*, 73 PEDIATRICS 31, 36 (1984); Brunell, *supra* note 2, at 303; Houts, *supra* note 2; Koplan, Schoenbaum, Weinstein & Fraser, *Pertussis Vaccine-An Analysis of Benefits, Risks and Costs*, 301 NEW ENG. J. MED. 906, 910 (1979) (hereinafter Koplan); Miller, Pollack & Clewer, *Whooping-Cough Vaccination, An Assessment*, THE LANCET, August 31, 1974, at 510; Warin, *Immunization: Balancing of the Risks*, 67 PROC. R. SOC. MED. 374 (1974).

<sup>11</sup> Brunell, *supra* note at 2; Miller, Ross, Alderslade, Bellnar & Rawson, *Pertussis Immunizations and Serious Acute Neurological Illness In Children*, 282 BRIT. MED. J. 1595 (1981); Strom, *Universal Vaccination*, *supra* note 9.

<sup>12</sup> See Barkin and Pichichero, *Diphtheria-Pertussis-Tetanus Vaccine: Reactogenicity of Commercial Products*, 63 PEDIATRICS 256, 260 (1979); Felton & Verwey, *The Epidemiological Evaluation of a Non-Cellular Pertussis Antigen*, 16 PEDIATRICS 637, 637 (1955); Koplan, *supra* note 10, at 906; Nagel, *Isolation from Bordetella Pertussis of Protective Antigen Free from Toxic Activity and Histamine Sensitizing Factor*, 214 NATURE 96, 96 (1967); Sato and Sato, *Bordetella Pertussis Infection in Mice: Correlation of Specific Antibodies Against Two Antigens, Pertussis Toxins, and Filamentous Hemagglutinin with Mouse Protectivity in an Intracerebral or Aerosol Challenge System*, 46 INFECTION AND IMMUNITY 415, 415 (1984); Sato, Chiba & Sato, *Monoclonal Antibody Against Pertussis Toxin: Effect on Toxin Activity and Pertussis Infections*, 46 INFECTION AND IMMUNITY 422, 422 (1984).

<sup>13</sup> Koplan, *supra* note 10, at 911. The Food and Drug Administration (FDA) estimates that the number of whooping cough cases would increase to 380,000 annually, from a current 1,000 to 3,000 cases, if immunization dropped from its present 90% rate to a 30-40% rate. Silberner, *DPT Vaccine: Weighing the Risk*, THE WASHINGTON POST, Mar. 27, 1985 (Health Section) at 6, col.2.

<sup>14</sup> See, e.g., Dick, *Reactions to Routine Immunization in Childhood*, 67 PROC. ROY. SOC. MED. 371, 371 (1974). See also Stewart, Letter to Editor, *Pertussis Vaccine-Benefits and Risks*, 302 NEW ENG. J. MED. 634, 634 (1980); Stewart, *Vaccination Against Whooping Cough, Efficacy Versus Risks*, THE LANCET, January 29, 1977, at 234 (hereinafter Stewart, *Vaccination against Whooping Cough*). Stewart has stated that DPT vaccination is "at best partial, probably temporary, and seldom if ever complete enough to protect the only group which is seriously at risk—namely infants in crowded homes." *Id.* at 237. Stewart believes that an epidemiological reason for mass immunization does not exist. *Id.* at 234. See also Bassilli, *Epidemiological Evaluation of Immunizations and Other Factors in the Control of Whooping-Cough*, THE LANCET, Feb. 28, 1976, at 471.

vaccine to certain children.<sup>15</sup> Critics emphasize the necessity to screen out children considered to be at high-risk of a neurological reaction.<sup>16</sup>

Challengers to the safety of DPT have targeted the vaccine manufacturers and some pediatricians as the culprits in the controversy. The manufacturers have allegedly failed to test properly and market the vaccine for many years despite their knowledge of its dangerous propensities.<sup>17</sup> It is contended by the DPT critics that many pediatricians have neglected to appreciate the significance of previous neurological sequelae,<sup>18</sup> a recognized contraindication to further inoculation,<sup>19</sup> while injecting into vulnerable children second, third, and booster doses of DPT. Many pediatricians have come under attack for their purported failure to advise and educate parents of young children regarding the risks of DPT prior to inoculation.<sup>20</sup>

Medical malpractice and drug liability actions involving pertussis vaccination are not new phenomena.<sup>21</sup> However, in view of the ever-growing public understanding of the deleterious effect of the vaccine on some children brought about by commentaries on television<sup>22</sup> and in newspaper articles,<sup>23</sup> more vaccine-damaged children, through their parents, are seeking redress in the courts.<sup>24</sup>

This article will discuss several theories of liability which have been asserted by plaintiffs in DPT cases as well as other potential theories of liability which likely will be advanced against the vaccine manufacturers and pediatricians. Although emphasis

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<sup>15</sup> Stewart, Letter to the Editor, *Whooping Cough and Pertussis Vaccine*, 287 BR. MED. J. 287, 288 (1983). See also Bassilli, *supra* note 14, at 473.

<sup>16</sup> See Strom, *Universal Vaccinations*, *supra* note 9.

<sup>17</sup> Tarr, *supra* note 1, at 26.

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

<sup>19</sup> See Physician's Desk Reference, (E. R. Barnhart, Pub., Tri-Immunol, Lederle Laboratories, at 1031-32 (1986)).

<sup>20</sup> Lewis, *DPT Vaccine-Worth the Risk?*, TRIAL, Aug., 1982, at 23, 29 (citing Seiden, PEDIATRICS 55 (16th ed. 1977)).

<sup>21</sup> See, e.g., *Tinnerholm v. Parke, Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd on other grounds*, 411 F.2d 48 (2d Cir.1969).

<sup>22</sup> See, e.g., *DPT-Old Vaccine, New Questions*, ABC News 20/20, Jeff Diamond, Producer, Show Number 505, February 5, 1985; *DPT Danger*, WNET/Thirteen, McNeil-Lehrer Report, Robert McNeil, Executive Editor, Transcript No. 2042, 1983; *DPT: Vaccine Roulette*, NBC Television Stations Division, NBC, Inc., Lea Thompson, NewsCenter Four, April 19, 1982.

<sup>23</sup> See, e.g., *The Fresno Bee*, *supra* note 2.

<sup>24</sup> As of April 1985, almost 150 reported lawsuits were filed against DPT vaccine manufacturers. Tarr, *supra* note 1.

will be placed on New Jersey case law in the analysis of liability theories, pertinent cases and statutes from other jurisdictions shall be interjected where appropriate to buttress or deny the scope of drug liability or pediatric malpractice in New Jersey concerning DPT and DPT inoculation.

A discussion of the legal ramifications of an adverse reaction to DPT cannot be undertaken validly without some historical perspective, nor without a survey of the current medical and scientific literature supporting and opposing continued administration of DPT vaccine to young children. Consequently, this article shall begin with a brief history of DPT and an explanation of the literature. Drawing upon existing and potential theories of liability, it shall conclude with a discussion of the asserted liability of vaccine manufacturers and pediatricians.

## II. HISTORICAL AND MEDICAL LOOK AT THE DPT VACCINE AND ITS ADMINISTRATION TO CHILDREN

Pertussis is a respiratory infection caused by *B. Pertussis* bacteria which localizes between the cilia of the epithelial cells of the respiratory tract.<sup>25</sup> The disease places infants at risk, but is rarely troublesome in older children and adults. Approximately one child in 10,000 who has the disease suffers pertussis-related brain damage, and one child out of 1,000 dies as a result of the neurological residua brought on by the disease.<sup>26</sup>

Although pertussis was a dreaded disease worldwide prior to the advent of widescale use of pertussis vaccine, mortality from the disease in the United States declined from 17.4 to 2.1 per 100,000 children from 1900 to 1940. While proponents of the vaccine attribute the steady decline in mortality and morbidity to vaccine use, other contributory factors have been recognized by both proponents and critics of the pertussis vaccine, including the cyclical nature of the disease, a decrease in the birth rate in the 1930s, the development of antibiotics, and improved socioeconomic conditions.<sup>27</sup>

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<sup>25</sup> Pittman, *Bordetella Pertussis-Bacterial and Host Factors in the Pathogenesis and the Prevention of Whooping Cough*, in *INFECTIOUS AGENTS AND HOST REACTIONS* (S. Mudd, Ed. 1970), at 239, 240.

<sup>26</sup> Foegen, *supra* note 3, at 6-7.

<sup>27</sup> See Barkin, *supra* note 12, at 260; Lewis, *supra* note 20, at 25; Stewart, *Pertussis Vaccine: The United Kingdom's Experience*, Position Paper, Third International Symposium on Pertussis, 262, 276; Warin, *supra* note 10, at 375.

*A. Pertussis—The Vaccine*

A crude pertussis vaccine comprised of live whole-cell *B. Pertussis* bacteria was first introduced in the early 1900s. Since its introduction, however, adverse reactions have been associated with the use of pertussis vaccine.<sup>28</sup> In the United States, pertussis vaccine was used experimentally in the 1930s.

Despite growing acceptance of the pertussis vaccine after the introduction of the mouse potency test,<sup>29</sup> some pediatric researchers expressed grave concern about the severity of the vaccine's side-effects.<sup>30</sup> In 1948, Byers and Moll published a study concerning severe infant encephalopathy with pertussis vaccination based upon fifteen infant hospitalizations in Boston.<sup>31</sup> Although Madsen had reported two deaths associated with the vaccine in 1933,<sup>32</sup> it was not until Byers and Moll published their report that the potentially devastating consequences of pertussis vaccination were truly appreciated by the medical community.

The findings of Byers and Moll were confirmed in later studies. In 1949, Toomey reported thirty-eight cases of convulsions, two deaths, and twelve irreversible lesions from information obtained from fifty-four American pediatricians.<sup>33</sup> In 1953, Halpern also acquired data from fifty-six pediatricians which demonstrated fifteen cases of convulsions, one death, and three irreversible cerebral lesions.<sup>34</sup> Concern about the neurological side-effects of the vaccine was not confined to the United States. Studies in Great Britain and Germany also reported alarming results involving DPT inoculations.<sup>35</sup> As concern about pertussis vaccine grew in the United States and abroad, more studies were initiated to uncover an explanation for whole-cell pertussis reac-

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<sup>28</sup> Madsen, *Vaccination Against Whooping Cough*, 101 J.A.M.A. 187 (1933); Sauer, *Whooping Cough: A Study in Immunization*, 100 J.A.M.A. 239 (1933).

<sup>29</sup> The mouse potency test was formulated to standardize the number of organisms per vaccine dose. Kendrick, *Mouse Protection Tests in the Study of Pertussis Vaccine*, 37 AM. J. PUB. HEALTH 803 (1947).

<sup>30</sup> See, e.g., Byers & Moll, *supra* note 8, at 437; Toomey, *Reactions to Pertussis Vaccine*, 139 J.A.M.A. 448 (1948).

<sup>31</sup> Byers & Moll, *supra* note 8.

<sup>32</sup> Madsen, *supra* note 28.

<sup>33</sup> Toomey, *supra* note 30.

<sup>34</sup> Halpern, *Reactions From DPT Immunization and Its Relationship to Allergic Children*, 47 PEDIATRICS 60 (1955).

<sup>35</sup> See, e.g., Kulinkampff, *Neurological Complications of Pertussis Inoculation*, 49 ARCH. DIS. CHILD. 46 (1974) (study in Great Britain describing neurological impairment after DPT inoculation); Strom, *Universal Vaccinations*, *supra* note 9, at 1184 (citing Kong, 8 HELV. PAEDIAT. ACTA 90 (1953)) (German study in 1957 showing post-vaccination complications to DPT injections).

tivity. These studies were not entirely successful, although they raised theories which are presently being tested and developed. Because of the limited knowledge of the B. Pertussis cell components and their effects on the human body,<sup>36</sup> no definitive solution to reactivity has been forthcoming.<sup>37</sup>

*B. Obstacles in Producing a Safer Vaccine*

Manufacturers have encountered two basic obstacles in the development of a safety pertussis vaccine—the exorbitant cost of production and distribution of an extracted or acellular vaccine, and the absence of a meaningful clinical test for human efficacy and reactivity.<sup>38</sup>

The cost of commercial production for an extracted or acellular vaccine radically exceeds the cost of producing the whole-cell vaccine. Although a manufacturer could produce a dose of whole-cell pertussis vaccine for five cents exclusive of marketing and distribution in 1976, the cost of producing a purified vaccine would be at least ten times as expensive per dose.<sup>39</sup> Since vaccine production has never been a highly profitable venture,<sup>40</sup> critics have suggested that marginal profits realized by manufacturers dampened enthusiasm for improving the pertussis vaccine in terms of efficacy and safety.<sup>41</sup>

In addition to costs of production and distribution, the lack of clinical testing is another reason given for the inability of researchers to develop a safer pertussis vaccine.<sup>42</sup> Because of the infrequent incidence of pertussis in the United States,<sup>43</sup> the number of humans available for clinical trials is small.<sup>44</sup> Thus, since 1947, reliance has been placed on the mouse potency and toxicity tests to determine efficacy and reactivity. Most knowl-

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<sup>36</sup> See *Final Report of the Panel on Review of Bacterial Vaccines and Bacterial Toxoids*, Department of Health, Education and Welfare, Public Health Service, FDA, Bethesda, Md., Gene H. Stollerman, Chairman, at 36, 250-52, Aug. 2, 1979 (hereinafter *Final Panel Report*); Pittman, *supra* note 25.

<sup>37</sup> *Final Panel Report*, *supra* note 36, at 29, 36, 45.

<sup>38</sup> It is believed that an extracted or acellular vaccine may be safer than the current whole-cell vaccine. See, e.g., *T.V. Report of DPT Galvanizes U.S. Pediatricians*, 248 J.A.M.A. 12, 22 (1982).

<sup>39</sup> Anderson, *The Problems Associated With a Development in Clinical Testing of an Improved Pertussis Vaccine*, 20 ADV. APP. MICROBIO. 43, 52 (1976).

<sup>40</sup> Houts, *supra* note 2, at 40.

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

<sup>42</sup> *Final Panel Report*, *supra* note 36, at 296.

<sup>43</sup> In 1983, there were less than 2,500 pertussis cases without any reported deaths. *The Fresno Bee*, *supra* note 2, at 5.

<sup>44</sup> *Final Panel Report*, *supra* note 36, at 36.



edgeable researchers and physicians acknowledge the shortcomings of these tests, but none have offered satisfactory test alternatives. In recent years, the mouse potency tests have come under increasing criticism. Alan Hinman, M.D., Director of the National Center for Disease Control in Atlanta has said that the mouse potency test "may not be the optimal model to measure protection against respiratory disease."<sup>45</sup>

As a consequence of the high costs of producing a safer vaccine, coupled with the lack of a test using humans, there are no extracted or acellular pertussis vaccines on the market today in the United States. Oddly, DPT producers need only comply with the much-criticized mouse tests prescribed in the federal regulations in order to market the vaccines which are ultimately injected into American infants.

### C. *The Nature of Adverse Reactions*

While virtually all pertussis vaccine researchers and pediatricians have acknowledged that neurological side-effects sometimes follow immunization, medical opinion about the number and percentage of affected infants is a source of debate. In 1977, Stewart published his observations of neurotoxic reactions following vaccinations in 160 cases.<sup>46</sup> The association between the adverse reactions and vaccine was strong in seventy-nine cases. In fourteen of those cases, shock and cerebral disturbance of a temporary nature occurred. In sixty-five out of seventy-nine cases, the shot was followed by convulsions, hyperkinesia, and severe mental defect.<sup>47</sup> Based on his observations of pertussis reactions in other prior studies, Stewart listed symptoms of what he termed "pertussis reaction syndrome."<sup>48</sup> In the presence of mounting concern over the "P" portion of DPT vaccine, the United States government funded a study headed by Baraff. Baraff's final report concluded that "[r]eaction rates of DPT vaccines currently licensed in the United States were found to be greater than previously reported."<sup>49</sup> In Baraff's study, only reactions which occurred within forty-eight hours after immunization were recorded. All others were considered to be coincidental

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<sup>45</sup> Hinman, *supra* note 5, at 256.

<sup>46</sup> Stewart, *supra* note 14.

<sup>47</sup> *Id.* at 234.

<sup>48</sup> *Id.* at 236. See also *infra* Table III of Appendix.

<sup>49</sup> Baraff, *Pertussis Vaccine Project Rates, Nature and Etiology of Adverse Reactions Associated with DTP Vaccine*, UCLA, Prepared for FDA, Bethesda, Md., March 18, 1980 at 19.

and probably caused by other pathological events.<sup>50</sup> "Less serious reactions" were defined as local pain, swelling, redness, fever, drowsiness, fretfulness, vomiting, anorexia, and persistent or high-pitched unusual crying. "More serious reactions" included hypotonic hyporesponsive episodes, convulsions, encephalopathy, neurologic sequelae, and death.<sup>51</sup>

Baraff reported that local reactions occurred in sixty-four percent of DPT vaccinees while minor systemic reactions occurred after fifty percent of DPT vaccinations.<sup>52</sup> He estimated that one out of 1750 immunizations resulted in convulsions. Hypotonic hyporesponsive episodes also occurred in one out of 1750 vaccinations. Baraff did not report any deaths or encephalopathies from DPT vaccine in his study.<sup>53</sup> All convulsions noted occurred within twenty-four hours after injection. Those infants experiencing shock-like collapse became pale, hypotonic, and unresponsive for durations of between ten minutes and thirty-six hours. All collapses occurred within ten hours after immunization and usually within four hours.<sup>54</sup> In every adverse reaction category compared, the DPT vaccine triggered reactions in a greater percentage of inoculated infants than did the DT vaccine. There were no convulsions or hypotonic hyporesponsive episodes following DT vaccine injections.<sup>55</sup>

In addition to the neurological reactions after DPT vaccinations, some observers maintain that DPT vaccine causes deaths which are diagnosed as Sudden Infant Death Syndrome (SIDS).<sup>56</sup> SIDS is the largest single cause of post-neonatal infant mortality. One-half of all SIDS deaths occur between the ages of three and four months.<sup>57</sup> Internal findings after death are intrathoracic petechiae of the lung, pericardium, and thymus. SIDS is typically associated with autopsy findings of pulmonary congestion and edema.<sup>58</sup>

The belief that a correlation exists between DPT vaccine and

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<sup>50</sup> *Id.* at 5.

<sup>51</sup> *Id.* at 8.

<sup>52</sup> *Id.* at 20.

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

<sup>54</sup> *Id.* at 10.

<sup>55</sup> Cody, *supra* note 6. See also *infra* Table IV of Appendix for a comparison of the adverse reactions following DPT and DT immunizations in the Baraff study.

<sup>56</sup> See, e.g., Geraghty, Letter to Editor, *DPT Immunization and SIDS*, 105 *PEDIATRICS* 169 (1980).

<sup>57</sup> Beckwith, *The Sudden Infant Death Syndrome*, 3 *CURRENT PROB. PEDIATRICS* 1 (1973).

<sup>58</sup> *Id.* at 19-20.

SIDS was initiated at least in the United States<sup>59</sup> when eleven children died in Tennessee within eight days of inoculation during the period from August 1978 through March 1979.<sup>60</sup> All eleven infants received DPT vaccines from a lot manufactured by Wyeth Laboratories. Death occurred within twenty-four hours after injection in four cases.<sup>61</sup> Despite these findings, however, the general opinion is that no connection between SIDS and DPT vaccine exists.<sup>62</sup>

#### D. Contraindications and Recommendations

Approximately fifty percent of all infants are immunized in public health clinics.<sup>63</sup> The DPT used at the clinics is purchased with federal funds. Since 1978, DPT can only be administered in

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<sup>59</sup> Bernier, *Diphtheria-Tetanus Toxoids-Pertussis Vaccination and Sudden Infant Deaths in Tennessee*, 101 PEDIATRICS 419 (1982). Concern about such a connection had arisen earlier in Australia. See Kalokerinos, *Sudden Death in Infancy Syndrome*, MED. J. OF AUST., Sept. 4, 1976, at 393-94; O'Reilly, Letter to Editor, *Cot Death Survey: Anaphylaxis and the House Dust Mite*, MED. J. OF AUST., Feb. 3, 1973, at 262.

<sup>60</sup> The Tennessee Department of Health notified the Center for Disease Control which commissioned Robert H. Bernier, M.D., to investigate the matter. Bernier, *supra* note 59, at 419. Bernier reported that he could not find a definite association between the vaccine and the deaths. *Id.* Nevertheless, Bernier did state that the "evidence seems adequate to indicate an unusual temporal association" between DPT vaccine and SIDS. *Id.* Following Bernier's investigation, a panel of experts convened at the Center for Disease Control and opined that although a causal connection was not established it could not be ruled out.

Bernier's report about the Tennessee deaths has been criticized on several grounds. His report excludes any reference to the vaccine lot used, which was purportedly double-strength, or to the fact that many of the infants died subsequent to the first injection. According to critics, Bernier failed to indicate that histories were not taken from parents of the infants prior to inoculation, and that he ignored previous reports as early as 1933 and 1946 published in the Journal of the American Medical Association concerning shock-like deaths after pertussis vaccination. Geraghty criticized the statistical exclusion by Bernier of a fifth death which occurred in Tennessee during the same period within 24 hours after immunization because the vaccine came from a different Wyeth lot.

Despite the criticism of Bernier's report, the official position of most private and public health groups is that a temporal association has been established at best. In support of the opinion that no connection between DPT vaccine and SIDS exists, commentators rely upon foreign studies which purport to show that the peak incidence of SIDS happens to fall fortuitously within the time frame of immunizations, or that SIDS babies are actually less likely to have been immunized. According to Bernier, while vaccination schedules vary from country to country, age distribution curves for SIDS deaths are similar throughout the world, adding further support for Bernier's contention that a causal connection has not been established. *Id.*

<sup>61</sup> Bernier, *supra* note 59.

<sup>62</sup> See *supra* note 60.

<sup>63</sup> Foegen, *supra* note 3, at 2.

the public sphere after the child's parent or guardian reads and signs an Important Information Form. This form contains information about DPT and describes certain adverse reactions which may occur.<sup>64</sup> The information provided in the form follows the recommendations of the Public Health Services Immunization Practices Advisory Committee (ACIP),<sup>65</sup> the governmental body which deals strictly with vaccines administered in the public sector.<sup>66</sup>

The counterpart to the ACIP is the Committee on Infectious Diseases of the American Academy of Pediatrics, also known as the Red Book Committee.<sup>67</sup> This Committee makes recommendations on vaccine use for pediatricians in private practice. The Red Book Committee and the ACIP coordinate with each other and strive for consistency in promulgating recommendations and contraindications of pertussis immunization.<sup>68</sup>

The ACIP and the Red Book Committee recommend four DPT doses: the first at two to three months, the next two at six to eight week intervals, and the fourth at one year after the third.<sup>69</sup> A booster is suggested between three and six years of age. Both organizations also believe that any unfavorable reactions to the DPT shot should result in an immediate halt to the injections.<sup>70</sup>

In the United States, vaccine manufacturers follow the recommended contraindications of the Red Book Committee and the ACIP in advising pediatricians to whom they distribute the vaccine. The manufacturers include package inserts with their products which provide more information regarding adverse reactions in addition to contraindications. The package inserts are intended to alert or educate administrators of DPT as to its side-effects rather than the parents or the guardians of the infant who probably never see the package insert.<sup>71</sup> Package inserts are revised and updated periodically by the vaccine manufacturers to

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<sup>64</sup> *Pertussis and Pertussis Vaccine*, Report of the Interagency Group to Monitor Development, Production and Usage, at 4-5.

<sup>65</sup> Foegen, *supra* note 3, at 1.

<sup>66</sup> *Id.* at 5.

<sup>67</sup> *Id.* at 4-5.

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

<sup>69</sup> Houts, *supra* note 2, at 23 (citing Mortimer, *Pertussis Immunization: Problems, Perspectives, Prospects*, 15 HOSP. PRAC. at 39 (1980)).

<sup>70</sup> See Brunell, *supra* note 2, at 303; Houts, *supra* note 2; *Recommendation of the Immunization Practices Advisory Committee, Supplementary Statement of Contraindications to Receipt of Pertussis Vaccine*, 33 M.M.W.R. 159, 171 (1984); *T.V. Report on DPT Galvanizes U.S. Pediatricians*, 248 J.A.M.A. 12, 14 (1982).

<sup>71</sup> 1 DIXON, DRUG PRODUCT LIABILITY, § 6.07(2)(a).

comport with recent studies dealing with reactivity.<sup>72</sup>

The manufacturers rely upon the pediatrician or health care personnel, as learned intermediaries, to pass along relevant information concerning the DPT shot to the parent or guardian.<sup>73</sup> Although the concept underlying package inserts has been commended, even proponents of DPT recognize that the package inserts have not been accomplishing their intended purpose.<sup>74</sup>

Lederle Laboratories (Lederle), a Division of American Cyanamid Co., manufactures and distributes the only commercial DPT vaccine on the market today. In Lederle's most recently published package insert for Tri-Immunol, the name given to its product, the pharmaceutical company describes the following contraindications to the administration of pertussis vaccine:

Immunization should be deferred during the course of any acute illness. The occurrence of any type of neurological symptoms or signs, including one or more convulsions (seizures) following administration of this product is a contraindication to further use. Use of this product is also contraindicated if the child has a personal or family history of central nervous system disorders.

The presence of any evolving or changing disorder affecting the central nervous system is a contraindication to administration of DPT regardless of whether the suspected neurological disorder is associated with occurrence of seizure activity of any type.<sup>75</sup>

In addition to the foregoing contraindications, the package insert restates the ACIP and Red Book Committee contraindications, and also recommends that elective immunization of patients over six months should be deferred during an outbreak of poliomyelitis.

The package insert specifically lists certain "warnings:"

The product is not recommended for immunizing persons after their seventh birthday. Do not attempt routine immunization if the child has a personal or family history of central nervous system disorders. Should any symptomatology related to a neurological disorder develop following administration, do not attempt further administration of pertussis vaccine. Convulsion, encephalitis, focal neurologic signs, collapse, shock, excessive screaming (persistent crying or

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<sup>72</sup> 21 C.F.R. § 314.8 (1984); 21 C.F.R. § 201.100 (1984).

<sup>73</sup> See DIXON, *supra* note 71, at § 7.02.

<sup>74</sup> Houts, *supra* note 2 (discussing patient package inserts).

<sup>75</sup> Package Insert, Tri-Immunol, Lederle Laboratories, Wayne, N.J., issued 1986.

screaming of three or more hours duration) excessive somnolence, severe alteration of consciousness, systemic allergic reactions or temperature of more than 105 degrees F. (40.5 degrees C.) are contraindications for any further use of pertussis vaccine.<sup>76</sup>

If any of these disorders occur, diphtheria and tetanus toxoids should be administered, but not pertussis vaccine.

In an effort to guide the administering physician, the package insert also recommends that the vaccine be used only for the age group between two months and the seventh birthday. The insert suggests that the doctor review the patient's history regarding "possible sensitivity," and become familiar with the recent literature about pertussis vaccine and the nature of adverse reactions in order to prevent side-effects. Lederle also states that inquiry regarding recent health status and prior manifestations of adverse reactions should precede the administration of any dose of DPT.<sup>77</sup>

Despite mention of adverse reactions in the literature and package inserts, the Red Book Committee and the ACIP have not undertaken any efforts to discover the extent of adverse reactions to DPT inoculation. Pursuant to federal regulations, the federal government is required to process and maintain, but not to investigate, adverse reaction reports.<sup>78</sup> Vaccine manufacturers are required by federal regulations to maintain and retain adverse reaction reports.<sup>79</sup> Although some manufacturers voluntarily submit these reports to a section of the Food and Drug Administration known as the Office of Biologics, none are mandated to do so.<sup>80</sup> In addition to whatever it receives from the vaccine manufacturers, the Office of Biologics receives adverse reaction reports from private health care providers on a voluntary basis.<sup>81</sup>

Since 1978, the Center for Disease Control purportedly has monitored adverse reactions to DPT vaccine, and acts as a depository for all adverse reaction notifications where DPT was administered at public health clinics.<sup>82</sup> Except for adverse reaction information which it may obtain from the Office of Biologics,<sup>83</sup> the

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

<sup>77</sup> Physician's Desk Reference, *supra* note 19.

<sup>78</sup> 21 C.F.R. § 211.198 (1986).

<sup>79</sup> 21 C.F.R. § 600.12 (1986).

<sup>80</sup> Interagency Group Report, *supra* note 64, at 4-5.

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

<sup>82</sup> Foege, *supra* note 3, at 4-5.

<sup>83</sup> Interagency Group Report, *supra* note 64, at 4-5.

Center collects only data from the public sphere.<sup>84</sup> Consequently, the data it received is limited to about fifty percent of all American vaccinations. Moreover, the public health clinics or departments forward adverse reaction reports to the Center only if the affected infant visits a hospital, clinic, or physician within four weeks after the shot.<sup>85</sup>

### III. LIABILITY OF DPT VACCINE MANUFACTURERS

#### A. *Strict Liability*

In New Jersey, as in other jurisdictions, to establish strict liability, a plaintiff must prove that the product was defective, that the defect existed when it left the defendant's control, and that the defect proximately caused injury to a foreseeable user.<sup>86</sup> The New Jersey courts subscribe to the risk-utility analysis in determining whether a product is defective.<sup>87</sup> This analysis is a balancing process between the benefits and dangers of the product,<sup>88</sup> and involves all relevant considerations, particularly the following seven factors first enunciated by Dean Wade:<sup>89</sup>

- (1) The usefulness and desirability of the product—its utility to the user and the public as a whole.
- (2) The safety aspects of the product—the likelihood

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<sup>84</sup> Foege, *supra* note 3, at 4-5.

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

<sup>86</sup> *Feldman v. Lederle Laboratories*, 97 N.J. 429, 449, 479 A.2d 374, 384-85 (1984); *O'Brien v. Muskin Corp.*, 94 N.J. 169, 179, 463 A.2d 298, 303 (1983); *Michalko v. Cooke Color & Chem. Corp.*, 91 N.J. 386, 394, 451 A.2d 179, 183 (1982).

A frequent problem with trying a DPT case arises in attempting to determine which manufacturer produced the product which caused the plaintiff's harm. This is no longer a problem in New Jersey because plaintiff now must only show that the specific manufacturer cannot be identified and that all manufacturers who could have distributed the product to the plaintiff are joined as defendants. The burden then shifts to the manufacturers to prove their own innocence. All parties who cannot exculpate themselves are appointed a percentage of responsibility based upon the proportion of the potential danger to the public created by the risk of their products as that risk specifically affected the plaintiff. *Shackil v. Lederle Laboratories*, No. A-2351-86T5, slip op. (Super. Ct. App. Div., August 12, 1987). This recent decision rejects a long standing opinion that market share liability does not apply in New Jersey. See Dreier, *Identification of the Defendant/Manufacturer in Generic Product Cases: Issues and Questions*, 17 SETON HALL L. REV. 513 (1987).

<sup>87</sup> *O'Brien*, 97 N.J. at 181-82, 463 A.2d at 304-05 (and cases cited therein).

<sup>88</sup> *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 655 (1st Cir. 1981); *Feldman*, 97 N.J. at 444, 479 A.2d at 382; *Ferrigno v. Eli Lilly and Co.*, 175 N.J. Super. 551, 577, 420 A.2d 1305, 1319 (Law Div. 1980).

<sup>89</sup> Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 837-38 (1973).

that it will cause injury, and the probable seriousness of the injury.

(3) The availability of a substitute product which will meet the same need and not be as unsafe.

(4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.

(5) The user's ability to avoid danger by the exercise of care in the use of the product.

(6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.

(7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.<sup>90</sup>

Under certain circumstances, if the trier of fact determines that the utility of the drug outweighs its risks, strict liability may not apply.<sup>91</sup> Where the drug passes the risk-utility test and is exempt from strict liability, the plaintiff can succeed in a prescription drug case only if he or she proves negligent testing or preparation of the drug, or negligent marketing by failing to properly warn of the dangers of the drug.<sup>92</sup> Thus, unlike the usual non-drug strict liability cases which focus on the safety of the product rather than the actions of the defendant, in a failure-to-warn strict liability case, knowledge of the product's defect, that is its dangerous propensity, is imputed to the manufacturer. In New Jersey, therefore, the analysis of a failure-to-warn strict liability case involving a prescription drug is almost identical with that of a negligence case alleging an improper warning.<sup>93</sup>

### 1. Unavoidably Unsafe Products

In cases where the prescription drug is classified as "un-

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<sup>90</sup> *Feldman*, 97 N.J. at 444 n.4, 479 A.2d at 382 n.4; *O'Brien*, 94 N.J. at 182, 463 A.2d at 304-05 (citation omitted). See also *Cepeda v. Cumberland Engineering Co.*, 76 N.J. 152, 174, 386 A.2d 816, 826-27 (1978); *Ferrigno*, 175 N.J. Super. at 578, 420 A.2d at 1319.

<sup>91</sup> *Feldman*, 97 N.J. at 445, 479 A.2d at 382. See also *O'Brien*, 94 N.J. at 184, 463 A.2d at 305-06 (applying rule to strict liability case involving defectively designed pool).

<sup>92</sup> *Ferrigno*, 175 N.J. Super. at 579, 420 A.2d at 1320.

<sup>93</sup> *Feldman*, 97 N.J. at 451, 479 A.2d at 385-86. The distinction between a failure-to-warn strict liability and a failure-to-warn negligence case concerns the burden of proof. See *infra* notes 228-256 and accompanying text.



avoidably unsafe," the risk-utility test is not applied to find out if a defect exists. Rather, the threshold issue is whether the product fits within the definition of an unavoidably unsafe product. If it does, then comment k of the *Restatement (Second) of Torts* § 402A<sup>94</sup> may govern liability. Comment k provides as follows:

*Unavoidably unsafe products.* 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. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and *accompanied by proper directions and warning*, is not defective, nor is it *unreasonably dangerous*. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because

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<sup>94</sup> RESTATEMENT (SECOND) OF TORTS § 402A (1965) states as follows:

Special Liability of Seller of Products for Physical Harm to User or Consumer.

(1) One who sells any product in a defective condition unreasonably dangerous to the user or the consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold;

(2) The rule stated in subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with seller.

*Id.*

he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.<sup>95</sup>

Whether a drug is unavoidably unsafe is to be determined on a case-by-case basis.<sup>96</sup> Many factors may be weighed to arrive at a decision regarding the legal status of the drug.<sup>97</sup> In New Jersey, many of the same considerations constituting the risk-utility analysis are important factors in categorizing the drug as unavoidably unsafe if the drug reasonably appeared efficacious at the time it was marketed and distributed.<sup>98</sup>

Establishing the product as unavoidably unsafe will not automatically trigger the application of comment k. A manufacturer must also prove that the drug was properly prepared and marketed, and that a proper warning was given. If all of these elements are established, comment k will apply and preclude strict liability. The practical effect of comment k is to convert a strict liability case into a negligence case by gauging the manufacturer's conduct in the preparation and marketing of the product. The manufacturer still must provide proper warnings concerning the risks associated with the drug.

In virtually all prescription drug or unavoidably unsafe drug cases throughout the country, the courts appear to assume that the efficacy of the product exceeds its risk without ever making an in-depth risk-utility analysis. The drugs involved in almost all of such cases have been tested under negligence principles rather than strict liability.<sup>99</sup> The law in New Jersey, on the other hand, prescribes application of the risk-utility analysis first, and only after the drug's

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<sup>95</sup> *Id.* at comment k.

<sup>96</sup> See *Feldman*, 97 N.J. at 449-50, 479 A.2d at 384-85.

<sup>97</sup> In a recent California case involving polio vaccine, for example, these factors included whether the product was highly desirable because of its alleged exceptional benefit, whether the risk was substantial (*i.e.* whether it posed a chance of permanent long-term disability) and unavoidable (*i.e.* whether it was manufactured to minimize the risk and whether any equally effective alternative product was available), and whether the benefits of the product outweighed the interest in promoting a manufacturer's accountability for a defective product. *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 830, 218 Cal. Rptr. 453, 464 (Cal. Ct. App. 1985).

<sup>98</sup> *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 128 (9th Cir. 1968); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1274, n.17 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974); *Feldman*, 97 N.J. at 455-56, 479 A.2d at 388.

<sup>99</sup> See *DeLuryea v. Winthrop Laboratories*, 697 F.2d 222, 228-29 (8th Cir. 1983) (negligence, not strict liability, applied to pain-killing drug); *Davis*, 399 F.2d at 128-29 (vaccine defective only if marketed without proper warning or improperly prepared); *Reyes*, 498 F.2d at 1273-75 (polio vaccine defective only if it is improperly prepared or marketed without a proper warning); *Chambers v. G.D. Searle & Co.*,

utility outweighs its risks as tested by the court, will the manufacturer be exempt from the usual strict liability principles.<sup>100</sup> Hence, in New Jersey, all prescription drugs are not equated with unavoidably unsafe products, and the negligence standard for failure to properly test, market, prepare, or warn is utilized only after the product is found to confer benefits which, on balance, exceed its dangers.<sup>101</sup>

The application of a negligence standard in lieu of strict liability for unavoidably unsafe drugs is rooted in the belief that the availability of certain drugs to society as a whole is more important than holding the drug manufacturer accountable for defects in the drugs.<sup>102</sup> If the focus in such cases was on the drug itself, and not the reasonableness of the manufacturer's conduct, courts and commentators feel that the threat of strict liability would chill research efforts and eventually reduce the availability of these drugs.<sup>103</sup> On the basis of public policy, therefore, part of the strict liability doctrine has been whittled away for unavoidably unsafe drugs.<sup>104</sup>

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441 F. Supp. 377, 380-81 (D. Md. 1975), *aff'd*, 467 F.2d 269 (4th Cir. 1977) (plaintiff limited to showing manufacturing or warning defects).

<sup>100</sup> See *Feldman*, 97 N.J. at 445, 479 A.2d at 382. See also *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 655 (1st Cir. 1981). *Ortho* held that the standard strict liability principles based upon a design defect could be applied to an oral contraceptive manufacturer because the drug could not be classified as an unavoidably dangerous product in the face of evidence of an equally effective and safer alternative drug. *Id.* Thus, the liability analysis explicitly recognized in *Feldman* was previously accorded consideration in *Brochu* when the First Circuit held that prescription drugs are not exempt from strict liability if at the time of distribution an alternative product could have as effectively accomplished the full intended purpose of the alleged defective product. Comment, *Can a Prescription Drug Be Defectively Designed?*, . . . " *Brochu v. Ortho Pharmaceutical Corp.*, 31 DEPAUL L.REV. 247, 259-68, 272 (1981).

<sup>101</sup> *Feldman*, 97 N.J. at 447, 479 A.2d at 382-83.

<sup>102</sup> See RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965); see also *Kearl*, 172 Cal. App.3d at 817, 218 Cal. Rptr. at 455; W. PROSSER, LAW OF TORTS, § 99, at 661 (4th ed. 1971).

<sup>103</sup> *Feldman v. Lederle Laboratories*, 189 N.J. Super. 424, 428-29, 460 A.2d 203, 205 (App. Div. 1982), *rev'd*, 97 N.J. 429, 479 A.2d 374 (1984). But see *Finn v. G.D. Searle & Co.*, 35 Cal.3d 691, 718, 200 Cal. Rptr. 876, 888, 677 P.2d 1147, 1165 (Cal. 1984) (Bird, C.J. dissenting); Reed & Watkins, *Product Liability Tort Reform: The Case for Federal Action*, 63 NEB. L. REV. 839, 848-49 (1984); Comment, *An Escape from Strict Liability: Pharmaceutical Manufacturer's Responsibility for Drug-Related Injuries Under Comment k to Section 402A of the Restatement (Second) of Torts*, 23 DUQ. L. REV. 199, 215-18 (1984).

<sup>104</sup> See *Feldman*, 97 N.J. at 449, 479 A.2d at 384.

New Jersey, like many other states, has recently been forced to study the area of products liability in an effort to determine if the ever expanding areas of liability are justified.

In July of 1987, the New Jersey Legislature passed legislation which defined when a party would be held liable in a Products Liability-Tort action. 1987 N.J.

## 2. Warnings

The courts have drawn a distinction between prescription

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Session Law Serv. Ch. 197 (West). As it relates to a product's fitness, a manufacturer or seller is liable if the product which causes the harm is found not to be reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

*Id.* A manufacturer or seller is not liable for a product which may be designed defectively if

(1) At the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product; or

(2) The characteristics of the product are known to the ordinary consumer or user, and the harm was caused by an unsafe aspect of the product that is an inherent characteristic of the product and that would be recognized by the ordinary person who uses or consumes the product with the ordinary knowledge common to the class of persons for whom the product is intended, except that this paragraph shall not apply to industrial machinery or other equipment used in the workplace and it is not intended to apply to dangers posed by products such as machinery or equipment that can feasibly be eliminated without impairing the usefulness of the product; or

(3) The harm was caused by an unavoidably unsafe aspect of the product and the product was accompanied by an adequate warning or instruction as defined in section 4 of this act.

*Id.* As it relates to the provision of the law which governs when there is no practical alternative, such a determination is not a valid defense if

b. The provisions of paragraph (1) of subsection a. of this section shall not apply if the court, on the basis of clear and convincing evidence, makes all of the following determinations:

(1) The product is egregiously unsafe or ultra-hazardous;

(2) The ordinary user or consumer of the product cannot reasonably be expected to have knowledge of the product's risks, or the product poses a risk of serious injury to persons other than the user or consumer; and

(3) The product has little or no usefulness.

*Id.* Failure to warn by the manufacturer or seller is not a valid claim against such a party

if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover the danger after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs,

drugs and over-the-counter drugs with regard to warnings.<sup>105</sup> In the context of an over-the-counter drug, the manufacturer must directly warn the user or consumer of the risks associated with taking the drug.<sup>106</sup> However, if the drug can be obtained only by a physician's prescription or administration, the manufacturer need not directly warn of the drug's dangers or side-effects.<sup>107</sup> Except in special limited instances, when a case involves a prescription drug, the manufacturer will satisfy its duty to warn if it presents appropriate factual information to the prescribing or administering physician sufficient to educate him or her about the product and all the potential pitfalls which a user might confront.<sup>108</sup> This is true even though only a small number or per-

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*taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.*

*Id.* (emphasis added). The warning given as to a drug carries with it a rebuttable presumption that the warning or instruction is adequate if it has been approved by the Federal Drug Administration.

This new law also sets forth the availability of punitive damages. Punitive damages will not be allowed in a food or drug case where the Food and Drug Administration has approved the product, unless the product's defects, or any other relevant information was withheld from the F.D.A. *Id.*

<sup>105</sup> *Torsiello v. Whitehall Laboratories*, 165 N.J. Super. 311, 322, 398 A.2d 132, 137-38 (App. Div. 1979).

<sup>106</sup> *Id.* at 320-21, 398 A.2d at 136-37.

<sup>107</sup> See, e.g., *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984); *Mauldin v. Upjohn Co.*, 697 F.2d 644, 647 (5th Cir. 1983), *reh. en banc denied*, 705 F.2d 450 (5th Cir. 1983); *Brochu*, 642 F.2d at 655; *Stanback v. Parke, Davis & Company*, 657 F.2d 642, 644 (4th Cir. 1981); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Timm v. Upjohn Co.*, 624 F.2d 536, 538 (5th Cir. 1980); *Dalke v. Upjohn Co.*, 555 F.2d 245, 247-48 (9th Cir. 1977); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 142 (3d Cir. 1973); *Brick v. Barnes-Hines Co.*, 428 F. Supp. 496, 497 (D.D.C. 1977); *Pierluisi v. E.R. Squibb & Sons, Inc.*, 440 F. Supp. 691, 694 (D.P.R. 1977); *Stottlemire v. Cawood*, 213 F. Supp. 897, 899 (D.D.C. 1963); *Stone v. Smith, Kline & French Laboratories*, 447 So.2d 1301, 1304-05 (Ala. 1984); *Buckner v. Allergan Pharmaceutical, Inc.*, 400 So.2d 820, 822 (Fla. App. 1981); *Cobb v. Syntex Laboratories, Inc.*, 444 So.2d 203, 205 (La. App. 1983); *Bacardi v. Holzman*, 182 N.J. Super. 422, 425, 442 A.2d 617, 622 (App. Div. 1981); *Calabrese v. Trenton State College*, 162 N.J. Super. 145, 154, 392 A.2d 600, 605 (App. Div. 1978), *aff'd*, 82 N.J. 321, 413 A.2d 315 (1980); *Ross v. Jacobs*, 684 P.2d 1211, 1213 (Okla. App. 1984); *Torsiello*, 165 N.J. Super. at 323, 398 A.2d at 138-39; *McKee v. Moore*, 648 P.2d 21, 24-25 (Okla. 1982).

<sup>108</sup> See, e.g., *Timm*, 624 F.2d at 538; *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Reyes*, 498 F.2d at 1276; *Hoffman*, 485 F.2d at 142; *McCue v. Norwich Pharmaceutical Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425-26 (2d Cir. 1969); *Davis*, 399 F.2d at 130; *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1967); *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963 (E.D. Wisc. 1981); *Bacardi*, 182 N.J. Super. at 425, 442 A.2d at 621-22.

centage of users may be adversely affected.<sup>109</sup> A warning about adverse reactions must be timely, emphatic, and conspicuous to be effective.<sup>110</sup> It must be designed to command the attention of the medical profession<sup>111</sup> but need only be reasonable under the circumstances.<sup>112</sup> If a manufacturer fails to revise a warning it knows is being disregarded, the warning may be inadequate.<sup>113</sup> Moreover, an otherwise proper warning may be diluted and rendered ineffective by overpromotion of the drug by the manufacturer.<sup>114</sup>

Where a drug can only be obtained through prescription, the only meaningful warning is one given directly to the physician since he or she has the superior knowledge necessary to weigh a patient's needs and susceptibilities.<sup>115</sup> As a "learned intermediary" between the manufacturer and patient, the prescribing physician exercises his or her medical judgment on an individualized basis by evaluating the risks and benefits of the drug.<sup>116</sup> In some

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<sup>109</sup> *Reyes*, 498 F.2d at 1279; *Basko*, 416 F.2d at 320; *Davis*, 399 F.2d at 129-30; *Bine v. Sterling Drugs, Inc.*, 422 S.W.2d 623, 629-30 (Mo. 1968).

<sup>110</sup> *See Sterling Drugs, Inc. v. Yarrow*, 408 F.2d 978, 994, (8th Cir. 1969) (stating the use of detailmen is the best method to give warning subsequent to a drug's distribution); *but see also Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 126 (W.D. Tenn. 1977) (court held that precise warnings of risk of a stroke associated with Norinyl birth control pills made accessible to medical profession in Physician's Desk Reference and package inserts were adequate where plaintiff suffered exact reaction warned against); Comment, *The Duty of Drug Manufacturers To Warn of Newly Discovered Side Effects of Marketed Drugs*, 2 RUT.-CAM. L.J. 145 (1970).

<sup>111</sup> *Pierluisi*, 440 F. Supp. at 694 (quoting *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 529 (Or. 1974)). In *Sterling Drugs*, the court stated that where the "dangers of the prolonged use of this drug [Aralen], mass produced and sold in large quantities, became reasonably apparent, it was not unreasonable to find that the [drug company] should have employed all of its resources . . . to warn the prescribing physicians of these dangers." *Sterling Drugs*, 408 F.2d at 992.

<sup>112</sup> *Yarrow*, 408 F.2d at 992; *Dunn v. Lederle Laboratories*, 121 Mich. App., 75-76, 328 N.W.2d 576, 579-80 (Mich. App. 1983); *Calabrese*, 162 N.J. Super. at 154, 392 A.2d at 605 (statistical information on benefits and risks of anti-rabies vaccine not necessary in warning).

<sup>113</sup> *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (citing *Incollingo v. Ewign*, 444 Pa. 263, 282 A.2d 206 (1971)).

<sup>114</sup> *Salmon*, 520 F.2d at 1362. *See also Whitley v. Cubberly*, 24 N.C. App. 204, 207-08, 210 S.E. 2d 289, 292 (N.C. App. 1974) (denying summary judgment to manufacturer because overpromotion may have diluted warnings). *Love v. Wolf*, 226 Cal. App. 2d 378, 391, 38 Cal. Rptr. 183, 197 (1964) (calendars and giveaways as overpromotion).

<sup>115</sup> *Davis*, 399 F.2d at 130; *Feldman*, 97 N.J. at 451, 479 A.2d at 385-86; *Ferrigno*, 175 N.J. Super. at 581, 420 A.2d at 1321.

<sup>116</sup> *Brooks*, 750 F.2d at 1231; *Lindsay*, 637 F.2d at 91; *Dalke*, 555 F.2d at 247-48; *Reyes*, 498 F.2d at 1270; *Schenebeck v. Sterling Drugs, Inc.*, 291 F. Supp. 368 (E.D. Ark. 1968), *aff'd*, 423 F.2d 919, 922 (9th Cir. 1970); *Bacardi*, 182 N.J. Super. at 424, 442 A.2d at 612; *Terhune*, 90 Wash. 2d at 11, 577 P.2d at 977; *Rheingold, Products*

jurisdictions, it is then the physician's obligation to warn the user of a prescription drug about its dangers.<sup>117</sup>

The manufacturer is held to the standard of an expert<sup>118</sup> and must, at a minimum, keep abreast of the current state of medical and scientific knowledge obtained through research, scientific literature, adverse reaction reports and other available means.<sup>119</sup> This includes "familiarity with practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products,"<sup>120</sup> and any newly discovered side-effects subsequent to distribution.<sup>121</sup> The adequacy of the warning information passed onto the physician depends upon what was known or reasonably discoverable at the time of marketing.<sup>122</sup> Where the public health is involved, a manufacturer may be expected to be informed, and affirmatively seek out information about the use of the product by the public.<sup>123</sup> A duty to warn may be founded upon complaints by a substantial number of doctors or consumers to a manufacturer concerning a particular adverse reaction;<sup>124</sup> however, the duty to warn is not keyed into a pure quantitative standard and may necessitate a warning to only

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*Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964).

<sup>117</sup> *McKee*, 648 P.2d at 25 (Okla. 1982); *Cooper v. Bowser*, 610 S.W.2d 825, 831 (Tex. App. 1980).

<sup>118</sup> *Karjala v. Johns-Manville Prod. Corp.*, 523 F.2d 155, 159 (8th Cir. 1975); *O'Hare v. Merck & Co.*, 381 F.2d 286, 291 (8th Cir. 1967); *Dunn*, 121 Mich. App. at 75-76, 328 N.W.2d at 579-80; *Feldman*, 97 N.J. at 452, 479 A.2d 386-87; *McEwen*, 270 Or. at 375, 528 P.2d at 528.

<sup>119</sup> *Lindsay*, 637 F.2d at 91; *Reyes*, 498 F.2d at 1277; *Borel v. Fibreboard Paper Prod. Corp.*, 493 F.2d 1076, 1089 (5th Cir. 1973); *Yarrow*, 408 F.2d at 987 (warnings on product cards and in Physician's Desk Reference concerning irreversible retinal damage caused by Aralen did not represent full state of reported medical knowledge as to percentage of patients affected); *Wright v. Carter Prod., Inc.*, 244 F.2d 53, 58 n.2 (2d Cir. 1957); *Dunn*, 121 Mich. App. at 76, 328 N.W.2d at 580; *Feldman*, 97 N.J. at 452-53, 479 A.2d at 386-87.

<sup>120</sup> *Reyes*, 498 F.2d at 1277.

<sup>121</sup> See Comment, *supra* note 110.

<sup>122</sup> *Feldman*, 97 N.J. at 452, 479 A.2d at 386; *Ferrigno*, 175 N.J. Super. at 576, 420 A.2d 1318 (contrasting drug cases with regular product liability design defect cases which under New Jersey law are actionable despite lack of actual knowledge of risk or harm); see also *Brochu*, 642 F.2d at 655; *Lindsay*, 637 F.2d at 91; *O'Hare*, 381 F.2d at 291; *Sanderson v. Upjohn Co.*, 578 F. Supp. 338, 340 (D. Mass. 1984); *Tinnerholm*, 285 F. Supp. at 451; *Beshada v. Johns-Manville Prod. Corp.*, 90 N.J. 191, 447 A.2d 539 (1982) (New Jersey Supreme Court held that an asbestos manufacturer is strictly liable to an injured plaintiff for failure to warn of dangers which were scientifically and technologically unknowable at the time of manufacture); *McEwen*, 270 Or. at 381, 528 P.2d at 528-29.

<sup>123</sup> *Feldman*, 97 N.J. at 457, 479 A.2d at 389.

<sup>124</sup> *Skill v. Martinez*, 91 F.R.D. 498, 514 (D.N.J. 1981), *aff'd*, 677 F.2d 368 (3d

a few users.<sup>125</sup>

In addition to the duty to warn of known or knowable side-effects at the time of marketing and distribution, however, the drug manufacturer must also warn of dangers discovered or discoverable subsequent to distribution.<sup>126</sup> In New Jersey, this post-distribution duty to warn must be transmitted by the manufacturer not only to prescribing physicians, but also to those persons to whom the drug had already been distributed.<sup>127</sup> The nature and extent of the post-distribution warnings depends on the circumstances of each case.<sup>128</sup>

Under present New Jersey case law, drug manufacturers must carry the burden of proving that the warnings given to the medical community comported with available scientific and medical literature at the time the drug was released for public use. They must demonstrate by a preponderance of the evidence that the information which a plaintiff contends should have been included in the warning was not reasonably obtainable by them both at the time of distribution and subsequent to placing the product into the stream of commerce.<sup>129</sup> This burden is imposed upon the manufacturers because of their superior position in gaining access to technological literature regarding the risks and dangers of the drug.<sup>130</sup>

The strict liability of a DPT vaccine manufacturer under New Jersey law depends upon the answers to four significant questions:

- (1) Is DPT vaccine, as presently produced in the United States, a defective product under the risk-utility test?
- (2) Is DPT vaccine an unavoidably unsafe product?
- (3) If the utility of DPT vaccine exceeds its risks, or if the vaccine is an unavoidably unsafe product, did the manufacturer properly market it and did proper warnings of its dangerous propensities accompany its distribution?

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Cir. 1982) (preliminary research findings); *Feldman*, 97 N.J. at 453, 479 A.2d at 387 (citing, *Hoffman*, 485 F.2d at 146 (letters from doctors)).

<sup>125</sup> *Estate of Tomer v. American Home Prod. Corp.*, 170 Conn. 681, 690, 368 A.2d 35, 40 (1976).

<sup>126</sup> Comment, *supra* note 110.

<sup>127</sup> *Feldman*, 97 N.J. at 457, 479 A.2d at 389 (citing Note, *The Manufacturer's Duty to Notify a Subsequent Seller of Improvements*, 33 STAN. L. REV. 1087 (1981)).

<sup>128</sup> "The FDA determines on the particular facts of each case whether the actions of the drug manufacturer constitute a reasonable warning." Comment, *supra* note 110, at 145. See also *Yarrow*, 408 F.2d at 991-92.

<sup>129</sup> Tarr, *supra* note 1.

<sup>130</sup> *Feldman*, 97 N.J. at 456, 479 A.2d at 388.



(4) If the DPT vaccine bore appropriate warnings of its risks when distributed, has the manufacturer issued meaningful post-distribution warnings of newly-discovered side-effects?

Except for substituting the consumer expectation test or other similar tests<sup>131</sup> in place of the risk-utility test in the first question, virtually all jurisdictions would agree with the liability analysis framed by the foregoing questions. The significance of each of the four questions, and the suggested answers, will be addressed seriatim against the backdrop of the existing medical and scientific literature and the historical background of pertussis vaccine discussed earlier.

a. *Is DPT Vaccine, as Presently Produced in the United States, a Defective Product Under the Risk-Utility Test?*

Whether DPT vaccine passes or fails the risk-utility test depends upon one's interpretation of the published literature concerning the development of pertussis vaccine. Because proponents and critics of the vaccine interpret the literature differently, evidence exists to support either side's conclusions about the defectiveness of the vaccine.

Public and private medical associations and groups in the United States unanimously believe that DPT vaccine, and pertussis vaccine in particular, is an extraordinarily useful and desirable product.<sup>132</sup> This is underscored by the massive effort to immunize all American infants which is backed financially by the federal government.<sup>133</sup> Almost all states, including New Jersey, require that DPT vaccine immunization be accomplished as a prerequisite to school entry.<sup>134</sup> Until recently, no one criticized the desire to eradicate the childhood diseases of diphtheria,

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<sup>131</sup> *Barker v. Tull Engineering Co.*, 20 Cal.3d 413, 423, 573 P.2d 443, 455-56 (1978).

<sup>132</sup> Foegel, *supra* note 3, at 2-3; Fulginiti, *supra* note 5; Houts, *supra* note 2, at 6:39.

<sup>133</sup> Hinman, *supra* note 2.

<sup>134</sup> *Id.* New Jersey is one of 44 states which mandates DPT immunization before school entry. The New Jersey Administrative Code provides:

No principal or other person in charge of a school shall knowingly admit or retain any pupil who has not submitted acceptable evidence of immunization according to the schedule specified below, except when there are exemptions as noted in this Subchapter.

N.J. ADMIN. CODE tit. 8 § 57-4.2 (1983).

The schedule referred to with regard to DPT vaccination states:

Every pupil shall have received four doses of diphtheria and tetanus toxoids and pertussis vaccine (DPT), and the last dose shall be administered not less than six months after the previous dose, except that pupils after the sixth birthday who have not completed these requirements

whooping cough and tetanus through universal vaccination. The foundation of the argument in favor of universal pertussis immunization is the belief that the pertussis vaccine was responsible for the drastic reduction of mortality and morbidity from the disease over the last forty-five years.<sup>135</sup> The fact that the incidence of whooping cough has decreased radically from 1940 until now cannot be assailed, but the role of the vaccine as a causative agent is open to doubt.

There is abundant literature, much of it published by Stewart<sup>136</sup> and his colleagues,<sup>137</sup> which downplays the role of the vaccine in the reduction of death and sickness caused by pertussis. Citing other important factors such as the development of effective antibiotics, improved health care, and better socio-economic conditions, researchers have concluded that pertussis vaccine did not play a major part in the overall decrease in the incidence of the disease.<sup>138</sup> According to Stewart,<sup>139</sup> pertussis is a cyclical disease marked by periodic epidemics having nothing at all to do with the vaccine. He argued that most of the reduction in mortality and morbidity occurred in Great Britain before pertussis immunization was even started.<sup>140</sup> In Germany, Ehrengut<sup>141</sup> observed decreasing incidences of pertussis during rising birth rates despite a drop in immunizations, thereby lending credence to Stewart's hypothesis.

Advocates of pertussis immunization counter these contentions by pointing to the British epidemics of the 1970s which allegedly were a result of British parents disfavoring immunization

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shall have received tetanus and diphtheria toxoids, adult type (Td) instead of DPT.

N.J. ADMIN. CODE tit. 8, § 57-4.10 (1981).

The exemptions noted in N.J. ADMIN. CODE tit. 8, § 57-4.2 (1983) to pre-school immunization are medically contraindicated immunizations requiring a written explanatory statement from a physician, and instances where immunizations would interfere with the free exercise of the pupil's religious rights. N.J. ADMIN. CODE tit. 8, § 57-4.3, 4.4 (1983).

Recently, the New Jersey Senate passed legislation, S-1696, by a vote of 38-0 which would exempt a child from being required to have the vaccine as a condition of admission to school if a treating physician states in writing that the vaccine is inadvisable because the child has a high risk of developing a major reaction.

<sup>135</sup> Brunell, *supra* note 2; Foege, *supra* note 3; Hinman, *supra* note 2.

<sup>136</sup> Stewart, *supra* notes 14 and 15.

<sup>137</sup> Ehrengut, *Whooping Cough Vaccination*, THE LANCET, Feb. 18, 1978, at 370; Strom *Universal Vaccination* *supra* note 9.

<sup>138</sup> See *supra* notes 136-37.

<sup>139</sup> Bassilli, *supra* note 14, at 473.

<sup>140</sup> Stewart, *supra* note 14, at 262.

<sup>141</sup> Ehrengut, *supra* note 137.

because of adverse media publicity.<sup>142</sup> William Foege, M.D., former Director of the Center for Disease Control, similarly cited statistics purporting to show that immunization in Japan dropped to a very low level after the introduction of pertussis vaccine in 1950, but then increased in the late 1970s because of a decrease in inoculations prompted by public awareness of two vaccine-related deaths.<sup>143</sup>

Proponents and critics of the vaccine do agree that pertussis vaccine can cause various types of adverse reactions, including severe long-term neurological disabilities. This fact has been recognized in the United States since at least 1948 when Byers and Moll published their study about neurological sequelae and pertussis immunization.<sup>144</sup> Even before that, Madsen<sup>145</sup> and others outside the United States,<sup>146</sup> reported a correlation between pertussis vaccination and death, shock, and convulsions. What advocates and critics do not agree about, however, is the number or percentage of infants adversely affected by pertussis vaccine. Depending upon which report or study is relied upon as authoritative, support can be obtained for either position.

As noted in Table I,<sup>147</sup> the Red Book Committee estimates that one infant out of 100,000 immunized infants will suffer permanent brain damage following inoculation with DPT vaccine in the United States.<sup>148</sup> The British Childhood Encephalopathy Study published in 1977 reported that one child in 110,000 immunized British children suffered post-vaccination neurological disorders, and one child out of 310,000 had permanent vaccine-induced brain damage.<sup>149</sup> These results are not in accord with findings of other pertussis vaccine researchers.

Ehrengut in West Germany,<sup>150</sup> Hannik in Holland,<sup>151</sup> and Strom in Sweden<sup>152</sup> observed much higher rates of adverse reac-

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<sup>142</sup> See Physician's Desk Reference, *supra* note 19; Foege, *supra* note 3, at 111.

<sup>143</sup> Foege, *supra* note 3, at 11.

<sup>144</sup> Byers, *supra* note 30.

<sup>145</sup> Madsen, *supra* note 9.

<sup>146</sup> Sauer, *supra* note 28.

<sup>147</sup> See *infra* Table I of Appendix.

<sup>148</sup> Fulginiti, *supra* note 5.

<sup>149</sup> Joint Committee on Vaccination and Immunization, *Whooping-Cough: Review of the Evidence on Whooping-Cough by the Joint Committee on Vaccination and Immunization 1977*, DHSS, London: Her Majesty's Stationary Office, 1977.

<sup>150</sup> Ehrengut, *supra* note 137.

<sup>151</sup> Hannik, *Changes in Plasma Insulin Concentration and Temperature of Infants After Pertussis Vaccination*, Third International Symposium on Pertussis, Department of Health, Education and Welfare, Pub. No. 79-1830, 1978 at 297.

<sup>152</sup> Strom *Further Experience of Reactions*, *supra* note 9.

tions ranging from convulsions and shock to brain damage and death. Stewart estimated that in Great Britain one infant out of between 10,000 and 54,000 immunized children suffered permanent brain damage subsequent to inoculation.<sup>153</sup>

Because of increasing concern in the United States over apparent vaccine-related side-effects, the federal government funded the Baraff study at UCLA covering the period 1977-1979. Although critics have chastised Baraff for failing to report certain deaths and other side-effects in his final report,<sup>154</sup> Baraff still concluded that the rate of reactions following pertussis immunization was shown to be greater than previously believed.<sup>155</sup> This study reported no encephalopathies or deaths, but indicated that both convulsions and hypotonic hyporesponsive episodes occurred in one out of 1750 immunized infants.<sup>156</sup>

Because of recognition within the medical research community of a need for a less reactive vaccine against whooping cough, efforts have accelerated to find a safer product. Although current attention has centered on the acellular Japanese vaccine,<sup>157</sup> the technology and methodology for producing a non-cellular vaccine existed as early as 1951 when Pennell and Thiele described a process which largely destroyed the toxicity of the bacterial cell components while retaining the vaccine's immunogenicity.<sup>158</sup> In 1953, Felton and Verwey followed up on the methodology reported by Pennell and Thiele by clinically testing the non-cellular vaccine. They also found that the vaccine demonstrated immunogenicity with reduced reactivity.<sup>159</sup> During the ensuing years, other researchers also published reports describing methods of extracting the toxic elements of the cell without adversely affecting the ability of the vaccine to protect against the disease.<sup>160</sup>

Notwithstanding the fact that the methodology for producing a less reactive but equally effective pertussis vaccine existed since 1951, it was not until the early 1960s that a partially detoxi-

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<sup>153</sup> Stewart, *supra* note 14.

<sup>154</sup> The Fresno Bee, *supra* note 2, at 3.

<sup>155</sup> Baraff, *supra* note 10.

<sup>156</sup> *Id.* at 19-20.

<sup>157</sup> See *supra* notes 114-121 and accompanying text. There are skeptics regarding the Japanese vaccine because the Japanese commence immunization at age 2 years when infants are less susceptible to adverse reactions. *Id.*

<sup>158</sup> Pennell, *Studies on the Fractionation of Hemophilus Pertussis Abstracts*, 66 J. OF IMMUNIZATION 627 (1951).

<sup>159</sup> Felton, *supra* note 12.

<sup>160</sup> See Pillemer, *Protective Antigen of Haemophilus Pertussis*, THE LANCET, June 19, 1954 at 1257; Nagel, *supra* note 12.

fied pertussis vaccine was commercially manufactured and marketed in the United States. When Eli Lilly & Co. (Lilly) applied for its patent for a non-cellular pertussis vaccine in 1961 known as Tri-Solgen, the pharmaceutical industry certainly recognized the severity of vaccine-induced side-effects and the need for an improved vaccine. Lilly's non-cellular vaccine dominated the market through the mid-1960s primarily because of reports from Lilly's personnel and other clinical researchers touting Tri-Solgen's reduced reactivity rate.<sup>161</sup>

In 1966, Lederle became concerned about its market share and the future of its product. Lederle personnel were initially skeptical of Lilly's claim about the decreased reaction rate exhibited by its product. Lederle proposed an internal clinical evaluation comparing its whole-cell vaccine, Tri-Immunol, with Lilly's Tri-Solgen to deflate Lilly's contentions.<sup>162</sup>

In 1967, Lederle tested Tri-Immunol against Tri-Solgen for reactivity on 335 infants. Lederle's internal correspondence, only recently publicly released, stated that the test results demonstrated that Lederle's product had a significantly higher reaction rate than Lilly's non-cellular vaccine.<sup>163</sup> Further clinical evaluations of an "improved DPT vaccine" were planned by Lederle, but for unknown reasons, Lederle never fulfilled its plans for additional tests.<sup>164</sup> Despite first-hand knowledge of its own product's shortcomings,<sup>165</sup> Lederle, like all other DPT manufacturers except Lilly, continued after 1967 to produce and market its whole-cell vaccine despite its known dangerous propensities.

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<sup>161</sup> Lederle Inter-office Correspondence, *supra* note 106.

<sup>162</sup> *Id.*

<sup>163</sup> *Id.* Inter-office correspondence and memoranda regarding the comparison testing undertaken by Lederle in the mid-1960s were released in 1985 by representatives of Dissatisfied Parents Together, a non-profit organization involved with children damaged by pertussis vaccine. These documents were acquired by discovery procedures in DPT litigation. See ABC News 20/20, *supra* note 22, at 1011.

<sup>164</sup> Inter-office Correspondence from M.S. Cooper to I.S. Danielson, Lederle Laboratories, May 18, 1967. Lederle has recently denied the significance of its own comparison test by stating that the adverse reactions compared were only of a minor nature. ABC News, 20/20, *supra* note 22, at 1011.

<sup>165</sup> The 1967 test results were not the first nor last indication that Lederle had problems associated with Tri-Immunol. In the early 1950s, Lederle received significant adverse reaction reports from pediatricians. In an inter-office memorandum dated February 14, 1958, Lederle revealed that it received information that "six out of the last ten children inoculated . . . experienced severe chills and fevers and resulted in the hospitalization of one child." Another Lederle document dated March 28, 1980 stated that Lederle had received 28 serious adverse reaction reports, four of which were reported as SIDS. ABC News 20/20, *supra* note 22, at 1011.

Since Lilly stopped producing Tri-Solgen in the mid-1970s, no partially or totally detoxified pertussis vaccines have been available commercially in the United States.

Because of the long-term availability of the methodology and technology involved in producing a non-cellular pertussis vaccine, one must question the commitment of the American DPT producers to the active commercial development of an improved vaccine during the past twenty-five years. DPT manufacturers have sought to expedite the commercial marketing of a less reactive vaccine only recently when liability concerns and product availability have become public issues. The weight of evidence suggests that for many years DPT manufacturers had the ability to eliminate, if not greatly reduce, the unsafe character of the pertussis vaccine without impairing its purported immunogenic qualities.

In an effort to justify the absence of a non-cellular vaccine on the market today, manufacturers have cited the increased cost of production as a detrimental factor in the development of a safer vaccine. According to one source, the production expense of a non-cellular vaccine is approximately ten times the cost of producing the whole-cell vaccine.<sup>166</sup> Since manufacturers derived marginal profits on the sale of DPT vaccine, it is claimed that increased cost forced producers out of the market.<sup>167</sup> Concern over rising liability insurance costs allegedly caused by vaccine litigation has already narrowed the market to two commercial producers, Lederle and Connaught Laboratories (Connaught).<sup>168</sup>

It is possible that increased production costs could further reduce available vaccine supplies. If pertussis vaccine is responsible for the decrease in morbidity and mortality from the disease as contended by the vaccine advocates, a reduction in the supply could result in a pertussis epidemic. Because of the strength of the immunization movement in the United States, however, the increased costs associated with the production and marketing of a non-cellular vaccine should not have a significant impact on either the vaccine supply or the number of whooping cough cases.

If demand for DPT vaccine remains constant, it is doubtful

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<sup>166</sup> Anderson, *The Problems Associated with a Development in Clinical Testing Vaccine*, 20 ADV. APP. MICROBIO. 43, 52 (1976).

<sup>167</sup> *Drug Firms Seek Exemption*, Wash. Post, Dec. 20, 1984, P. A4, Col. 2; Russell, *supra* note 1.

<sup>168</sup> Russell, *supra* note 1, at A2; see also Tarr, *supra* note 1, at 27.

that vaccine supplies will decrease.<sup>169</sup> As long as there is a stable market for the vaccine, and a manufacturer can maintain its profit margin, the manufacturer will probably continue to produce the product. Since an increase in vaccine production costs will ultimately be borne either by the parents of the infants, via an increased pediatrician's fee to cover the vaccine's increased purchase price, or by the federal government in mass immunizations, profits derived from vaccine sales should not be affected.

Generally, an increase in expense to a consumer diminishes demand for a product. However, in the case of DPT vaccine, demand for the product may not be related to consumer expense. Unlike other products, DPT vaccine has legislative support. The public health laws mandate DPT immunization before a child can be enrolled in school.<sup>170</sup> This legislation effectively removes most parental discretion regarding immunization. Parents, faced with the option of having their child immunized or not going to school, do not have a realistic choice. Except for those parents of children who may be exempted statutorily from DPT vaccination for health or religious reasons,<sup>171</sup> almost all other parents will insure that their children receive DPT vaccine if for no other reason than school enrollment. Since the cost of DPT inoculation is an irrelevant factor in this decision-making process, the public demand for the vaccine should remain unchanged.

Since mandatory DPT immunization legislation exerts a steadying influence on consumer demand regardless of product cost, manufacturers also may be able to pass on increased liability insurance costs to consumers without decreasing demand for the vaccine. Manufacturers are unwilling, however, to pay extraordinary insurance costs to maintain a product line which does not generate sufficient profits. The liability exposure and litigation and insurance costs are too great to justify continued marketing of the vaccine according to the pharmaceutical companies.<sup>172</sup>

In 1984, Wyeth sold its DPT vaccine distribution rights to

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<sup>169</sup> Engelberg, *Officials Say Some Doctors Failed To Conserve Vaccine Supplies*, N.Y. Times, Feb. 18, 1985, A10, col.2; see also Silberner, *supra* note 13. During the last year, public concern arose over purported vaccine shortages. In addition to Wyeth Laboratories and Connaught Laboratories terminating production, several million doses of Lederle vaccine failed to pass FDA testing, thereby further reducing the supply.

<sup>170</sup> See *supra* note 134.

<sup>171</sup> *Id.* See, e.g., N.J. ADMIN. CODE tit. 8, § 57-4.3 (1983); Houts, *supra* note 5, at 40.

<sup>172</sup> Houts, *supra* note 2, at 40; Russell, *supra* note 1; Tarr, *supra* note 1.

Lederle allegedly because of litigation expenses associated with the DPT vaccine. Shortly thereafter, Connaught stopped taking new orders for the vaccine and refused to pay increased liability premiums. Within six months, in 1984, Lederle's price per dose increased from \$1.20 to \$2.80. According to one Lederle representative, monetary damages demanded in pending lawsuits were 200 times greater than actual vaccine sales in 1983.<sup>173</sup>

As a result of the reduction in the vaccine supply caused by Wyeth's and Connaught's actions, several compensation plans were proposed and introduced in Congress.<sup>174</sup> These proposals were directed at extending federal compensation to children damaged by the vaccine. It was believed that enactment of a compensation law would induce manufacturers to re-enter the market, thereby avoiding the vaccine shortages.<sup>175</sup>

If it is feasible to increase the cost of DPT vaccine to cover liability concerns without increasing demand for the product by consumers, then federal compensation legislation may be unnecessary. Assuming the DPT vaccine is an extraordinarily useful and desirable product and that its absence or reduction in the market will result in a resurrection of the childhood diseases of diphtheria, whooping cough, and tetanus, pharmaceutical companies have substantial leverage in forcing federal action to remedy the problem. If Lederle, the only present commercial DPT distributor, ceases distribution and production, DPT vaccine will be unavailable when existing supplies are depleted. Thus, even a hint that DPT vaccine would be unavailable spurred grave public concern and efforts to enact federal legislation.

Many critics believe that the manufacturers are exaggerating liability problems and that the problems which do exist are directly traceable to the producers' long-term lack of commitment or disinclination toward the development of a safer vaccine. According to those persons skeptical of the motives of DPT manufacturers, the pharmaceutical companies are seeking immunity from liability via federal legislation by threatening to terminate

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<sup>173</sup> Tarr, *supra* note 1, at 27, col. 2.

<sup>174</sup> Pear, *U.S. Plan to Curb Damage Claims Aims to Avert Vaccine Shortages*, N.Y. Times, Apr. 7, 1985, at 1, col.2; Tarr, *supra* note 1, at 27, col. 2.

<sup>175</sup> *Id.*; see also *supra* note 167 and accompanying text. In late 1986, Congress enacted the National Childhood Vaccine Injury Act of 1986 which creates a federal compensation program for persons injured by a vaccine (including the DPT vaccine) defined in a Vaccine Injury Table. The Act establishes limits on monetary awards. The program is to be administered through special masters in the federal district court system.



production. The argument is that if the manufacturers would market a safer product and pass on increased production costs to the consumer, profit margins would not erode while liabilities for vaccine-induced injuries would greatly diminish.<sup>176</sup>

As with many other pharmaceutical products, users cannot protect themselves against the risks of pertussis vaccine except by declining to use it. Thus, the conduct of the infant or parent is not an issue. Because of the inability of the user to protect himself or herself by exercising ordinary care, it is especially critical that warnings and other information about the vaccine be communicated to both administering physicians and the parents of the infants. At least if warnings and other information are given, a reasoned decision by the pediatricians or the parents, or both, can be reached. Pediatricians who are advised properly of the contraindications of DPT vaccine will be sensitive to the personal and family history of the infant. Armed with pertinent knowledge about adverse reactions, they should also be diligent in taking detailed histories of their infants and documenting previous medical treatment and prior post-injection reactions or physical changes. In short, an informed pediatrician will be alert to the potential risks of the vaccine. Pediatricians will screen immunization candidates and select for vaccination only those infants who do not appear at risk.

After consideration of all relevant factors in the risk-utility test, no clear-cut answer as to the defectiveness of the vaccine is apparent. There is certainly evidence to correlate the vaccine with the control of pertussis. Even accepting the estimates of Stewart and others regarding the percentages of affected infants, the relative number of children permanently injured is small compared to the total number of vaccinees. On the other hand, many of those damaged by the vaccine have suffered severe disability from devastating neurological side-effects. Although the non-cellular variety of the vaccine is not marketed presently in the United States, it is obvious that the know-how existed at least thirty years ago, but only Lilly saw fit to develop and distribute the non-cellular vaccine. By Lederle's own admission, its whole-cell product was more reactive than Lilly's non-cellular vaccine, yet Lederle continued to sell its vaccine to doctors without telling them about the comparison testing which it had undertaken.

Because a vaccinee cannot reasonably protect himself or her-

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<sup>176</sup> Edelson, *supra* note 1, at F12, col. 4; Tarr, *supra* note 1, at 26, col. 3.

self from an adverse reaction, warnings or information must be provided to the pediatrician and the parents in order for them to engage in a meaningful dialogue about the risks and benefits of vaccination. Thus, warnings and education of the medical community about the product take on the utmost importance.

For the purposes of the risk-utility test in determining whether the vaccine is a defective product under strict liability principles, the focus is on the product rather than the conduct of the manufacturer. Thus, it may be that the vaccine was improperly prepared, tested, or marketed, or that the manufacturer failed to warn or provide information about the product to the pediatrician or parents of the vaccinee. In such case, the manufacturer may be liable on a negligence or failure-to-warn theory. However, because the inquiry under the risk-utility test is limited to the product itself, it is doubtful that a court would conclude, after weighing the factors discussed previously, that the risks of DPT vaccine outweigh its benefits.

In spite of convincing evidence about the risks of the vaccine, the long-standing public acceptance of the vaccine as a major boon to health care will probably tip the scales in favor of the product's utility. In all likelihood, the courts will treat DPT vaccine as they have treated the oral polio vaccine where the manufacturer's conduct would be the touchstone of liability in negligence or failure-to-warn cases. Therefore, the plaintiff will have to prove negligence, failure-to-warn, or a breach of warranty by the DPT vaccine manufacturer in order to establish liability.

b. *Is DPT Vaccine an Unavoidably Unsafe Product?*

The text of comment k to the *Restatement (Second) of Torts*, section 402A, refers to vaccines as examples of unavoidably unsafe products. The courts have followed suit and have placed several vaccines in this category.<sup>177</sup> Comment k explains that certain products render a benefit to society which should be encouraged notwithstanding their risks. However, under a balancing test weighing the public interest and the dangers of the product, if the product does not serve an overriding public interest, its risks may exceed its utility thereby precluding the application of comment k.

Whether DPT vaccine is unavoidably unsafe depends upon

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<sup>177</sup> See, e.g., *Calabrese*, 162 N.J. Super. at 153, 392 A.2d at 603 (rabies vaccine).

an analysis of the risk-utility factors and any other relevant considerations.<sup>178</sup> The strongest argument against classification of the whole-cell pertussis vaccine as an unavoidably unsafe product, however, is the existence of an alternative product, the non-cellular or extracted vaccine, which is supposedly as effective but less dangerous than its counterpart.

There is support in the literature for the proposition that as early as 1951, the commercial pertussis manufacturers could have removed most, if not all, of the cell wall containing the toxins during the preparation of the vaccine.<sup>179</sup> Evidence also exists to show in at least two controlled comparison tests, one beginning in 1951<sup>180</sup> and the other in 1963,<sup>181</sup> that the whole-cell vaccine did not fare as well as the extracted vaccine in terms of reactivity. Recent studies have also confirmed that pertussis vaccine with the cell wall debris completely or partially removed is a safer product.<sup>182</sup>

The qualification of a product as unavoidably unsafe is premised on the proposition that scientific and technological know-how did not exist when the product was marketed to render it safer without detrimentally affecting its utility. If it can be shown that a safer, equally effective alternative product to the whole-cell vaccine could have been manufactured given the state of scientific knowledge, then the whole-cell vaccine may not be classified as an unavoidably unsafe product.

A counter-argument is that although methods have existed for some time to produce a safer product, there is no way at the present time to manufacture a reaction-free vaccine. Even the critics of the whole-cell vaccine recognize that the non-cellular vaccine will produce some reactions following inoculation. Thus, even if the manufacturers could have developed a safer vaccine, there would still be unsafe characteristics to the product which would render it unavoidably unsafe. According to this viewpoint, there are no degrees to an unavoidably unsafe product: if the product cannot be made completely safe, it qualifies under the definition.

In any event, it is not the "unsafe" product which is granted

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<sup>178</sup> *Kearl*, 172 Cal. App. 3d at 829-30, 218 Cal. Rptr. at 463-64. See also *Feldman*, 97 N.J. at 447, 479 A.2d at 383 (whether a drug is an unavoidably dangerous product should be decided on a case-by-case basis).

<sup>179</sup> *Pennell*, *supra* note 158.

<sup>180</sup> *Felton*, *supra* note 12.

<sup>181</sup> See *supra* note 2.

<sup>182</sup> *Barkin*, *supra* note 12; *Sato*, *supra* note 12.

immunity from strict liability under comment k, but only the "unavoidably unsafe product." It is certainly arguable, therefore, that the ability of a vaccine manufacturer to produce a safer product should preclude the application of comment k even though the complete safety of the non-cellular or extracted vaccine could never be certified.

In spite of the evidence leading to the availability of a safer product, most segments of the medical community refuse to criticize the pharmaceutical companies for neglecting the development of a better pertussis vaccine. A large majority of pediatricians are firm in their resolve to continue immunization with whole-cell vaccine because of its claimed disproportionate benefit to the public interest.

Through the efforts of medical groups, health officials and the federal and state governments, the public has also been conditioned for many years to believe that all vaccines, not just pertussis vaccine, are crucial to the promotion of good health care. Because of this belief in the propriety of the whole-cell vaccine and its alleged effect on the virtual eradication of whooping cough, there is an inherent bias in some quarters in favor of the whole-cell vaccine. Unfortunately, the dispute over the effect of pertussis vaccine on the reduction of whooping cough cases will never be resolved because of the absence of clinical tests when the vaccine was first introduced.

c. *If the Utility of DPT Vaccine Exceeds its Risks, or if the Vaccine is an Unavoidably Unsafe Product, Did the Manufacturer Properly Market it and Did Proper Warnings of its Dangerous Propensities Accompany its Distribution?*

If DPT vaccine is not an unavoidably unsafe product under comment k, it will not be exempted from strict liability analysis.<sup>183</sup> Conversely, if DPT vaccine fits the definition of an unavoidably unsafe product, it is not subject to strict liability analysis unless the manufacturer has failed to properly prepare and market the product or adequately warn about its risks.<sup>184</sup>

In accordance with the general rule, DPT manufacturers must warn physicians about the known neurological sequelae and adverse reactions associated with the vaccine. They must also in-

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<sup>183</sup> *Feldman*, 97 N.J. at 441-42, 479 A.2d at 380 (discussing comment k).

<sup>184</sup> *See id.* at 446-49, 479 A.2d at 383-84.

form the administering physician of all pertinent information which the manufacturer knows or should know would be material to the pediatrician who is considering immunization. As long as scientific or medical evidence exists tending to show that a certain danger is associated with use of the vaccine, the manufacturer may not ignore or discount that information in drafting the warning because it believes it to be unconvincing.<sup>185</sup> Above all, the DPT producers must avoid affirmative misrepresentations about the potency or toxicity of the pertussis portion of the vaccine which would falsely reassure uninformed pediatricians about the purported safety of the vaccine. As experts in the drug field, manufacturers must report the relevant and current medical and scientific literature to the physician as the "learned intermediary."

The adequacy of the warnings given by the drug companies regarding DPT vaccine focuses on the printed language appearing on the labels affixed to the vaccine bottles. Federal regulations require that the labels on all DPT vaccine bottles state that the vaccine contained therein has potency of twelve mouse protection units per dose, the recommended potency dosage per immunization in the United States.<sup>186</sup>

Before a manufacturer can distribute DPT vaccine, it must obtain approval from the FDA.<sup>187</sup> Such approval can only be obtained after the FDA tests the vaccine lot sought to be distributed for both potency and toxicity. If the test results demonstrate that the lot contains between eight and thirty-six mouse protective units, the FDA will approve the vaccine lot for public use.<sup>188</sup> The actual test results from the FDA are made known to the manufacturer contemporaneous with approval.

Once a manufacturer receives approval for the release of a particular vaccine lot from the FDA, it may distribute that lot. Bottles filled with DPT vaccine drawn from the approved lot are then distributed to physicians and state or local health departments.

Although Federal regulations mandate that all DPT vaccine bottles have labels affixed to them which state that they contain

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<sup>185</sup> *Seley v. G.D. Searle & Co.*, 67 Ohio St.2d 192, 198, 423 N.E.2d 831, 837 (1981); *accord Wooderson v. Ortho Pharmaceutical Corporation*, 235 Kan. 387, 681 P.2d 1038, *cert. denied*, 469 U.S. 965 (1984).

<sup>186</sup> 21 C.F.R. § 620.6(d) (1986).

<sup>187</sup> 21 C.F.R. § 620.1-621 (1986).

<sup>188</sup> 21 C.F.R. § 620.4(g) (1986).

vaccine having twelve mouse protective units per dose, they may actually contain between eight and thirty-six mouse protective units. The regulations do not require manufacturers to specify the exact results of the FDA potency test on the bottle labels. Thus, while DPT vaccine manufacturers are complying with the labelling requirements of federal law, they are not discharging their duty to adequately advise physicians about the potency of the vaccine which is being injected into American infants. Because FDA and other governmental regulations are only minimum standards, compliance does not automatically relieve a manufacturer from liability.<sup>189</sup> Where a manufacturer possesses information material to the risks of taking a drug, it is not enough to simply satisfy FDA labeling requirements,<sup>190</sup> even if the FDA has exhaustively regulated the area.<sup>191</sup>

Considering that physicians rely upon pharmaceutical companies to accurately and thoroughly advise them regarding the nature of their products, and the probability that physicians and other vaccine administrators are not familiar with the FDA testing and labelling requirements, DPT manufacturers should be required to inform and warn the physicians using the vaccine about the disparity between actual potency determined by the FDA tests and the hypothetical potency stated on the labels of the vaccine bottles.

Many studies have cited the correlation between the number of organisms per dose and reactivity.<sup>192</sup> Standardization of pertussis vaccine doses was thought to have been accomplished with the introduction of the mouse potency test in 1948. However, with the recent challenge to the validity of the test,<sup>193</sup> and the

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<sup>189</sup> *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 997 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); *Malek v. Lederle Laboratories*, 125 Ill. App. 3d 870, 872, 466 N.E.2d 1038, 1039-40 (1984); *Torsiello*, 165 N.J. Super. at 326 n.4, 310, 398 A.2d at 140 n.4 (citing *D'Arienzo v. Clairol, Inc.*, 125 N.J. Super. 224, 230, 310 A.2d 106, 108 (Law Div. 1973)).

<sup>190</sup> *Brochu*, 642 F.2d at 659-60; *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867, 879 (E.D. Mich. 1985); *Brick*, 428 F. Supp. at 498; *Stromsodt*, 257 F. Supp. at 997; *Stevens v. Parke Davis & Co.*, 9 Cal. 3d 51, 66, 507 P.2d 653, 107 Cal. Rptr. 45, 53, 661 (1973); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 141, 475 N.E.2d 65, 70 (1985); *Torsiello*, 165 N.J. Super. at 326 n.4, 398 A.2d at 140 n.4; *Bewers v. American Home Prod. Corp.*, 117 Misc. 2d 991, 459 N.Y.S.2d 666, 676 (Sup. Ct. 1982), *rev'd on other grounds*, 99 A.D.2d 949 472 N.Y.S.2d 637 (1984).

<sup>191</sup> See, e.g., *Odgers*, 609 F. Supp. at 879-81.

<sup>192</sup> See Sato, *Monoclonal Antibody Against Pertussis Toxin: Effect on Toxin Activity and Pertussis Infections*, 46 INFECT. AND IMM. 422 (1984).

<sup>193</sup> See *supra* note 30.

results of studies showing variability in lot-to-lot potency, standardization of organisms per dose remains a perplexing problem.<sup>194</sup> Because the medical and scientific literatures establish organism density as a cause of adverse reactions following immunization,<sup>195</sup> the vaccine manufacturers, as experts in the field, must be charged with knowledge of the reported association. Armed with the knowledge about reactivity and the actual results of the FDA testing, drug manufacturers who do not inform physicians of the actual mouse protective units per dose as determined by the FDA tests are negligent. The administering doctors must be aware of the actual potency of the DPT vaccine which is being used. Absent such knowledge, the administrators of the vaccine may be injecting into infants a vaccine which has triple the potency than is reported on the bottle label. Without stating the actual potency on the label, pediatricians assume that each dose of pertussis vaccine contains twelve mouse protection units.

The pediatrician is usually the person who immunizes the infant. As the "learned intermediary" between the manufacturer and parent, the pediatrician must be aware of the nature of the risks and benefits associated with DPT vaccine when he or she considers including the "P" portion of the shot. The pediatrician relies upon the vaccine manufacturer to provide relevant information gleaned from the medical literature regarding the risks and benefits of the product. If the manufacturer fails to supply to the pediatrician all data material to the medical decision, the chances of an erroneous decision by the pediatrician increases.

Vaccine manufacturers must advise physicians who administer pertussis vaccine that studies have reported a correlation between the number of pertussis organisms per dose and the risk of adverse reactions. At present, DPT vaccine producers discuss contraindications to the product, and, in general, the risks of immunization in their package inserts or advertisements published in the Physician's Desk Reference ("PDR"). However, they do not specifically discuss the potency-reactivity association, nor do they state the actual mouse protective units per total human immunizing dose on the vaccine bottle label.<sup>196</sup>

In California, the Physicians for Study of Pertussis Vaccine has initiated a bill in the legislature requiring vaccine manufac-

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<sup>194</sup> See *supra* note 25.

<sup>195</sup> See *supra* note 192.

<sup>196</sup> See *infra* notes 199-216 and accompanying text (discussing evaluation of warnings and contraindications in Physician's Desk Reference).

turers to state the actual potencies of all pertussis vaccines distributed statewide.<sup>197</sup> As a result, pediatricians will know the strength of the vaccine which they will be using. This group contends that if the pediatrician possesses knowledge of the actual number of mouse protective units per total dose contained in a vaccine bottle, he or she can adjust the dosage to insure that the infant receive twelve mouse protective units even though the regular dose may be in excess of the standard.<sup>198</sup> For example, if the actual potency of a particular vaccine dose is thirty-six mouse protective units, and the pediatrician is aware of the true potency, the doctor can inject 0.17cc of vaccine instead of the standard 0.50cc thereby effectively immunizing at twelve mouse protective units. This dose adjustment will also increase the supply of the vaccine and reduce the cost to the consumer.

The warnings and contraindications of DPT vaccine are presently stated in the PDR and package inserts. Information about the product is not limited to these sources, but many doctors rely upon these publications in administering or prescribing a drug or vaccine.

Because the PDR and package inserts are suppose to disclose the current material facts about the product, a chronology of warnings and contraindications can be developed by tracing the disclosures in these publications over the years. By considering the nature and extent of disclosures regarding the alleged deficiencies of the vaccine, and comparing the disclosures to the existing literature at the time, an opinion can be derived as to whether the vaccine manufacturers satisfied their obligation to disclose appropriate warnings and contraindications. The impression obtained after analysis is, until recently, that the manufacturers failed to properly disclose any meaningful warnings and contraindications in the PDR and package inserts. In some instances, the language used tended to dilute the impact of any cautionary disclosures.

*Parke, Davis & Co.*

The 1960 package insert for Triogen, issued September 16, 1959, the Parke, Davis & Co. ("Parke Davis") DPT vaccine, does not disclose any warnings or contraindications. However, the

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<sup>197</sup> Assembly Bill No. 1198, introduced March 4, 1985, proposing to add Section 26656 to the Health and Safety Code relating to the Sherman Food, Drug and Cosmetic Law.

<sup>198</sup> *Physicians for Study of Pertussis Vaccines*, *supra* note 16, at 11-12.



package insert states that encephalopathy and death can occur rarely following pertussis inoculation, and that in the event a "marked reaction" occurs, the dosage should be reduced.<sup>199</sup>

The 1962 package insert, issued December 1961, for the same product listed for the first time a section for "contraindications," but only one contraindication was described. It was suggested only that immunization be deferred in the presence of "cerebral damage, an active infection or acute respiratory disease."<sup>200</sup>

Finally in September 1966, Parke Davis published its first absolute contraindication in the package insert. If "encephalopathic symptoms" occurred following a shot, further pertussis vaccine was contraindicated. The 1966 package insert did not define "encephalopathic symptoms;"<sup>201</sup> however, in the 1969 PDR, Parke Davis defined these symptoms to include convulsions and lethargy and noted that the encephalopathy could be permanent or result in death.<sup>202</sup>

Parke Davis revised its package insert for Triogen in 1970. In several respects the 1970 insert disclosed additional information about the product, but it omitted encephalopathy as an absolute contraindication to further pertussis vaccine even though four years earlier Parke Davis recommended against immunization in the presence of post-immunization encephalopathy.<sup>203</sup>

The 1970 package insert for Triogen listed thrombocytopenia purpura as a contraindication for the first time. It also suggested deferral of pertussis vaccine if the patient had an acute febrile illness until the infection was "properly controlled." In the event of a fever over 103F., somnolence, or convulsions following a shot, the manufacturer recommended that subsequent doses be given "with caution." If a "prolonged" convulsion occurred, fractional doses of pertussis vaccine were suggested as "test doses" with immunization completed slowly in that manner.<sup>204</sup>

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<sup>199</sup> Package Insert, *Triogen, Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed*, Parke Davis, Detroit, Michigan, issued September 16, 1969.

<sup>200</sup> Package Insert, *Triogen, Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed*, Parke Davis, Detroit, Michigan, issued December 1961.

<sup>201</sup> Package Insert, *Triogen, Diphtheria and Tetanus Toxoids and Pertussis Vaccines, Adsorbed*, Parke Davis, Detroit, Michigan, issued September 1966.

<sup>202</sup> Physician's Desk Reference (E. R. Barnhart, Pub. 1969) Triogen, Parke Davis, at 1413.

<sup>203</sup> See Package Insert, *Triogen, Diphtheria and Tetanus Toxoids and Pertussis Vaccines, Adsorbed*, Parke Davis, Detroit, Michigan, issued November 1970.

<sup>204</sup> *Id.*

Parke Davis again revised its package insert for Triogen in September 1974, but took a more conservative approach to pertussis immunization in the face of neurological problems. According to the 1974 insert, pertussis immunization should not be repeated "if any central nervous system disorder or thrombocytopenia develops after use of this vaccine."<sup>205</sup> Unlike the 1970 package insert which recommended that fractional doses of pertussis vaccine be continued if a prolonged convulsion occurred, the 1974 insert stated that no further pertussis vaccine should be administered after a prolonged vaccine-induced convulsion.<sup>206</sup>

*Eli Lilly & Co., Inc.*

In 1962, Lilly advertised its triple antigen, Tripidigen, in the PDR. It noted that neurological disorders after pertussis vaccine inoculation were uncommon. The PDR suggested that a shot should be postponed if the patient had an active infection. Unlike all other manufacturers at the time, Lilly was more cautious where central nervous system disorders or convulsions had occurred. In such cases, Lilly recommended that the immunization process be postponed until the patient was two years old.<sup>207</sup>

In 1965, Lilly's split-cell pertussis vaccine, Tri-Solgen, was described in the PDR. The same information was disclosed for Tri-Solgen as was disclosed previously for Tripidigen.<sup>208</sup> In 1969, however, Lilly touted Tri-Solgen as being less reactive than the whole-cell pertussis vaccine. Although the 1969 PDR stated that neurological reactions sometimes occurred following immunization, the language chosen by Lilly in disclosing the potential problem diluted any warning intended.<sup>209</sup>

Lilly stated in the 1974 PDR that when there was a personal or family history of neurological disorders or convulsions, pertussis vaccine should be given only fractionally. The immunization series was to be completed only if no "untoward reactions" occurred. The reference to postponing pertussis vaccination until the child was two years old in a case of a central nervous sys-

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<sup>205</sup> Package Insert, *Triogen, Diphtheria and Tetanus Toxoids and Pertussis Vaccines, Adsorbed*, Parke Davis, Detroit, Michigan, issued September 1974.

<sup>206</sup> *Id.*

<sup>207</sup> Physician's Desk Reference, (E. R. Barnhart, Pub. 1962) Tripidigen, Lilly, at 691-92.

<sup>208</sup> Physician's Desk Reference, (E. R. Barnhart, Pub. 1965) Tripidigen, Lilly, at 224.

<sup>209</sup> Physician's Desk Reference, (E. R. Barnhart, Pub. 1969) Tripidigen, Lilly, at 847.

tem disorder was deleted in 1974.<sup>210</sup>

*Wyeth Laboratories*

It was not until 1979 that Wyeth disclosed any warnings and contraindications regarding its DPT vaccine in the PDR. According to the package insert for Ultrafined, issued September 19, 1979, a febrile acute respiratory infection or other active infection warranted deferral of the vaccine. In the event post-immunization encephalopathy and fever of 103F., convulsions with or without fever, alterations of consciousness, focal neurological signs, screaming episodes, shock, collapse, or thrombocytopenia purpura occurred, further inoculation with either DPT or pertussis vaccine alone was contraindicated. If an evolving or changing neurologic disorder was present, the package insert advised against continued DPT or pertussis vaccine immunization.<sup>211</sup>

The 1979 package insert for Ultrafined also mentioned SIDS following DPT inoculation, but downplayed the possible connection by stating that "DPT (is) usually administered to infants between the age of 2 and 6 months and that approximately 85 percent of SIDS cases occur in the period 1 through 6 months of age, with the peak incidence at age 2 to 4 months."<sup>212</sup> During the period 1960 through 1979, the PDR briefly described Wyeth's triple antigen, but was silent with regard to potential adverse reactions, precautions, or other pertinent information about the dangerous propensities of the product.

*Lederle Laboratories*

The contents of the PDR and package inserts for Lederle's product, Tri-Immunol, paralleled the other DPT manufacturers. In 1961, Lederle listed tuberculosis, or other "latent or active infections, debilitating diseases or severe anemia" as contraindications without further recommendation or discussion. Lederle also advised that patients with "sensitivity" be immunized with caution. What constituted or how to determine sensitivity was not addressed in the PDR.<sup>213</sup>

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<sup>210</sup> Physician's Desk Reference, (E. R. Barnhart, Pub. 1974) Tripidigen, Lilly, at 935.

<sup>211</sup> Package Insert, *Ultrafined, Diphtheria and Tetanus Toxoids and Pertussis Vaccines, Adsorbed*, Parke Davis, Detroit, Michigan, issued September 19, 1979.

<sup>212</sup> *Id.*

<sup>213</sup> See Physician's Desk Reference, (E. R. Barnhart, Pub. 1969) Tri-Immunol, Lederle Laboratories, at 619.

Lederle's warning and contraindication sections of its package insert were greatly expanded by the late 1970s. As to contraindications, Lederle included neurological symptoms or convulsions following pertussis immunization, a personal or family history of central nervous system disorders, and the presence of any evolving or changing nervous system disorder as absolute prohibitions against further use of the product in the 1985 PDR. In the same edition, Lederle also recommended deferral of immunization during the course of any acute illness, and discussed the contraindications promulgated by both the Red Book Committee and the ACIP.<sup>214</sup>

In the section headed as "warnings," Lederle restated the absolute contraindications to pertussis vaccine and specifically incorporated the Red Book Committee and the ACIP recommendations against immunization where convulsions, encephalopathy, focal neurological signs, collapse, shock, excessive screaming or somnolence, severe alteration of consciousness, systemic allergic reactions or temperatures in excess of 105F. occurred.<sup>215</sup> As with Wyeth in 1979, Lederle reported SIDS following DPT vaccination, but stated that a causal relationship was not established.<sup>216</sup>

Considering that the literature was replete with descriptions of vaccine-damaged children as early as the 1940s, all the vaccine manufacturers were slow to begin disclosing crucial information to the administering physician and the general public concerning the deleterious effects of their products. It has only been within the last ten years that the pharmaceutical companies started passing on more comprehensive information about the adverse reactions caused by pertussis vaccine. Nevertheless, the information contained in the most recent PDR and package insert for DPT vaccine still fails to encompass pertinent facts and other data necessary to a proper immunization decision by both the patient's parent and the learned intermediary.

In addition to the absence of any discussion regarding the actual potency of the pertussis vaccine and discrepancies with the vaccine bottle label as to the number of mouse protective units, the current literature from Lederle, the only remaining commercial distributor of DPT vaccine, does not discuss the most impor-

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<sup>214</sup> Physician's Desk Reference, Supp. (E. R. Barnhart, Pub. 1985) Tri-Immunol, Lederle Laboratories, at A12.

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

tant issue confronting the pediatricians—the risk-benefit assessment and whether to immunize a particular child against whooping cough.

The package insert being provided to administering physicians at the present time states that the risk of experiencing a permanent neurological problem is greater from the disease itself rather than the vaccine. Without disputing the validity of the conclusion stated in the literature, manufacturers should provide factual support and other statistical data for the assessment. Because of the wide divergence in statistical reports throughout the world concerning the comparative risks of immunization and the disease, this information should be disclosed in summary form to the doctor so that he and the parent of the patient could discuss it and arrive at a well-informed immunization decision. The need for disclosure of the experience in other countries with pertussis vaccine is underscored by the lack of any large-scale clinical test prior to the introduction of pertussis vaccine in the United States, and the unreliability of the mouse potency test.

Since the vaccine manufacturers were charged with knowledge of the reported adverse reactions associated with pertussis vaccine in the 1940s, they will find it difficult to sustain their burden in New Jersey of proving that the warnings given with the product comported with the current literature. This was true at least until the mid-1970s when manufacturers began to disclose more information about pertussis vaccine in their promotional and advertising literature. Thus, a child who was inoculated with pertussis vaccine prior to 1975, and who suffered related injuries, probably has a viable cause of action against the manufacturer based upon its failure to warn of the product's dangerous propensities.

- d. *If the DPT Vaccine Bore Appropriate Warnings of its Risks When Distributed, Has the Manufacturer Issued Meaningful Post-Distribution Warnings of Newly-Discovered Side-Effects?*

Post-distribution warnings in drug cases usually are pertinent because of the continuous or repetitive use by a patient of a drug over a long period of time. If newly discovered side-effects of the drug are disclosed to the treating physician and patient, the appropriate action can be taken to avoid the side-effects by termination of use, alteration in the dosage, or some other action

in order to minimize or eliminate the chance of experiencing the side-effect.

In a DPT vaccine case, post-distribution warnings are equally important despite the fact that the inoculations are not continuous but occur only several times over a few years. The recommended immunization schedule in the United States encompasses five shots: three in the first year of life, one during the second year, and a booster before school entry. Thus, even if a child has received one or more shots, the child could still suffer an adverse reaction to subsequent shots during the next four years of his or her life. If post-distribution warnings are made known to those deciding on whether to continue the vaccination process, the decision can be an enlightened one using currently available scientific knowledge.

The vaccine industry's disclosure of adverse reactions, contraindications, and warnings to the medical profession and the general public lagged far behind the revelations in the literature throughout the world. Consequently, in most DPT vaccine cases, the manufacturer will find it difficult to establish that proper warnings accompanied the product when distributed.<sup>217</sup> Where a child suffers an adverse reaction which was unknown when the vaccine was distributed, but which subsequently became known, the manufacturer will have to show that the occurrence pre-dated the manufacturer's actual or constructive knowledge of the side-effect, or that it actually had warned about the potential problem encountered.

In recent years, the vaccine manufacturers have disclosed contraindications and warnings in a more thorough manner. For example, when the SIDS deaths occurred in Tennessee in 1979 following DPT inoculations, the manufacturers quickly included statements in the PDR and package inserts about the occurrences. They did not make a causal connection, however, between the deaths and the vaccine.<sup>218</sup> Caution should be exercised by the DPT producers so as not to downplay the potential connection between the pertussis vaccine and physical and mental problems which may follow. This is true even if preliminary analysis and study appear to discount a causal connection.

Establishing a system where post-distribution warnings are regularly given assumes that reports from public and private im-

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<sup>217</sup> See *supra* notes 183-216 and accompanying text.

<sup>218</sup> Physician's Desk Reference, (E. R. Barnhart, Pub. 1980) Tri-Immunol, Lederle Laboratories.

munizations concerning side-effects can be gathered and analyzed promptly and accurately. At the present time, the Centers for Disease Control collects data from the public sphere, but no group organizes the input of information from the private physicians.<sup>219</sup> A mandatory system of reporting adverse reactions to a central location will help researchers keep abreast of any additional damaging aspects of the pertussis vaccine.

*B. Negligence in Failing to Develop an Alternative Product*

The claim that DPT vaccine producers have negligently prepared, tested, and marketed their products is founded upon the medical and scientific literature correlating adverse reactions with the whole-cell vaccine. Although the relationship between various pertussis toxins contained in the whole-cell vaccine is still not fully understood by researchers, the deleterious effect of the cell wall of *B. Pertussis* on some immunized infants was recognized in the 1940s. In an attempt to reduce neurological disorders of the magnitude described by Byers and Moll and others, research papers were written in the 1950s and 1960s describing methods of removing at least a portion of the cell wall to partially purify or detoxify the vaccine. Despite the publication of these findings, only Lilly made and distributed an extracted pertussis vaccine in the United States.

A manufacturer must adequately test a product for safety prior to marketing. If the current literature exposes side-effects or dangers in the use of the product, the manufacturer cannot ignore the problems and must test for them.<sup>220</sup> If the testing demonstrates the viability of an alternative product which is potentially safer, the manufacturer must pursue additional research and development without minimizing the dangers of its current product to the public.<sup>221</sup>

The law requires that DPT vaccine manufacturers know and appreciate the current state of medical and scientific knowledge concerning vaccines. A manufacturer's duty to test and investigate the propensities of its product corresponds with the foreseeability of the risk of harm to potential users in light of current scientific or medical knowledge.<sup>222</sup> Thus, DPT producers were

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<sup>219</sup> Interagency Group Report, *supra* note 64, at 4-5; Foegen, *supra* note 3, at 4-5.

<sup>220</sup> *Stromsodt*, 257 F. Supp. at 996-97; *Ferrigno*, 175 N.J. Super. at 579, 420 A.2d at 1320 (citing *Tinnerholm*, 285 F. Supp. at 432).

<sup>221</sup> See generally, *Tinnerholm*, 285 F. Supp. at 432; *Brochu*, 642 F.2d at 655.

<sup>222</sup> *O'Hare*, 381 F.2d at 291 (citing *Wright*, 244 F.2d at 56-57). See also *Borel*, 493

charged with knowledge of several pertinent facts regarding whole-cell pertussis vaccine as early as the 1950s; namely (a) that serious adverse reactions, including permanent brain damage, was caused by the vaccine in certain cases, (b) that certain elements of the whole-cell vaccine, particularly the cell wall, were toxic and responsible for the side-effects, (c) that the more potent the vaccine, the more likelihood that adverse reactions would follow inoculation, and (d) that numerous studies<sup>223</sup> described a detoxification process for pertussis vaccine which, after clinical testing of the extracted vaccine in at least one instance,<sup>224</sup> did not detrimentally affect the vaccine's immunogenic characteristics.

The criticism leveled at the DPT manufacturers is that they did nothing to improve their products in the preparation and testing phases once the facts about the whole-cell versus the non-cellular vaccine became known. It took Lilly ten years to apply for a patent on partially purified pertussis vaccine after Pennell and Thiele described a purification process. Lederle, even after obtaining undeniable proof that its vaccine was more reactive than Lilly's, never marketed a non-cellular or extracted product. The evidence demonstrates that the pharmaceutical companies which made and sold whole-cell DPT vaccines over the last thirty years were content to continue producing and marketing these products which they knew or should have known could have been improved with available technology.

It is true that, by and large, the vaccine released for public use through the years complied with FDA testing requirements. This does not foreclose, however, evidence of inadequate testing nor preclude liability as a matter of law.<sup>225</sup>

Public sentiment in favor of vaccination was so strong when

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F.2d at 1090; *Schenebeck*, 423 F.2d at 371-72; *Bertrand v. Johns-Manville Sales Corp.*, 529 F. Supp. 539-42 (D. Minn. 1982); *Stromsodt*, 257 F. Supp. at 995-96.

<sup>223</sup> See Barta, *Pertussis Prepared with Sodium Desoxycholate*, 90 J. OF IMMUNOLOGY 72 (1963); Burrell, *Effect of Calcium Chloride on the Preparation of Extract of H. Pertussis*, 108 SCIENCE 311 (1948); Nagel, *supra* note 12, at 96; Pennell, *Studies on the Fractionation of Hemophilus Pertussis Abstracts*, 66 J. OF IMMUNOLOGY 124; Pillemer, *Protective Antigen of Haemophilus Pertussis*, THE LANCET, June 19, 1954 at 1257; Pillemer, *Separation and Immunologic Evaluation of Soluble Pertussis Antigen*, 106 SCIENCE 36 (1947); Robbins, *Separation of Pertussis Toxin*, 74 PROC. SOC. EXPER. BIOL. & MED. 76 (1950); Robbins, *The Separation of a Protective Antigen from a Toxic-Producing Strain of Hemophilus Pertussis*, 65 J. OF IMMUNOLOGY 393 (1950).

<sup>224</sup> Felton, *supra* note 12, at 637.

<sup>225</sup> *Ferrigno*, 175 N.J. Super. at 579, 420 A.2d at 1320 (citing *Jackson v. New Jersey Mfr. Ins. Co.*, 166 N.J. Super. 448, 462, 400 A.2d 81, 88 (App. Div. 1979)).



pertussis vaccine was introduced on a large scale in the United States that certain deficiencies in the vaccine apparently were not sufficiently scrutinized. Because whooping cough devastated the population in the 1930s, any progress in controlling the disease was viewed by the public as acceptable. As a result, pertussis manufacturers, satisfied that their vaccines were eliminating whooping cough, failed to fully appreciate the damaging aspects of the vaccines. There was never a prospective clinical test undertaken in the United States using whole-cell pertussis vaccines before their placement into the stream of commerce. Most studies, even after pertussis vaccine was in use for some time, have been retrospective. It was not until the federally-funded Baraff study at UCLA in 1977 that a comprehensive analysis of reaction rates was made.

The allegations against the DPT manufacturers for negligent preparation and testing are dissimilar from those proffered in cases involving adulterated or contaminated drugs or vaccines. Unlike the adulteration or contamination cases where the products were not manufactured as intended,<sup>226</sup> the DPT vaccines, except in several unusual cases,<sup>227</sup> have been manufactured in accordance with the producer's specifications. Thus, the negligence asserted against the DPT manufacturers involves the failure to prepare, test, or develop an alternative product which has been reported to be safer and as effective as their existing product.

### C. *Negligent Failure to Warn*

A drug manufacturer has a common-law duty to warn about the dangerous propensities of its product which it actually or constructively knows about at the time of distribution. A manufacturer is negligent if it breaches this common-law duty. In a negligent failure to warn case, the considerations regarding the adequacy, timing, and reasonableness of the warnings are identical to those discussed in the context of a strict liability warning case.<sup>228</sup>

Strict liability and negligence are generally distinguished by

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<sup>226</sup> See *Davis*, 599 F.2d at 126; *Gottsdanker v. Cutters Laboratories, Co.*, 182 Cal. App.2d 602, 615, 6 Cal. Rptr. 320, 326 (1960) (Salk vaccine contained live virus due to inadequate testing procedures).

<sup>227</sup> See, e.g., *Tinnerholm*, 285 F. Supp. at 314.

<sup>228</sup> *Kearl*, 172 Cal. App.3d at 832, 218 Cal. Rptr. at 465-66; *Dunn*, 121 Mich. App. at 76, 328 N.W.2d at 580.

proof of actual or constructive knowledge of risk. Usually in a negligence action, the defendant's actions or conduct is the focus, whereas in a strict liability case, the product itself is analyzed and actual or constructive knowledge is imputed to the manufacturer.<sup>229</sup>

In a failure-to-warn case, however, most jurisdictions, including New Jersey,<sup>230</sup> mandate proof that the defendant actually or constructively knew of the risk which necessitated the warning regardless of whether the case is couched in terms of negligence or strict liability. Negligence and strict liability warning cases, therefore, are deemed "functional equivalents."<sup>231</sup>

A crucial distinction in New Jersey, however, between negligent and strict liability warning cases concerns the burden of proving the manufacturer's actual or constructive knowledge of the dangers associated with the product. In a warning case sounding in negligence, the plaintiff must demonstrate that the manufacturer knew or should have known, given the medical and scientific knowledge at the time the product was distributed, that the use of the drug would cause adverse side-effects. However, in a strict liability warning case the burden is placed on the manufacturer to show that it could not have possibly known about the dangers at the time the drug was marketed and distributed.<sup>232</sup>

In order to establish a *prima facie* case against a DPT manufacturer for negligent failure-to-warn, the plaintiff must prove (a) that the pertussis portion of the product had risks attenuated with its use, (b) that the manufacturer knew about these risks at the time the vaccine was sold or, alternatively, that the manufacturer should have known of the risks because they had been reported in the literature, (c) that the manufacturer failed to adequately warn or present sufficient information to the adminis-

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<sup>229</sup> *Petty v. United States*, 740 F.2d 1428, 1437 (8th Cir. 1984); *Reyes*, 498 F.2d at 1274-75; *Yarrow*, 408 F.2d at 992-93; *Davis*, 399 F.2d at 129; *Kearl*, 172 Cal. App. 3d at 832, 218 Cal. Rptr at 465; *Chapman*, 180 Ind. App. at 46, 388 N.E.2d at 550.

<sup>230</sup> In New Jersey, this common law duty to warn was recognized even before the formulation of Section 402A of the RESTATEMENT (SECOND) OF TORTS (1965). *Martin v. Bengue, Inc.*, 25 N.J. 359, 362, 371, 136 A.2d 626, 632 (1957).

<sup>231</sup> *Feldman*, 97 N.J. at 452, 479 A.2d at 386. See also *Stone v. Smith, Kline & French Laboratories*, 731 F.2d 1575, 1578 (11th Cir. 1984); *Kearl*, 172 Cal. App.3d at 832, 218 Cal. Rptr. at 465-66; *Chapman*, 180 Ind. App. at 48, 388 N.E.2d at 550-51. Other jurisdictions have found at least a theoretical distinction between warning cases and negligence and strict liability. In those jurisdictions, the relevant question is whether the product "is so harmful to persons . . . that a reasonable prudent manufacturer . . . with this knowledge would not have placed it on the market." *Petty*, 740 F.2d at 1440-41 (citations omitted).

<sup>232</sup> *Feldman*, 97 N.J. at 455-46, 479 A.2d at 388.

tering doctor about the risks,<sup>233</sup> and (d) that this failure proximately caused the injuries suffered by the plaintiff.<sup>234</sup>

What would otherwise be an adequate warning may be rendered inadequate and ineffective by overpromotion or false assurances concerning a drug or vaccine.<sup>235</sup> Overpromotion or false assurances may occur in many ways, such as by a vigorous sales and marketing effort,<sup>236</sup> use of particular language in the PDR, package inserts, or other literature,<sup>237</sup> and by following the marketing with upbeat advertisements or pamphlets.<sup>238</sup> When a manufacturer does not amend a warning which it knows is being widely disregarded, an inference may arise regarding the insufficiency of the warning.<sup>239</sup>

Part of the problem with the DPT vaccine is directly traceable to the massive governmental effort toward universal immunization which has been continuously growing in strength and momentum since the wide-scale introduction of the pertussis vaccine in the 1940s. Despite recent dissent in some circles, the governmental effort has not slowed. In 1980, 96% of all children enrolling in school had been immunized against pertussis. In 1982, the United States government expended \$21.8 million dollars in purchasing vaccines for use in public vaccination programs.<sup>240</sup> At the present time, forty-four states mandate pertussis inoculation prior to school entry.<sup>241</sup>

This governmental effort toward universal pertussis immunization, sparked many years ago by the fear of the disease and fueled by the manufacturers' slanted perception of its product,

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<sup>233</sup> See *supra* notes 109-118 and accompanying text regarding the learned intermediary theory.

<sup>234</sup> See *infra* notes 243-256 and accompanying text concerning the burden of proving causation.

<sup>235</sup> *Salmon*, 520 F.2d at 1362-63 (calendar promotion); *Stevens*, 9 Cal. 3d at 57, 507 P.2d at 661; *Love*, 226 Cal.2d at 389, 38 Cal. Rptr. at 189 (amount of sales); *Krug*, 416 S.W.2d at 150 (false assurances); *Stahlheber v. American Cyanamid Co.*, 451 S.W.2d 48, 62 (Mo. 1970) (false assurances); *Whitley*, 24 N.C. App. at 207-08, 210 S.E.2d at 292 (sales campaign); *Incollingo*, 444 Pa. at 288-89, 282 A.2d at 220 (detailmen).

<sup>236</sup> See, e.g., *Sterling Drugs*, 263 F. Supp. at 162-63; *Stevens*, 9 Cal.3d at 66, 507 P.2d at 661, 107 Cal. Rptr. at 53; *Love*, 226 Cal. 2d at 389, 38 Cal. Rptr. at 189; *Whitley*, 24 N.C. App. at 208, 210 S.E.2d at 292; *Incollingo*, 44 Pa. at 288-89, 282 A.2d at 220.

<sup>237</sup> *Salmon*, 520 F.2d at 1362-63 (calendar); *Krug*, 416 S.W.2d at 150 (letter).

<sup>238</sup> *Stevens*, 9 Cal.3d at 67, 507 P.2d at 662, 107 Cal. Rptr. at 57.

<sup>239</sup> *Salmon*, 520 F.2d at 1362 (citing *Incollingo*, 44 Pa. at 292, 282 A.2d at 222).

<sup>240</sup> *Foege*, *supra* note 3; 21 C.F.R. § 310.501 (1984).

<sup>241</sup> *Hinman*, *supra* note 5, at 256.

has effectively resulted in the overpromotion of DPT vaccine. It is certainly a difficult task at this time for a manufacturer to provide a thorough and objective warning about the product's dangerous propensities given the environment which has been created and fostered. The object, however, should not be to disparage the vaccine, but rather, to educate the prescribing physician that selective use is not objectionable per se. Since the immunization effort has filtered down to the local level, a major overhaul of the FDA testing and labelling requirements may be in order to steer the future course of immunization practices. Because the benefits of vaccination have become so well-entrenched, federal regulations, similar to the regulations which govern oral contraceptive warnings and labels, may be needed to present an objective picture for the administering physician.

As the previous discussion has indicated, while the extent of manufacturers' warnings in both the PDR and package inserts concerning side-effects and contraindications has been expanding in recent years for DPT vaccine<sup>242</sup> there are still gaps in this literature. There is sufficient evidence for the trier of fact to determine that a DPT manufacturer failed to adequately warn about the vaccine's deleterious effects in view of the methods now being utilized to bring home to the doctor what problems to look for and when to inoculate or continue with the immunization process. This is especially true when the manufacturer is charged with knowledge of the environment in which it is distributing and marketing its product. The manufacturers must know that in many instances parental discretion on whether and when to immunize is absent. Overpromotion of the vaccine has nullified parental discretion. Only the doctors, as learned intermediaries, have the ability to weigh the considerations impacting upon a decision to immunize, and the opportunity to arrive at an individualized balancing of the medical risks and benefits to a particular infant. Thus, the manufacturers must neutralize the effect of overpromotion by using all available means, including detailmen, "Dear Doctor" letters, pamphlets, and other advertisements to present an objective appraisal of its product to the doctor.

A plaintiff's burden does not end after it is established that a defective warning was given. Rather, a plaintiff must still prove that the warning itself proximately caused the plaintiff's injury.<sup>243</sup>

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<sup>242</sup> See *supra* notes 199-216 and accompanying text.

<sup>243</sup> *Lindsay*, 637 F.2d at 92. But see *Hamilton v. Hardy*, 37 Colo. App. 375, 549

In this regard, there is a split of authority in the United States. Some jurisdictions impute a rebuttable presumption that a prescribing physician would heed a reasonable warning if given by the manufacturer.<sup>244</sup> However, if a defending drug manufacturer offers evidence in rebuttal tending to show that the doctor's conduct would have been unaltered even if a proper warning was made, the presumption disappears.<sup>245</sup> If it is affirmatively established that the doctor would not have heeded a reasonable warning, the manufacturer is insulated from liability for failure to warn.<sup>246</sup>

Other jurisdictions require that a plaintiff must show that if an adequate warning was given, it would have been heeded by the prescribing physician and altered his conduct.<sup>247</sup> Where the doctor independently knows of the risks without a warning, his conduct in prescribing the drug or using the vaccine, may or may not constitute an intervening or superseding cause.<sup>248</sup>

Some jurisdictions impose a duty upon the doctor to learn about the characteristics of the drug he is prescribing,<sup>249</sup> while others have not found a prescribing physician's failure to keep abreast of the literature to be an intervening cause sufficient to relieve the manufacturer from liability for failure to warn.<sup>250</sup> Thus, in certain cases, the carelessness of the physician, in an anticipated or unanticipated manner, may not absolve the manufacturer from culpability if the manufacturer's failure to warn contributed to the carelessness.<sup>251</sup>

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P.2d 1099, 1109 (Colo. App. 1976) (suggesting that once a defective warning is established, liability automatically follows); *Seley*, 67 Ohio St.2d at 199-200, 423 N.E.2d at 837 (holding that what prescribing doctor would or would not have done after receiving inadequate warnings is not part of plaintiff's burden of proof).

<sup>244</sup> *Petty*, 740 F.2d at 1437; *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1538-39 (D.D.C. 1984); *Reyes*, 498 F.2d at 1281; *Cunningham*, 532 P.2d at 1382; *Payne v. Soft Sheen Prod., Inc.*, 486 A.2d 712, 725 (D.C. 1985); *Wooderson*, 235 Kan. at 410, 681 P.2d at 1057.

<sup>245</sup> *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 386 (S.D. Ohio, 1984); *Sheehan v. Pima County*, 135 Ariz. 235, 237-38, 660 P.2d 486, 488-89 (Ariz. App. 1982); *Dyer*, 118 Ariz. at 469, 577 P.2d at 1088; *Chapman*, 180 Ind. App. at 55, 388 N.E.2d at 555.

<sup>246</sup> *Stanback*, 657 F.2d at 645; *Fraley v. American Cyanamid Co.*, 589 F. Supp. 826, 827 (D. Colo. 1984); *Williams*, 591 F. Supp. at 387.

<sup>247</sup> *May v. Parke Davis & Co.*, 142 Mich. App. 404, 418, 370 N.W.2d 371, 379 (1985); *Dunn*, 121 Mich. App. at 87, 328 N.W.2d at 582.

<sup>248</sup> *Dunn*, 121 Mich. App. at 89, 328 N.W.2d at 584-85.

<sup>249</sup> *Jones v. Irvin*, 602 F. Supp. 399, 402 (S.D. Ill. 1985).

<sup>250</sup> *Baker v. St. Agnes Hosp.*, 70 A.2d 400, 404, 421 N.Y.S.2d 81, 86 (Sup. Ct. 1979).

<sup>251</sup> *Brochu*, 642 F.2d at 660 (relying on *McCue*, 453 F.2d at 1035); *Salmon*, 520

The only New Jersey case addressing the issue of the plaintiff's burden in proving causation in a failure to warn case holds that if a warning was given, it is presumed it would have been heeded by the doctor. The plaintiff need not affirmatively establish that the prescribing physician would have acted differently if the warning had been given. The case suggests, however, that if the defendant introduces evidence to show that the doctor would not have acted differently even if the warning was given, the presumption will be rebutted.<sup>252</sup> In New Jersey, as in some other jurisdictions, the seller of a product may reasonably assume that an adequate warning will be read and heeded if given.<sup>253</sup>

In the jurisdictions which subscribe to the rebuttable presumption theory, including New Jersey, the vaccine manufacturer has the obligation to show that the doctor who gave the injection would have done so regardless of a proper warning. The testimony of the doctor would constitute the only direct evidence to carry this burden. If the doctor testifies that a warning would not have altered the decision to immunize at that time, a plaintiff will be hard-pressed to establish causation since an attack on the doctor's credibility is then the plaintiff's sole recourse.<sup>254</sup>

The difficulty of proving that an infant's injuries were caused by the DPT vaccine<sup>255</sup> is magnified by the probability that the administering physician will testify in most cases that the decision to immunize would have been made despite appropriate warnings. The probability of such testimony is bottomed on the routine manner in which pertussis vaccine is given. Buttressed by the overwhelming governmental support for immunization programs, all segments of the public, including pediatricians, have been subjected to a biased portrayal of the pertussis vaccine in encouraging universal vaccination. It is suggested that the ever-increasing popularity of vaccines tend to negate their use in discriminating fashion. Despite the warnings and contraindications

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F.2d at 1362-63 (jury can find both manufacturer and prescribing physician liable); *Chapman*, 180 Ind. App. at 55, 388 N.E.2d at 555; *Reeder*, 125 Mich. App. at 225, 336 N.W.2d at 6 (jury can infer that doctor's failure to read the Physician's Desk Reference or package insert negated manufacturer's liability).

<sup>252</sup> *Ferrigno*, 176 N.J. Super. at 582, 420 A.2d at 1320.

<sup>253</sup> *Torsiello*, 165 N.J. Super. at 312, 398 A.2d at 132 (embracing Section 402A, comment j of the RESTATEMENT (SECOND) OF TORTS (1965)); see also, *Ferrigno*, 176 N.J. Super. at 579-80, 420 A.2d at 1319.

<sup>254</sup> See *Williams*, 591 F. Supp. at 387 (holding that because of the issue of credibility, causation is still a jury question despite the prescribing doctor's testimony that he would not have altered his conduct).

<sup>255</sup> See *infra* notes 243-255 and accompanying text.

stated in the PDR and package insert for pertussis vaccine, because of the strength of the immunization movement in the United States, and its propagandizing effect, many physicians would read the diluted warnings, and then vaccinate anyway. In many cases, therefore, the plaintiff is in a quandary—while the plaintiff can prove the warning was inadequate or absent entirely, he or she cannot combat the doctor's testimony that immunization would have been completed in any event. If the decision to immunize was negligent under the circumstances, redress via a medical malpractice action may be available to the plaintiff. Alternatively, in some jurisdictions, the negligence of the doctor, particularly if it is foreseeable, may not rise to the level of an intervening or superseding cause if the manufacturer's failure to warn contributed to the doctor's negligence, thereby creating joint and several liability on the part of the manufacturer and the doctor.<sup>256</sup>

#### D. Breach of Warranty

Liability and warranty arises when damage is caused by the failure of a product to comport with express or implied representations of the manufacturer or supplier.<sup>257</sup> In the absence of an express warranty, a manufacturer or supplier can still be liable for a breach of the implied warranties of merchantability or fitness for a particular purpose which arise with the sale of every chattel.<sup>258</sup> Negligence is not a factor in a warranty analysis unless the plaintiff's allegations are premised upon a failure to warn or inadequate warning theory.<sup>259</sup> If the product was "defective" or

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<sup>256</sup> *Id.*

<sup>257</sup> *Tinnerholm*, 285 F. Supp. at 440; *Stromstodt*, 257 F. Supp. at 994 (quoting 2 FRUMER & FRIEDMAN, PRODUCTS LIABILITY § 16.01 (1)).

<sup>258</sup> N.J. STAT. ANN. §§ 12A:2-313, 12A:2-314, 12A:2-315, and 12A:2-319 (West 1961). See also *Standard Steel Co. v. Bethlehem Steel Corp.*, 597 F. Supp. 164, 185 (D. Conn. 1984); *Stromstodt*, 257 F. Supp. at 995; *McDonald v. Miannecki*, 79 N.J. 275, 284, 398 A.2d 1283, 1287 (1979); *Maritime Mfrs., Inc. v. Hi-Skipper Marine*, 19 Ohio St. 3d 93, 95, 483 N.E.2d 144, 146 (1985).

<sup>259</sup> See *Bly v. Otis Elevator Co.*, 713 F.2d 1040, 1045 (4th Cir. 1983); *Tinnerholm*, 285 F. Supp. at 440; *Stromstodt*, 257 F. Supp. at 994; *John Deere Co. v. Lindsey Landclearing Co.*, 122 Ga. App. 827, 831, 178 S.E.2d 917, 920 (1970); *Smith*, 405 Mich. at 81, 273 N.W.2d at 479-80; *Spencer v. Ford Motor Company*, 141 Mich. App. 356, 361, 367 N.W.2d 393, 396 (1985); *Kerr v. Corning Glass Works*, 284 Minn. 115, 119, 169 N.W.2d 587, 593 (1969); *Smith v. Old Warson Dev. Co.*, 479 S.W.2d 795, 798 (Mo. 1972); *Courtois v. General Motors Corp.*, 37 N.J. 525, 542, 182 A.2d 545, 553 (1962); *Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358, 372, 161 A.2d 69, 75 (1960); *Pearson v. Franklin Laboratories, Inc.*, 254 N.W.2d 133, 141 (S.D. 1977). But see *Reid v. Eckerd's Drugs, Inc.*, 40 N.C. App. 476, 479,

unreasonably dangerous for its intended use when placed into the stream of commerce, liability in non-warning warranty cases will attach if the defect proximately caused the injuries regardless of the conduct of the manufacturer or supplier.<sup>260</sup>

Most jurisdictions, including New Jersey,<sup>261</sup> have held that the elements comprising a breach of warranty are identical to those in a strict liability case,<sup>262</sup> particularly in cases where the "defect" is an inadequate warning.<sup>263</sup> However, in some jurisdictions,<sup>264</sup> when a failure to warn or inadequate warning case is couched in terms of a breach of implied warranty, "the existence of a product defect and breach of duty is determined by the same standard—reasonable care under the circumstances."<sup>265</sup> Since

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253 S.E.2d 344, 347 (1979), *cert. denied*, 297 N.C. 611, 257 S.E.2d 219 (1979) (implying that negligence is not a consideration where a defect is an inadequate warning for warranty purposes).

<sup>260</sup> See *Serksnas v. Engine Support, Inc.*, 392 F.2d 392, 393 (S.D. Fla. 1975) (applying Florida law); *Fruehauf Trailer Div. v. Thornton*, 174 Ind. App. 1, 15, 366 N.E.2d 21, 28 (1977); *Smith*, 405 Mich. at 81, 273 N.W.2d at 479 (citing *Heckel v. American Coupling Corp.*, 381 Mich. 19, 179 N.W.2d 381 (1970), and *Piercefield v. Remington Arms Co.*, 375 Mich. 85, 133 N.W.2d 129 (1969)); *Rice v. James Hanrahan & Sons*, 20 Mass. App. 701, 714, 482 N.E.2d 833, 839 (Mass. App. 1985); *Herbstman v. Eastman Kodak Co.*, 68 N.J. 1, 7-8, 342 A.2d 181, 186-87 (1978); *Jakubowski v. Minnesota Mining and Mfg.*, 42 N.J. 177, 182, 199 A.2d 826, 828 (1964).

<sup>261</sup> See *Dawson v. Chrysler Corp.*, 630 F.2d 950, 955 (3d Cir. 1980), *cert. denied*, 450 U.S. 959 (1980) (citing *Huddell v. Levin*, 537 F.2d 726 (3d Cir. 1976)); *Manieri v. Volkswagenwerk*, 151 N.J. Super. 422, 430, 376 A.2d 1317, 1321 (App. Div. 1977); *Realmuto v. Straub Motors*, 65 N.J. 336, 345, 322 A.2d 440, 444 (App. Div. 1974) (citing *Lamendola v. Mizell*, 115 N.J. Super. 514, 526, 280 A.2d 241, 247 (Law Div. 1971) and *Heavner v. Uniroyal, Inc.*, 63 N.J. 130, 142-57, 305 A.2d 412, 418-27 (1973)); *Monsanto Co. v. Alden Leeds, Inc.*, 130 N.J. Super. 245, 255, 326 A.2d 90, 95 (Law Div. 1974) (interpreting Missouri law).

<sup>262</sup> See *Bly*, 713 F.2d at 1045; *Gootee v. Colt Indus., Inc.*, 712 F.2d 1057, 1067 (6th Cir. 1983); *Gumbs v. International Harvester Co., Inc.*, 718 F.2d 88, 94 (3d Cir. 1983); *Reyes*, 498 F.2d at 1272; *Serksnas*, 392 F.2d at 392; *Sterner Aero A.B. v. Page Airomotive, Inc.*, 499 F.2d 709, 712 (10th Cir. 1974); *Davis*, 599 F.2d at 126.

<sup>263</sup> See *Bly*, 713 F.2d at 1043; *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979); *Basko*, 416 F.2d at 427; *Davis*, 399 F.2d at 126; *Brick*, 428 F. Supp. at 497; *Love*, 226 Cal. App.2d at 391, 38 Cal. Rptr. at 197-98; *Chapman*, 180 Ind. App. at 47, 388 N.E.2d at 551; *Gutowski v. M & R Coating Inc.*, 60 Mich. App. 499, 503, 231 N.W.2d 456, 461 (1975).

<sup>264</sup> *Smith*, 405 Mich. App. at 81, 273 N.W.2d at 480. See also, *Hasler v. United States*, 517 F. Supp. 1262, 1268 (E.D. Mich. 1981), *rev'd on other grounds*, 718 F.2d 202 (6th Cir. 1983) (failure to warn may constitute negligence or breach of implied warranty); *Holmgren v. Massey-Ferguson, Inc.*, 394 F. Supp. 910, 912 (D.N.D. 1973), *rev'd on other grounds*, 516 F.2d 856 (8th Cir. 1974); *Central Soya Coat, Inc. v. Rose*, 135 Mich. App. 180, 352 N.W.2d 727, 729 (1984) (failure to provide adequate instructions or warnings constitutes product defect sufficient to sustain implied warranty).

<sup>265</sup> *Smith*, 405 Mich. App. at 81, 273 N.W.2d at 480.



negligent failure to warn and inadequate warnings in the context of strict liability have been discussed in detail previously,<sup>266</sup> this discussion will center on pure defect warranty cases, i.e. those cases where it is asserted that the manufacturer has either breached an express representation about the product, or the product itself was unmerchantable or unfit for the purpose for which it was to be used.

### 1. Express Warranty:

The Uniform Commercial Code ("UCC"), as adopted in most states, defines an express warranty as:

- (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes a part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
- (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.<sup>267</sup>

A claim based on the breach of an express warranty by the seller of goods requires proof that the affirmation of fact or promise had a natural tendency to induce the buyer to purchase the goods, that the buyer relied on the statements in making the purchase,<sup>268</sup> that the statements were untrue, and that the breach of the express warranty caused the buyer's damages.<sup>269</sup>

Express warranties can exist in promotional brochures, advertising material, and generally in any statement purporting to be fac-

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<sup>266</sup> See *supra* notes 86-131 and accompanying text.

<sup>267</sup> N.J. STAT. ANN. § 12A:2-313 (1) (West 1961).

<sup>268</sup> *Wendt v. Beardmore Suburban Chevrolet, Inc.*, 219 Neb. 775, 780, 366 N.W.2d 424, 428 (1985); *Thursby v. Reynolds Metals Co.*, 466 So.2d 245, 250 (Fla. App. 1984). In New Jersey, no proof of the buyer's reliance is necessary other than the seller's statements of a kind which would normally induce the purchase. *Bregman Screen & Lumber Co. v. Bechefskey*, 16 N.J. Super. 35, 41, 83 A.2d 804, 809 (App. Div. 1951). *But see, Tinnerholm*, 285 F. Supp. at 443 (holding that under New York law, plaintiff must prove reliance by physician in purchasing Quadrigen, a quadruple antigen combining diphtheria and tetanus toxoids with pertussis and polio vaccines).

<sup>269</sup> *Borowicz v. Chicago Mastic Co.*, 367 F.2d 751, 759 (7th Cir. 1966); *see also*, *Melanson Co. v. Hupp Corp.*, 282 F. Supp. 859, 862 (D.N.J.), *aff'd*, 391 F.2d 902 (3d Cir. 1966); *Peterson v. North Am. Plant Breeders*, 218 Neb. 258, 262, 354 N.W.2d 625, 629-30 (1984).

tual which is intended to be central to the selling process.<sup>270</sup> Express warranties about DPT vaccine may be found in the PDR, "Dear Doctor" letters, and any promotional and advertising documents published and distributed to doctors or consumers by the vaccine manufacturer. In some instances, express warranties may arise when the manufacturer's detailman discusses the vaccine with the purchasing doctor.

The intent here is not to survey all the voluminous literature circulated throughout the years by DPT vaccine manufacturers in an effort to discover and isolate affirmations of fact or promises which may be construed as express warranties. Nevertheless, over the years there have been striking statements or representations made by vaccine manufacturers in the literature which constitute express warranties about their products. In many cases, these warranties became an integral part of the bargain between the manufacturer as the seller and the doctor as the buyer. A brief discussion of some of these statements and representations will also serve to highlight the marketing methods used by the manufacturers in promoting their DPT vaccines.

The 1986 PDR states that the total immunizing dose of Lederle's pertussis vaccine, Tri-Immunol, contains 12 mouse protection units.<sup>271</sup> This statement is also printed on every label affixed to every bottle of Tri-Immunol which is commercially distributed. Ever since federal regulations<sup>272</sup> began mandating labelling stating that each total immunizing dose of pertussis vaccine contains 12 mouse protection units, vaccine manufacturers have restated this purported fact on countless vaccine bottle labels. A review of the PDR summaries and package inserts for various brands of DPT vaccine over the last 25 years reveals continual reaffirmation that each total immunizing dose of pertussis vaccine contains 12 mouse protection units.<sup>273</sup>

It is not true that every total immunizing dose of pertussis vaccine contains exactly that amount. Studies derived from govern-

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<sup>270</sup> *Colorado-Ute Elect. Ass'n, Inc. v. Envirotech Corp.*, 524 F. Supp. 1152, 1156 (D. Colo. 1981); *Crest Container Corp. v. R.H. Bishop Co.*, 111 Ill. App. 3d 1068, 1074-75, 445 N.E.2d 19, 23-24 (1982). *But cf.*, *Butler v. Travelers Ins. Co.*, 202 So.2d 354, 356 (La. App. 1967), *cert. denied*, 251 La. 217, 203 So.2d 555 (1967).

<sup>271</sup> *See supra* note 19.

<sup>272</sup> 21 C.F.R. § 620.6(g) (1986).

<sup>273</sup> A random reading of package inserts and Physician Desk Reference summaries demonstrates that the following products all allegedly contain 12 mouse protection units per total immunizing dose: Triogen (Parke, Davis & Co., 1962), Ultrafined (Wyeth Laboratories, 1968, 1978-1981), Tri-Solgen (Lilly, 1968), Tri-Immunol (Lederle, 1986).

ment statistics have shown that vaccine lots which have passed FDA tests and which have been released for public use have contained as low as 7.3 mouse protection units and as high as 37.3 mouse protection units.<sup>274</sup> Because the chances of incurring an adverse reaction to pertussis vaccine increases as the density or opacity of the vaccine increases,<sup>275</sup> a deviation from the standard 12 mouse protection units is significant. A pediatrician who accepts the veracity of the statements on the bottle label and in the PDR, and relies on them in purchasing the vaccine from the manufacturer for use in his practice, may be injecting more of the vaccine than anticipated, thereby jeopardizing the health of the infant.<sup>276</sup>

If any infant is damaged by pertussis vaccine which contains more than the standard potency, the administering pediatrician relied on the warranty of the manufacturer stated on the vaccine bottle label or in the PDR or other literature distributed by the manufacturer, and it can be demonstrated that the higher potency of the vaccine was a substantial contributing factor in causing the reaction, the vaccine manufacturer will be liable for breaching an express warranty notwithstanding federal labelling regulations.

In addition to the statements about the potency of vaccine doses, there are several other affirmations of fact worthy of mention which have been included in some manufacturer's literature. These may also be considered express warranties.

For example, in 1959, Parke Davis marketed its DPT vaccine, known as Triogen, and stated the following in its package insert:

McComb and Trafton,<sup>277</sup> in studying the immune responses and reactions to diphtheria and tetanus toxoids with pertussis vaccine, aluminum phosphate precipitated, observed *almost complete absence of reactions*.<sup>278</sup>

This bold statement was made in spite of numerous studies and reports contained in the literature linking all types of pertussis vaccine with various forms of adverse reactions.<sup>279</sup> No serious side-ef-

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<sup>274</sup> See *supra* note 25.

<sup>275</sup> See *supra* note 192.

<sup>276</sup> In California, legislation has been proposed to require vaccine manufacturers to state the actual potencies of the vaccines so that pediatricians can adjust the doses to effect immunization at 12 mouse protection units. See *supra* notes 190-95 and accompanying text.

<sup>277</sup> McComb, *Immune Responses and Reactions to Diphtheria and Tetanus Toxoids with Pertussis, Aluminum Phosphate Precipitated*, 243 NEW ENG. J. OF MED. 442 (1950).

<sup>278</sup> Package Insert, *Diphtheria-Tetanus-Pertussis Aluminum Phosphate, Adsorbed*, Triogen, Parke, Davis, Detroit, Michigan, issued September 16, 1959, p.3 (emphasis added).

<sup>279</sup> See *supra* notes 28-71 and accompanying text.

fects were noted in the package insert. The clear intent to the insert was to place reliance on a single study without giving due regard to the other reports discussing the nature and extent of vaccine-induced injuries. In view of the fact that a slanted perception was created in the package insert, the representation made should be construed as an express warranty. It is certainly an affirmation of fact adopted by the vaccine manufacturer having a natural tendency to induce a doctor to buy the product.

Parke Davis continued to include the statement about the McComb-Trafton study in its literature until 1970. At that time, the statement was deleted and the following statement, referring to the McComb-Trafton study was included in the package insert:

The advantages of aluminum phosphate as a mineral carrier of antigen have been reported by a number of workers.<sup>280</sup>

A complete revision of the language in the 1959 version was probably a result of liability concerns since the later statement has a substantially different meaning and impact than the earlier statement. In its 1974 package insert, Parke Davis deleted the revised language of the 1970 insert and did not include any statement about the McComb-Trafton study, the absence of adverse reactions, or the advantages of aluminum phosphate.

The illustration of another express warranty can be found in the 1968 PDR concerning Lilly's DPT vaccine, Tri-Solgen. Tri-Solgen was an extracted vaccine, and in comparison studies<sup>281</sup> made by Lederle, was evidently just as efficacious with less reactivity. Nevertheless, Tri-Solgen still caused adverse reactions although not as severe as those caused by the whole-cell vaccine products made by other manufacturers.

In the 1968 PDR, Lilly stated as follows:

In no case has it been necessary to discontinue a series of injections or to reduce the size of individual doses because of severe reactions.<sup>282</sup>

This statement published by Lilly in the PDR constitutes an express warranty about the quality and safety of Tri-Solgen. The statement is not limited to reported cases only, but broadly represents that every infant who was inoculated with Tri-Solgen did not have a severe enough reaction to justify discontinuation of the im-

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<sup>280</sup> Package Insert, *Triogen, Diphtheria and Tetanus Toxoids and Pertussis Vaccines Adsorbed*, Parke, Davis, Detroit, Michigan, issued November 1970.

<sup>281</sup> See *supra* notes 161-65 and accompanying text.

<sup>282</sup> Physician's Desk Reference, (E. R. Barnhart, Pub., 1968) Tri-Solgen, Lilly, at 807.

munization process or reduction in the dosages given. The representation is so broad that it is misleading. If the manufacturer warns of the dangerous propensities of the product, and provides all material and pertinent information to the doctor, the decision to discontinue the immunization regimen or reduce the size of individual dosages primarily rests with the administering physician. Thus, Lilly's warranty may only serve to underscore its dereliction in passing on information to physicians in order to educate them about adverse reactions and contraindications.

Over the last several years, the information provided to doctors concerning adverse reactions and contraindications has been expanded. As this expansion occurs, more restrictive and limiting language has been used by the vaccine manufacturer in the package inserts, PDR and other promotional and advertising material. The presence of this language in documents weakens allegations premised upon express warranty, although it does not entirely destroy warranty claims.

## 2. Implied Warranty of Merchantability:

If the seller is a merchant with respect to goods of the kind sold to the buyer, an implied warranty of merchantability attaches to the sale.<sup>283</sup> In order to recover under a theory of breach of the implied warranty of merchantability, a plaintiff must prove that a "merchant," as defined under state law,<sup>284</sup> sold a product which was defective or not "merchantable" at the time of sale, and that the defect proximately caused the plaintiff's injuries.<sup>285</sup>

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<sup>283</sup> *Ontai v. Straub Clinic and Hosp., Inc.*, 66 Haw. 237, 659 P.2d 734, 744 (1983).

<sup>284</sup> "Merchant" is defined in the UCC, as adopted in New Jersey, as "a person who deals in goods of the kind or otherwise by his occupation holds himself out as having knowledge or skills peculiar to the practices or goods involved in the transaction or to whom such knowledge or skill may be attributed by his employment of an agent or broker or other intermediary who by his occupation holds himself as having such knowledge or skill." N.J. STAT. ANN. § 12A:2-104(1) (1961). See also, *International Petroleum Serv., Inc. v. S & N Well Serv., Inc.*, 230 Kan. 452, 639 P.2d 29 (1982).

<sup>285</sup> *Standard Steel Co.*, 597 F. Supp. at 187; *Wittkamp v. United States*, 343 F. Supp. 1075, 1078 (E.D. Mich. 1972); *Mosier v. American Motors Corp.*, 303 F. Supp. 44, 50 (S.D. Tex. 1967), *aff'd*, 414 F.2d 34 (5th Cir. 1967) (applying Ohio law); *Woodill v. Parke, Davis & Co.*, 58 Ill. App. 3d 349, 354, 374 N.E.2d 683, 688 (1978), *aff'd*, 79 Ill.2d 26, 402 N.E.2d 194 (1980); *Van Wyk v. Borden Laboratories, Inc.*, 345 N.W.2d 81, 87 (Iowa 1984); *Hollinger v. Shoppers Paradise of New Jersey, Inc.*, 134 N.J. Super. 328, 337, 340 A.2d 687, 695 (Law Div. 1975), *aff'd*, 142

Under the Uniform Commercial Code, "merchantable" goods are those which are at least such as:

- (a) pass without objection in the trade under the contract description; and
- (b) in the case of fungible goods, are of fair average quality within the description; and
- (c) are fit for the ordinary purposes for which such goods are used; and
- (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
- (e) are adequately contained, packaged, and labeled as the agreement may require; and
- (f) conform to the promises or affirmations of fact made on the container or label if any.<sup>286</sup>

The same proof which establishes a defect for strict liability purposes, may also render a product unmerchantable.<sup>287</sup> Where a product is in a condition at the time of sale which is not contemplated by the ultimate consumer, and which causes the product to be unreasonably dangerous, it is both defective under Section 402A of the Restatement (Second) of Torts, Comment g (1965),<sup>288</sup> and unmerchantable.<sup>289</sup>

In determining whether DPT vaccine is defective or unmerchantable in a particular case, the initial inquiry is whether the vaccine manufacturer falls within the definition of a "merchant" under state law. A merchant is defined virtually the same under all state laws. The critical factor in the UCC definition as enacted in New Jersey is whether the seller "holds himself out as having knowledge or skill peculiar to the practices or goods involved in the transaction. . . ."<sup>290</sup> Pharmaceutical companies which develop, market

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N.J. Super. 356, 361 A.2d 578 (App. Div. 1976); *Reid*, 40 N.C. App. at 479, 253 S.E.2d at 347.

<sup>286</sup> N.J. STAT. ANN. § 12A:2-314(2) (1961). Two pre-UCC cases in New Jersey are consistent with N.J. STAT. ANN. § 12A:2-314(2) (1961): *Adams v. Peter Tramontin Motor Sales, Inc.*, 42 N.J. Super. 313, 126 A.2d 358 (App. Div. 1956) and *Mones v. Imperial Bottling Works*, 14 N.J. Misc. 369 (Ch. 1936).

<sup>287</sup> *Tinnerholm*, 285 F. Supp. at 444; *Matter of Cadillac V8-6-4 Class Action*, 93 N.J. 412, 427-28, 461 A.2d 736, 743 (1983). See also *Price v. Buckingham Mfg. Co.*, 110 N.J. Super. 462, 266 A.2d 140 (App. Div. 1970) (defect for strict liability purposes exists where an article is not reasonably fit for ordinary purposes for which the article is sold and used).

<sup>288</sup> See *Tinnerholm*, 285 F. Supp. at 444; J. White & R. Sommers, *HANDBOOK OF THE UNIFORM COMMERCIAL CODE* § 9-7 at 355 (2d ed. 1980).

<sup>289</sup> *Cadillac*, 93 N.J. at 427-28, 461 A.2d at 743.

<sup>290</sup> *Id.*

and sell vaccines, including DPT vaccine, are certainly merchants under the definition for the purposes of the implied warranty of merchantability.

Once it is established that the vaccine manufacturer is a merchant, a dual analysis of the product must be undertaken in relation to the seven-pronged merchantability test under the UCC. The first part of the analysis involves scrutinizing DPT vaccine in general terms, weighing its relative benefits and risks, and fixing its role in the reduction of pertussis mortality and morbidity. The secondary analysis is more specific—was the particular pertussis vaccine which allegedly caused the injuries merchantable?

Most pertussis vaccine researchers and the medical community at large believe that the benefits of pertussis vaccine far exceed its risks.<sup>291</sup> Despite debate prompted by Stewart and his colleagues,<sup>292</sup> the weight of opinion clearly favors the proposition that pertussis vaccine was the single most important factor in thwarting the onslaught of whooping cough.<sup>293</sup> Based on this favorable perception of pertussis vaccine, a challenge to the merchantability of DPT vaccine will be difficult to sustain. As long as the vaccine passes without objection in the drug industry and is not adulterated, but is of “fair average quality” and “adequately contained, packaged and labeled,” the product will be considered merchantable. If it is true that pertussis vaccine induces immunity from whooping cough in a high percentage of vaccinees without undue risk of damage, then pertussis vaccine is generally “fit for the ordinary purposes” for which the product is used.

Notwithstanding the weight of opinion regarding the benefits of DPT vaccine, the potential development of a safer and equally effective product casts doubt on whether the pertussis vaccine, as presently distributed, is truly merchantable. Although the technological know-how was available many years ago to develop a partially detoxified pertussis vaccine which was just as efficacious as the whole-cell

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<sup>291</sup> See *supra* notes 46-55 and accompanying text.

<sup>292</sup> Stewart, *supra* note 15.

<sup>293</sup> See Koplan, *supra* note 10, at 910. In discussing the risk-benefit assessment, Koplan predicted that

with a vaccination program in a cohort of one million, there would occur five cases of post-vaccination encephalitis and 0.1 cases of pertussis-associated encephalitis; without a program there would be 2.3 cases of pertussis-associated encephalitis. We predict 0.3 deaths from pertussis and 1.7 deaths from post-vaccination encephalitis with a vaccination program as compared with 7.6 deaths from pertussis without a vaccination program.

*Id.* at 909.

variety, the vaccine manufacturers, with the exception of Lilly, neglected to follow through with the necessary product development and marketing. Thus, while one manufacturer's DPT vaccine may "pass without objection in the trade," and be of "fair average quality" when compared to another manufacturer's vaccine, the standard vaccine of the industry itself when compared to the non-cellular or extracted vaccine, is unmerchantable.<sup>294</sup> However, because the merchantability test under the UCC primarily involves a comparison between the product actually sold and other similar products available for sale without considering the capability of the manufacturer to develop and sell a better product, there is no incentive for product improvement under the warranty theory. The development of a safer pertussis vaccine has been retarded by such a narrow interpretation of the concept of merchantability.<sup>295</sup> Thus, a definition of merchantability which is based only on a comparison among presently marketed products is a serious impediment to a claim founded on a breach of implied warranty of merchantability with regard to DPT vaccine.

A breach of the implied warranty of merchantability can be established if the injuries suffered in a specific case were caused by a DPT shot containing more than 12 mouse protection units. Because the minimum requirements of merchantability mandate that the product conform to the statements made on the labeling of the product, any lot of pertussis vaccine exceeding the standard 12 mouse protection units is unmerchantable. This is true since the label on every DPT vaccine bottle provides that the contents contain 12 mouse protection units per total immunizing dose. However, in order to recover for a breach of the implied warranty of merchantability, a plaintiff must still prove that the lack of

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<sup>294</sup> In *Tinnerholm*, 285 F. Supp. at 444-45, liability of a vaccine manufacturer was founded on a breach of warranty because the method of production increased the chance of contracting encephalitis by the vaccinee, and there were other safer alternative products on the market. *Id.*

<sup>295</sup> A narrow interpretation of the warranty of merchantability was not the only impediment to the development of a safer vaccine. As Monte Preiser, an attorney who represents children damaged by pertussis vaccine has stated:

The (DPT vaccine saga) is an indictment of the entire drug and vaccine related system of sales than any vaccine known to cause such serious damage could be permitted to remain on the market absent tests to determine its reactogenicity. This indictment falls squarely on the shoulders of not only the vaccine manufacturers but the Food and Drug Administration, the Center for Disease Control, the American Medical Association and the American Academy of Pediatrics.

Preiser, *Preparation of a DPT Vaccine Case*, TRIAL DIPLOMACY J., Spring 1984, at 10, 12.



merchantability was a substantial contributing factor in causing the damages suffered. At least one court has held that an increase in the risk of incurring an adverse reaction because of the method of production utilized in manufacturing the product can constitute a breach of implied warranty.<sup>296</sup> Thus, on the basis of the studies linking reactivity with increased pertussis vaccine potency, and other supporting evidence relating the shot to the injuries, a breach of the implied warranty of merchantability may be established if all the elements exist in a specific case.

### 3. Implied Warranty of Fitness for a Particular Purpose:

The UCC defines the implied warranty of fitness for a particular purpose as follows:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose.<sup>297</sup>

In a DPT vaccine case, the vaccine manufacturer as seller obviously has reason to know the particular purpose for which the product will be used at the time it is sold and distributed. In order to establish a breach of this warranty, the plaintiff must demonstrate that there was reliance on the manufacturer's skill or judgment in furnishing the product, and that the vaccine was not fit for its intended purpose.<sup>298</sup>

Under New Jersey law, a vaccine manufacturer may be liable for an allergic response to a product when an implied warranty of fitness for a particular purpose exists.<sup>299</sup> The fact that only a small proportion of product users would suffer injury does not preclude liability for a breach of warranty.<sup>300</sup>

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<sup>296</sup> *Tinnerholm*, 285 F. Supp. at 444.

<sup>297</sup> N.J. STAT. ANN. § 12A:2-315 (West 1961).

<sup>298</sup> See *Gumbs*, 718 F.2d at 93; *Ashland Oil, Inc. v. Miller Oil Purchasing Co.*, 678 F.2d 1293, 1314 (6th Cir. 1982); *Dugan v. Meyers Const. Co., Inc. v. Worthington Pump Corp.*, 746 F.2d 1166, 1175 (6th Cir. 1976); *Owens-Corning Fiberglass Corp. v. Sonic Dev. Corp.*, 546 F. Supp. 533, 540 (D. Kan. 1982); *International Petroleum*, 230 Kan. at 455, 639 P.2d at 33; *Kobeckis v. Budzko*, 225 A.2d 418, 420 (Me. 1967); *A-Leet Leasing Corp. v. Kingshead Corp.*, 150 N.J. Super. 384, 392, 375 A.2d 1208, 1211-12 (App. Div. 1977).

<sup>299</sup> *Feldman*, 97 N.J. at 447, 479 A.2d at 373.

<sup>300</sup> *Newmark v. Gimbel's*, 102 N.J. Super. 279, 289, 246 A.2d 11, 17 (App. Div. 1968), *aff'd*, 54 N.J. 585, 258 A.2d 697 (1969). Nothing was said about comment j of the RESTATEMENT (SECOND) OF TORTS, § 402A (1965), which states that a seller of "a product only has to warn about its allergic properties where a substantial

Other jurisdictions have not been as liberal as New Jersey, however, in permitting recovery when an allergic reaction occurs.<sup>301</sup> Some courts have held that breach of implied warranty arises only when the adverse effects of a drug ought reasonably to have been foreseen by a person of ordinary care in an appreciable number of cases,<sup>302</sup> or where a substantial percentage of users are at risk.<sup>303</sup> As one court has stated:

Courts have been extremely reluctant to permit recovery on the theory of warranty wherein hypersensitivity or allergy produces harmful results from an otherwise safe drug.<sup>304</sup>

If a pertussis vaccine recipient suffers an adverse reaction to a properly administered DPT shot, some jurisdictions would deny recovery under implied warranty unless the recipient showed that he or she was a member of a class of persons known to be at risk.

Because the words "appreciable" or "substantial" are not clearly defined by the courts, recovery may be limited in implied warranty cases to only those persons who are described in the manufacturer's literature as being susceptible to damage: those with a personal or family history of central nervous system disorder, or who have previously experienced a severe reaction to a DPT shot, or who are seven years of age or older. Since vaccine manufacturers have warned against use of the vaccine among members of those groups in the PDR and package inserts, an implied warranty claim may fail in those jurisdictions requiring the plaintiff to be a member of the described classes. Nevertheless, if the medical literature demonstrates that other persons are at risk, in addition to those de-

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number of the population is allergic to them, the ingredients' dangers are not generally known by users, or if known, are dangers that a user would not expect to find in the product." *Id.*

<sup>301</sup> *Chambers*, 441 F. Supp. at 380 (applying District of Columbia law); *Whittington v. Eli Lilly & Company*, 333 F. Supp. 98, 101 (S.D.W.V. 1971), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (applying West Virginia law); *Griggs v. Combe, Inc.*, 456 So.2d 790, 791-92 (Ala. 1984); *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 352, 353, 29 Cal. Rptr. 322, 329 (1963); *Howard v. Avon Prod., Inc.*, 155 Colo. 444, 447, 395 P.2d 1007, 1010 (1964); *O.M. Franklin Serum Co. v. C.A. Hoover & Son*, 437 S.W.2d 613, 618 (Tex. App. 1969) (*citing Cudmore v. Richardson-Merrill, Inc.*, 398 S.W.2d 640 (Tex. App. 1965), *rev'd*, 444 S.W.2d 596 (Tex. 1969); *Esborg v. Bailey Drug Co.*, 61 Wash.2d 347, 378 P.2d 298, 304 (1963)).

<sup>302</sup> *O.M. Franklin Serum Co.*, 437 S.W.2d at 618 (*citing Cudmore*, 398 S.W.2d at 640). *See also Esborg*, 61 Wash.2d at 353, 378 P.2d at 304.

<sup>303</sup> *Magee*, 214 Cal. App. 2d at 352-53, 29 Cal. Rptr. at 329. *See also Howard*, 155 Colo. at 447, 395 P.2d at 1010.

<sup>304</sup> *Whittington*, 333 F. Supp. at 101. *See also Chambers*, 441 F. Supp. at 380 (*citing Whittington*, 333 F. Supp. at 101, and distinguishing the vaccine in *Tinnerholm*, 285 F. Supp. at 445, on the grounds of its impurity); *Griggs*, 456 So.2d at 791-92.

scribed by the manufacturer in its literature, a vaccine manufacturer may be liable under the theory of implied warranty if the product is unfit for immunization purposes.

#### IV. LIABILITY OF PHYSICIANS ADMINISTERING DPT VACCINE

##### A. *Informed Consent*

The doctrine of informed consent in most jurisdictions, including New Jersey, "is a negligence concept predicated on the duty of a physician to disclose to a patient information that will enable him to 'evaluate knowledgeably the options available and the risks attendant upon each' before subjecting that patient to a course of treatment."<sup>305</sup>

A patient has a right to forego a medical procedure if he believes it to be too dangerous even though, from a medical viewpoint, the benefits appear to outweigh the risks.<sup>306</sup> Without sufficient information about the benefits and risks, the patient cannot make a meaningful choice.<sup>307</sup>

There are three basic prerequisites for informed consent: the patient must have the capacity to reason and make judgments,<sup>308</sup> the decision must be made voluntarily and without coercion, and the patient must have a clear understanding of the risks and benefits of the proposed treatment alternatives or nontreatment, along with a full understanding of the nature of the disease and the prognosis.<sup>309</sup>

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<sup>305</sup> *Perna v. Pirozzi*, 92 N.J. 446, 459, 457 A.2d 431, 438 (1983) (quoting *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972)). Accord *Harnish v. Children's Hosp. Medical Center*, 387 Mass. 152, 153-54, 439 N.E.2d 240, 242-43 (1982); *Doerr v. Movius*, 154 Mont. 346, 347, 463 P.2d 477, 478 (1970); *Skripek v. Bergamo*, 200 N.J. Super. 620, 633, 491 A.2d 1336, 1343 (App. Div. 1985); *Calabrese*, 162 N.J. Super. at 156, 392 A.2d at 606; *Kaplan v. Haines*, 96 N.J. Super. 242, 255-58, 232 A.2d 840, 846-49 (App. Div. 1967), aff'd, 51 N.J. 404 (1968); *Petterson v. Lynch*, 59 Misc. 2d 469, 470, 299 N.Y.S. 2d 244, 245 (Sup. Ct. 1969).

<sup>306</sup> *Canterbury*, 464 F.2d at 780; *Harnish*, 387 Mass. at 153, 439 N.E.2d at 242; *Wilkinson v. Vesey*, 110 R.I. 606, 619, 295 A.2d 676, 685 (R.I. 1972); *Anderson v. Hooker*, 420 S.W.2d 235, 238 (Tex. App. 1967).

<sup>307</sup> *Canterbury*, 464 F.2d at 780; *Harnish*, 387 Mass. at 153, 439 N.E.2d at 242; *Negaard v. Estate of Feda*, 152 Mont. 47, 51, 446 P.2d 436, 441 (1968); *Matter of Conroy*, 98 N.J. 321, 347, 486 A.2d 1209, 1222 (1985); *Anderson*, 420 S.W.2d at 238.

<sup>308</sup> If the patient is incompetent, the consent must be obtained from someone legally authorized to give it for him. See NEW JERSEY MODEL JURY CHARGES-CIVIL, *Informed Consent*, at 217. In the case of an infant, a parent's informed consent is necessary. *Younts v. St. Francis Hospital & School of Nursing, Inc.*, 205 Kan. 292, 299, 469 P.2d 330, 337 (1970).

<sup>309</sup> *Conroy*, 98 N.J. at 347, 486 A.2d at 1222 (quoting Wunzer, *The Physician's Re-*

In an informed consent case, the patient must prove that the doctor withheld pertinent information concerning the risks of the procedure or treatment, the alternatives, or the potential results if the procedure or treatment was not undertaken.<sup>310</sup> Exactly what information a doctor must disclose to the patient depends upon what would be disclosed by the average qualified physician in the community or, in the case of a specialty, by the average qualified specialist.<sup>311</sup> Only information which is deemed material to the decision-making process by the average qualified physician or specialist need be given to the patient.<sup>312</sup>

In New Jersey, as in most jurisdictions, expert testimony is required to demonstrate what information is considered to be material to the patient's decision,<sup>313</sup> unless the dangers are so obvious that no expert testimony is needed to prove that the failure to warn constituted negligence.<sup>314</sup> Other jurisdictions, however, do not mandate expert testimony as to materiality, believing that what constitutes sufficient information is within the ken of laymen.<sup>315</sup>

Under the minority rule, since it is the patient's needs against which the scope of the doctor's disclosures are tested, all informa-

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*sponsibility Toward Hopelessly Ill Patients*, 310 NEW ENG. J. MED. 955, 957 (1984)). See also *Perna*, 92 N.J. at 460, 457 A.2d at 438-39; *P. v. Portadin*, 179 N.J. Super. 465, 472, 432 A.2d 556, 562 (App. Div. 1981).

<sup>310</sup> *Perna*, 92 N.J. at 460, 457 A.2d at 438 (citing *Canterbury*, 464 F.2d at 787-88); accord, *Skripek*, 200 N.J. Super. at 633, 491 A.2d at 1343.

<sup>311</sup> *Canterbury*, 464 F.2d at 783; *DiFilippo v. Preston*, 53 Del. 539, 553, 173 A.2d 333, 339 (1961); *Harnish*, 387 Mass. at 153, 439 N.E.2d at 242; *Roberts v. Young*, 369 Mich. 133, 140, 119 N.W.2d 627, 630 (1963); *Ross v. Hodges*, 234 So.2d 905, 909 (Miss. 1970); *Negaard*, 152 Mont. at 51, 446 P.2d at 441; *Perna*, 92 N.J. at 460 n.2, 457 A.2d at 438, n.2; *Kaplan*, 96 N.J. Super. at 257, 232 A.2d at 847; *Anderson*, 420 S.W.2d at 238; *Watkins v. Parpala*, 2 Wash. App. 484, 489, 469 P.2d 974, 979 (Wash. App. 1970). Other jurisdictions judge the adequacy of disclosure under what is called a "reasonable prudent medical practitioner" standard. *Nathanson v. Kline*, 187 Kan. 186, 190, 354 P.2d 670, 673 (Kan. 1960).

<sup>312</sup> *Harnish*, 387 Mass. at 154, 439 N.E.2d at 243.

<sup>313</sup> *Rosenberg v. Cahill*, 99 N.J. 318, 325, 492 A.2d 371, 377 (1985); *Sanzari v. Rosenfeld*, 34 N.J. 128, 134-35, 167 A.2d 625, 628 (1961); *Maslonka v. Hermann*, 173 N.J. Super. 566, 573, 414 A.2d 1350, 1353-54 (App. Div. 1980), *rev'd on other grounds*, 85 N.J. 533 (1981); *Calabrese*, 162 N.J. Super. at 156-57, 392 A.2d at 606; *Kaplan*, 96 N.J. Super. at 257, 232 A.2d at 848.

<sup>314</sup> *Nathanson*, 187 Kan. at 190, 354 P.2d at 673; *Mitchell v. Robinson*, 334 S.W.2d 11, 14 (Mo. 1960); *Rosenberg*, 99 N.J. at 325, 492 A.2d at 377; *Govin v. Hunter*, 374 P.2d 421, 424 (Wyo. 1962).

<sup>315</sup> *Harnish*, 387 Mass. at 154, 439 N.E.2d at 243-44. But see *Nathanson*, 187 Kan. at 190, 354 P.2d at 673 (stating that whether any disclosures were made is question of fact which may be the subject of lay testimony, but that once the nature of the disclosure is known, expert testimony must be produced to show a deviation from standard medical care); *Watkins*, 2 Wash. App. at 484, 469 P.2d at 974 (stating that expert testimony is necessary unless disclosure would obviously have been made).

tion which would be viewed by the patient as material to the decision regarding treatment must be divulged. Thus, competent lay testimony about materiality of risks would be relevant to determine whether the physician acted reasonably in his disclosures in view of what he knows or should know to be the patient's informational needs.<sup>316</sup>

A plaintiff seeking to recover under the informed consent doctrine not only must show that the doctor's failure to disclose the information deviated from accepted standards of medical care, but also that this deviation was a proximate cause of the injuries suffered.<sup>317</sup> If the plaintiff would have consented to the proposed treatment even with full disclosure, the plaintiff will be unable to sustain the burden of proving causation.<sup>318</sup>

There is a split of authority regarding the test to be applied in establishing proximate cause. In New Jersey, one appellate court has adopted a subjective standard holding that the plaintiff must prove only that he or she would have refused the treatment or procedure.<sup>319</sup> An earlier appellate court decision adopted the majority rule, an objective standard, requiring the plaintiff to prove not only the subjective standard, but also that a reasonably prudent person in the plaintiff's situation would have refused the treatment or procedure.<sup>320</sup>

If the doctor fails to disclose any of the known and existing risks associated with the proposed treatment or procedure which would affect the patient's decision, and these risks are demonstrated by the patient through expert testimony, (or in a minority of jurisdictions by competent lay testimony), the burden in New Jersey shifts to the

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<sup>316</sup> *Canterbury*, 464 F.2d at 786-87, 792; *Harnish*, 387 Mass. at 154, 439 N.E.2d at 243.

<sup>317</sup> *Nathanson*, 187 Kan. at 190, 354 P.2d at 673; *Skripek*, 200 N.J. Super. at 633-34, 491 A.2d at 1343.

<sup>318</sup> *Karp v. Cooley*, 493 F.2d 408, 422 (5th Cir.), *cert. denied*, 419 U.S. 845 (1974); *Canterbury*, 464 F.2d at 790; *Sard v. Hardy*, 281 Md. 432, 447, 379 A.2d 1014, 1024 (1977); *Skripek*, 200 N.J. Super. at 634, 491 A.2d at 1344.

<sup>319</sup> *Conroy*, 98 N.J. at 347, 486 A.2d at 1222; *Skripek*, 200 N.J. Super. at 630, 491 A.2d at 1342. *See also* *Cunningham v. United States*, 683 F.2d 847, 849 (4th Cir. 1982); *Canterbury*, 464 F.2d at 790-91; *Percle v. St. Paul Fire & Marine Ins. Co.*, 349 So.2d 1289, 1300-01 (La. App. 1977), *writ denied*, 350 So.2d 1218 (La. 1977); *Harnish*, 387 Mass. at 157, 439 N.E.2d at 244; *Cornfeldt v. Tongen*, 262 N.W.2d 684, 701 (Minn. 1977), *on remand*, 295 N.W.2d 638 (Minn. 1980); *Gerety v. Demers*, 92 N.M. 396, 410-11, 589 P.2d 180, 194-95 (N.M. 1978).

<sup>320</sup> *Skripek*, 200 N.J. Super. at 630, 491 A.2d 1342, *See also* *Scott v. Bradford*, 606 P.2d 554, 558-59 (Okla. 1980) (applying the subjective test for proximate cause effectively creating strict liability once the deviation from medical standards is established.).

physician to prove by expert testimony that his or her silence conformed with acceptable medical practice.<sup>321</sup> In other jurisdictions, this silence, if consistent with medical standards accepted within the community, is termed the physician's privilege of non-disclosure.<sup>322</sup>

The doctor who inoculates the infant can only transmit to the parents information of which he or she knows either by independent research or through warnings or other information supplied by the vaccine manufacturer. If insufficient information is presented to the doctor by the manufacturer, a cause of action premised on a failure to warn theory may exist against the manufacturer. For the purposes of this discussion, however, it is assumed that the warnings and contraindications stated in the manufacturer's advertisements, package inserts and other forms of communication to the prescribing physician are adequate. Hence, in New Jersey, the issues in an informed consent DPT vaccine case where the manufacturer's warnings are proper, include the following:

(1) Did the physician advise the parents of the infant about the relative risks and benefits of pertussis vaccine prior to immunization?

(2) How much information about the nature and cause of adverse reactions did the doctor pass along to the parents?

(3) Did the physician comport with the prevailing medical standards in the community, or act as a reasonably prudent medical practitioner, in disclosing the information which was given to the parents? Or stated another way, did the doctor deviate from accepted standard medical practice when he disclosed only a part of the information concerning the risk-benefit analysis?

(4) Would a reasonably prudent parent have decided to forego, temporarily or permanently, the child's immunization if he or she possessed the material information about the vaccine which was not disclosed by the doctor?

(5) Were the infant's injuries causally related to the DPT vaccine?

Most of the foregoing issues are factually determinative and can only be decided on an individualized basis depending upon the exact nature and extent of the disclosures made by the administering

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<sup>321</sup> *Calabrese*, 162 N.J. Super. at 156-57, 392 A.2d at 606. See also *Canterbury*, 464 F.2d at 791-92; *Lopez v. Sywer*, 115 N.J. Super. 237, 251 (App. Div. 1971) (silence may be regarded presumptively as constructive misrepresentation); *Kaplan*, 96 N.J. Super. at 252, 232 A.2d at 844.

<sup>322</sup> See *Canterbury*, 464 F.2d at 787, 791; *Harnish*, 387 Mass. at 153, 439 N.E.2d at 244.

physician. Thereafter, the legal issues of whether the disclosures were in accordance with the physician's standard of care must be confronted.

In applying the standard of care against which the physician's disclosures must be tested to determine their adequacy for informed consent purposes, it is always important to consider what a reasonably prudent parent would believe is material in deciding to have his or her child submit to, or forego, inoculation with pertussis vaccine. Thus, even though in New Jersey a physician must disclose all material information which a reasonably prudent physician in the community would have disclosed under similar circumstances, this standard is intertwined with what a reasonably prudent parent would perceive is material to the immunization decision without the benefit of hindsight.

There is no clearcut answer to what constitutes material disclosures. However, it is certain that complete silence about the detrimental characteristics of pertussis vaccine does not comply with the doctor's standard of care. How much disclosure is necessary is a jury question. As at least one court has stated:

A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefit of the therapy or the detriments of the existing malady may summon discussion with the patient.<sup>323</sup>

The medical literature has documented that pertussis vaccine has been associated with severe adverse reactions, including death, encephalopathy, convulsions with and without fever, and other neurological sequelae. Disputes have persisted among researchers and physicians over the percentage of infants affected by the vaccine, and the role of the vaccine itself in controlling whooping cough. It is not suggested that an administering physician must advise the parents about all the benefits and risks of pertussis vaccine, or about every possible pitfall which might be faced. Nevertheless, there are certain facts of which a reasonably prudent parent would consider to be pertinent in balancing the risks and benefits of immunization, and which a reasonably prudent practitioner should disclose prior to inoculation.

Table V incorporates information which a reasonably prudent parent would consider to be material in deciding whether or when

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<sup>323</sup> *Hitchcock v. United States*, 479 F. Supp. 65, 79 (D.D.C. 1979), *aff'd*, 665 F.2d 354 (D.C. Cir. 1981) (citing *Canterbury*, 464 F.2d at 788) (discussing rabies vaccine).

his or her child should receive the "P" portion of the shot.<sup>324</sup> This information should be disclosed verbally by the pediatrician to the parent prior to inoculation, and a dialogue between the parent and physician should be encouraged. The interaction between parent and physician will serve to assist the parent in understanding the facts about DPT vaccine and in making a meaningful decision about immunization.

The Important Information Form used in the public immunization clinics is intended to insure material disclosure and informed consent. Such a form can be used in the private sphere in conjunction with the verbal disclosure, but should not be relied upon as the sole means of educating the parents.

#### *B. Wrongful Immunization*

Wrongful immunization is a negligent breach of duty by the physician which occurs when a DPT vaccine shot is given despite the presence of contraindications generally accepted by the medical community. Like other medical malpractice actions, it is bottomed on a deviation from standard medical care by physicians practicing the particular specialty in the community.<sup>325</sup>

In New Jersey, medical malpractice occurs when a doctor fails to exercise the degree of medical care, knowledge and skill ordinarily possessed and exercised in similar situations by the average practitioner in the field.<sup>326</sup> If the physician is a specialist, the test for malpractice is whether the doctor exercised a special degree of skill normally possessed by the average specialist having regard to the present state of scientific knowledge.<sup>327</sup> A doctor who complies with the applicable standard of care is not liable for an honest mistake in judgment.<sup>328</sup>

A wrongful immunization action and a claim against a vac-

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<sup>324</sup> See *infra* Table V of Appendix

<sup>325</sup> No reported cases appear to discuss "wrongful immunization." However, where a doctor gives a shot to a child who should not be immunized, a medical malpractice action may be viable.

<sup>326</sup> *Walck v. Johns-Manville Prod. Corp.*, 56 N.J. 533, 560, 267 A.2d 508, 523 (1970) (doctor); *Germann v. Matriss*, 55 N.J. 193, 208, 260 A.2d 825, 833 (1970) (dentist). See also *Caron v. United States*, 548 F.2d 366, 370 (1st Cir. 1976), *aff'd*, 410 F. Supp. 378 (D.R.I. 1976); *Malone v. Univ. of Kansas Medical Center*, 220 Kan. 371, 373, 552 P.2d 885, 888 (1976); *Brown v. Colm*, 11 Cal. 3d 639, 640, 522 P.2d 688, 689, 114 Cal. Rptr. 128, 129 (1974).

<sup>327</sup> *Clark v. Wichman*, 72 N.J. Super. 486, 493, 179 A.2d 38, 42 (App. Div. 1962); *Coleman v. Wilson*, 85 N.J.L. 203, 207, 88 A. 1059, 1060 (E. & A. 1913).

<sup>328</sup> *Scheuler v. Strelinger*, 43 N.J. 330, 344-45, 204 A.2d 577, 584-85 (1964). *Accord*, *Walck*, 56 N.J. at 562, 267 A.2d at 524.



cine manufacturer for failure to warn about the dangerous propensities of the product or its contraindications are at opposite ends of the liability spectrum. If a vaccine manufacturer discloses all pertinent information concerning the vaccine to the doctor, warns about its adverse effects, and properly explains the vaccine's contraindications, the administering pediatrician has no safety hatch to escape liability if he inoculates the infant despite the presence of contraindications. Conversely, the doctor cannot be held responsible for a child's adverse reaction if the vaccine manufacturer fails to properly warn or disclose all material information to the physician about the product.

The 1986 PDR lists contraindications to Lederle's product, Tri-Immunol, presently the only commercially distributed DPT vaccine on the market. These contraindications have been discussed previously, and will be repeated at this juncture only for the sake of clarity.

Deferral during acute illness; any neurological symptoms or signs; convulsions; personal or family history of central nervous system disorder; the presence of any evolving or changing disorder affecting the central nervous system; encephalitis; collapse or shock; excessive somnolence or severe alterations of consciousness; excessive screaming or crying (three or more hours); temperature over 105 degrees F.; systemic allergic reactions; hypersensitivity to vaccine components; history of previous serious reaction.<sup>329</sup>

The list of contraindications includes Lederle's own recommendations, as well as the contraindications promulgated by the Red Book Committee and the ACIP.

Failure of an administering physician to follow the PDR's contraindications in 1986 is certainly strong evidence in a wrongful immunization case where the cause of action arose after the 1986 PDR was published. However, the 1986 list differs in varying respects from contraindications published in years past, and incorporates more comprehensive information than heretofore disclosed. Thus, depending upon when the immunization occurs, the standard of care must be analyzed concurrently and without the benefit of hindsight. Only recently have the Red Book Committee and the ACIP expanded the contraindications to pertussis vaccine. A doctor who immunized a child in the face of a contraindication which was not generally accepted or followed by the medical community at that

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<sup>329</sup> See Physician's Desk Reference, (E. R. Barnhart, Pub., 1986) Tri-Immunol, Lederle Laboratories, at 1032.

time, but only subsequently became accepted or followed, will not be liable on a wrongful immunization theory.

The more difficult question in deciding whether a physician is liable for medical malpractice involves factual circumstances which may spark heated debate among practitioners. The following are illustrative scenarios which would promote different opinions among medical communities in the United States or abroad.

1. A child is born prematurely and with a collapsed lung, but is discharged from the hospital seven days after birth in good condition. At age two months, he weighs six pounds. Should the pediatrician follow the recommendations of the Red Book Committee and the ACIP and give the child his first DPT shot at age two months even though the child weighs only six pounds and had a history of premature birth with a collapsed lung?

2. A child experienced a fever of 104 degrees F. within hours after her first DPT shot. The day after the shot, she broke out in a severe red rash over her entire body which lasted for two weeks. The doctor could not find an etiology for the rash. Should the pediatrician administer the second DPT shot or remove the "P" portion and give only DT?

3. A child who had two DPT shots with the only adverse reaction each time being lethargy for about 24 hours after the shot. Before the third shot, the mother advises the doctor that she just recently learned that she, the mother, suffered a convulsion following pertussis vaccine when she was a child without permanent damage. Should the pediatrician administer the third DPT shot?

The foregoing examples are simplistic, but they illustrate that the solutions to these dilemmas are not easy. Nevertheless, the actions of the pediatricians in each instance must be tested in view of all of the pertinent facts and the prevailing community medical standards. As in most medical malpractice issues, expert testimony is essential,<sup>330</sup> although unanimity among expert practitioners will never be reached.

## V. CONCLUSION

The continued use of DPT vaccine in its present form is a

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<sup>330</sup> For New Jersey cases, see *supra* notes 243-56 and accompanying text. See also *In re Katsetos*, 170 Conn. 637, 644-45, 368 A.2d 172, 177-78 (Conn. 1976); *Slack v. Moorehead*, 152 Ga. App. 68, 70, 262 S.E.2d 186, 188 (Ga. App. 1979); *Eckley v. St. Therese Hosp.*, 62 Ill. App. 3d 299, 304, 379 N.E.2d 306, 310-11 (Ill. App. 1978); *Reinhardt v. Colton*, 337 N.W.2d 88, 95 (Minn. 1983); *Vassos v. Roussalis*, 658 P.2d 1284, 1288 (Wyo. 1983).

controversial issue. Adverse reactions triggered by pertussis vaccine are often severe with permanently damaging effects. The number of children actually injured by pertussis vaccine has been disputed by the proponents and critics of the vaccine. Moreover, the role of widescale pertussis immunization in the reduction of whooping cough since the 1940s has been questioned, despite strong governmental support for public vaccination programs.

Studies have demonstrated that whole-cell pertussis vaccine contains toxins which cause serious neurological side-effects. For over 30 years, purification processes have been described in the literature. During these processes, some of the toxicity of the bacterial cell was removed. Studies have shown the continued efficacy of a detoxified vaccine.

Despite the availability of production methods for a safer extracted or non-cellular pertussis vaccine, pharmaceutical companies, with the exception of Lilly, continued to manufacture and distribute the more dangerous whole-cell pertussis vaccine. Recent efforts to refine techniques in developing a safer pertussis vaccine, similar to the vaccine used in Japan, are long overdue. These efforts have been accelerated by the adverse publicity about pertussis vaccine and the growing concern about the questionable integrity of the pharmaceutical companies in marketing a product which could have been made safer many years ago.

Criticism has also been directed at the pharmaceutical companies for their lack of commitment in educating the public and the doctors about the risks associated with the vaccine. Over the years, the failure to provide timely and descriptive warnings and contraindications regarding pertussis immunization have caused many unnecessary vaccine-induced injuries which could have been avoided by appropriate disclosures.

Liability theories against both vaccine manufacturers and physicians who administer the vaccine have been discussed herein. The success or failure of a plaintiff's theory of liability will rest largely on the weight accorded the divergent opinions about pertussis vaccine. If the publications of Stewart, Ehrengut and Strom correctly state the risk-benefit ratio of pertussis vaccine, a solid foundation for liability exists under any theory.

Most neurological symptoms occur in infants about the same time the series of DPT vaccine inoculations are given.<sup>331</sup> Thus, a plaintiff must be prepared to rebut the defense that the shot was

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<sup>331</sup> See Miller, *supra* note 9, at 1595; Miller, *supra* note 10, at 511.

purely coincidental to the injuries suffered. If an underlying neurological disease of unknown etiology was a contributing element in the adverse reaction precipitated by the vaccine, this fact alone will not preclude the imposition of liability as long as the vaccine itself was a substantial contributing factor. The burden of establishing causation rests with the plaintiff. Despite the publications which document the relationship between pertussis vaccine and neurological damage in general terms, this burden can be insurmountable in a specific case unless strong circumstantial evidence exists to demonstrate that a normal infant without any prior history of neurological symptoms or disease, suffered injuries as a direct result of the administration of the vaccine.

There is presently a nationwide fear that pertussis vaccine is in short supply. Because of the absence in the market of previous producers, official medical groups have asked physicians to conserve supplies and delay giving booster shots. According to the pharmaceutical companies, they cannot survive in the market because of the existing DPT litigation which purportedly squeezed an already tight profit margin.

The drug companies contend that the solution to the problem is federal legislation which would foist the payment of compensatory damages on the federal government. The vaccine manufacturers assert that absolving them from paying monetary damages will result in channelling revenue into the development of a safer vaccine.

The opponents of federal legislation precluding manufacturer's liability accept the need for governmental compensation as a supplemental measure, but believe that the statute should not affect the existing theories of liability against the drug companies. By preserving legal remedies, critics insist that pharmaceutical companies will try harder to develop a safer product. They believe that pharmaceutical companies can maintain and even increase their profit margins by passing on the cost of research and development to the consumer via an increase in the purchase price of pertussis vaccine. Some vaccine critics feel that the vaccine producers have purposely created the shortage to stir up public support for the federal compensation program in an attempt to avoid liability for vaccine-induced injuries.<sup>332</sup>

Amidst the legal controversy surrounding DPT vaccine,

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<sup>332</sup> See *supra* note 175 and accompanying text (discussion of National Childhood Vaccine Injury Act of 1986).

unanimous support exists for the development of a safer vaccine. While research and testing are ongoing, several other issues must be addressed to educate parents and pediatricians about the potency of the pertussis vaccine, and to vest in parents more knowledgeable discretion in immunization decisions.

To accomplish these aims, the mouse potency test must be re-evaluated and improved, federal regulations concerning labeling must be revised to mandate disclosure of the actual number of mouse protection units in the vaccine bottle rather than the hypothetical 12 mouse protection units, and state statutes and regulations must be revamped to permit school enrollment without requiring pertussis immunization.

It is hoped that the future development of a safer vaccine, coupled with regulatory modifications, will minimize and possibly eradicate severe adverse reactions to pertussis vaccine, and educate all those individuals who play a part in immunization decisions.

## VI. APPENDIX

TABLE I  
RISKS OF NEUROPATHIES FOLLOWING PERTUSSIS  
IMMUNIZATION

<u>STUDY/AUTHOR</u>	<u>STUDY LOCATION</u>	<u>STUDY PERIOD/ DATE OF PUBLICATION</u>	<u>RISK OF NEUROPATHIES</u>
Baraff <sup>a</sup>	U.S.	1977-1979	1:1,750 convulsions per immunization; 1:1,750 hypotonic hypo responsive episodes per immunization; no evidence of encephalopathy or permanent brain damage.
British Childhood Encephalopathy Study <sup>b</sup>	UK	1977	1:110,000 neurological illnesses per immunization; 1:310,000 permanent brain damage per immunization.
Ehrengut <sup>c</sup>	West Germany	1974	1:2,200 convulsions per immunized child.
Dick <sup>d</sup>	UK	1974	1:10,000 permanent brain damage per immunized child.
Griffith <sup>e</sup>	UK	1964-1977	1:800,000 convulsions per immunization.
Hannik <sup>f</sup>	Holland	1976-1978	1:2,750 convulsions per immunized child.
Hannik <sup>g</sup>	Holland	1974	1:500,000 deaths and neurological residua per immunized child.
Medical Research Council <sup>h</sup>	UK	1956	1:11,000 convulsions per immunization.
Miller <sup>i</sup>	UK	1976-1979	1:110,000 serious neurological disorders per immunization within 7 days; 1:310,000 neurological sequelae per immunization one year post-immunization.
Redbook Committee <sup>j</sup>	U.S.	1982	1:100,000 permanent brain damage per immunized child.
Stewart <sup>k</sup>	UK	1968-1972	1:54,000 encephalopathies per immunized child.

Stewart <sup>l</sup>	UK	1957-1976	1:10,000-1:50,000 permanent brain damage per immunized child.
Strom <sup>m</sup>	Sweden	1955-1958	1:6,000 neurological complications per immunized child; 1:17,000 deaths and encephalopathies per immunized child.
Strom <sup>n</sup>	Sweden	1959-1965	1:3,600 convulsions, shock, meningal involvement per immunized child; 1:9,500 shock per immunized child; 1:6,500 convulsions per immunized child.

## NOTES

- a. Baraff, *supra* note 49, at 20.
- b. Joint Committee on Vaccination and Immunization: Whooping Cough Vaccination: Review of the Evidence on Whooping Cough by the Joint Committee on Vaccination and Immunization 1977; DHSS London: Her Majesty's Stationery Office, 1977.
- c. Ehrengut, Convulsive Reactions After Pertussis Immunization, *Dtsch. Med. Wochensh.* 99:2273 (1974).
- d. Dick, *supra* note 14.
- e. Griffith, *Reactions After Pertussis Vaccine: A Manufacturer's Experience and Difficulties Since 1964*, 1 *BRIT. MED. J.* 809 (1978).
- f. Manclark, *International Symposium on Pertussis*, Dept. of Health, Education and Welfare, Pub. No. 79-1830, U.S. Gov't Printing Office at 279-82 (1979) (citing Hannik, *Pertussis Vaccine Experience in the Netherlands*).
- g. Report on an Informal Consultation on Immunization Against Whooping Cough. WHO. 1974; 75.1:1-34.
- h. A Report to the Whooping Cough Immunization Committee of the Medical Research Council and to the Medical Officers of Health for Cardiff, Leeds, Leyton, Manchester, Middlesex, Oxford, Poole, Tottenham, Walthamston and Wembley. *Vaccination Against Whooping Cough. Relation between protection in children and results of laboratory tests.* 2 *BRIT. MED. J.* 454 (1956).
- i. Miller, *supra* note 9.
- j. Fulginiti, *supra* note 5.
- k. Stewart *supra* note 14.
- l. Stewart *supra* note 27.
- m. Strom, *Universal Vaccinations*, *supra* note 9.
- n. Strom, *supra* note 9.

TABLE II  
ESTIMATION BY GORDON T. STEWART, M.D. OF  
PERTUSSIS-RELATED AND DPT-RELATED  
NEUROPATHIES

<u>NEUROPATHIES</u>	<u>AVERAGE RATIO</u>
Permanent brain damage caused by pertussis	1:300,000 children.
Permanent brain damage after DPT vaccine	Between 1:17,000 and 1:178,000 children.
Death caused by pertussis vaccine	Between 1:12,600 and 1:130,000 children.
Death after pertussis vaccine	1:100,000 children.
Neurotoxic reactions	Between 1:750 and 1:3,000 children.
Systemic reactions	Between 1:2 and 1:10 children.

TABLE III  
PERTUSSIS REACTION SYNDROME

1. Persistent crying and/or screaming between 4 and 48 hours after immunization.
2. Marble pallor, rigidity, unresponsiveness, shock of sudden onset within 48 hours and usually between 6 and 12 hours after immunization.
3. Irritability and interrupted sleep for a few days or longer.
4. Refusal or vomiting of feeds.
5. Altered response to parents.
6. Paresis or localized paralysis.
7. Convulsions.
8. Hyperkinesis.
9. Infantile spasms extending into convulsions or epilepsy.
10. Progressive unresponsiveness to parents.
11. Flaccid paralysis.
12. Partial or complete amentia.



TABLE IV  
DPT/DT REACTIONS IN BARAFF — UCLA STUDY:  
PERCENTAGES OF CHILDREN AFFECTED PER  
VACCINATION

<u>REACTION</u>	<u>VACCINE</u>	<u>PERCENTAGE</u>
Local redness	DPT	37.4 percent
" "	DT	7.6 percent
Local swelling	DPT	40.7 percent
" "	DT	7.6 percent
Pain	DPT	50.9 percent
"	DT	9.9 percent
Fever	DPT	31.5 percent
"	DT	14.9 percent
Drowsiness	DPT	31.5 percent
"	DT	14.9 percent
Fretfulness	DPT	53.4 percent
"	DT	22.6 percent
Vomiting	DPT	6.2 percent
"	DT	2.6 percent
Anorexia	DPT	20.9 percent
"	DT	7.0 percent
Persistent crying	DPT	3.1 percent
" "	DT	.7 percent

TABLE V  
PERTUSSIS — THE DISEASE

- Highly communicable
- Two-thirds of all reported cases occur in children under one year of age.
- Only ten disease-related deaths have been reported in the last ten years during the period of widespread vaccine usage.

ADVERSE REACTIONS

- Deaths, encephalitis, convulsions, somnolence, collapse, excessive screaming or crying, fever of 105°F.
- Usually occur within 48 hours post-injection, but can occur up until a week after inoculation.
- Dispute as to frequency of adverse reactions; estimates of permanent brain damage range from 1:100,000 in the U.S. to 1:10,000 in Great Britain.
- Some observers have associated pertussis vaccine with Sudden Infant Death Syndrome but official medical authorities have not found a definite link.

CONTRAINDICATIONS

- Acute illness.
- Personal or family history of central nervous system disorder.
- Prior adverse reaction following a DPT shot.

OPTIONS

- Only a DT inoculation.
- Deferral of "P" portion until older.
- Great Britain and Japan have reported pertussis epidemics following a decline in pertussis vaccine usage.
- State law requires full pertussis immunization in virtually all cases prior to enrollment in school.