No. 10-1524

IN THE SUPREME COURT OF THE UNITED STATES

April Term 2010

Dan Cooks, *et al.*

Petitioners

-V-

Carolina Laboratories, Inc.

Respondent

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

BRIEF FOR RESPONDENT

ORAL ARGUMENT REQUESTED

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QUESTIONS PRESENTED

I. Whether the appellate court erred in holding that the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 to -34 (2006), does not preempt state products liability suits for design defects.

II. Whether the appellate court correctly applied the *Bell Atlantic Corporation v. Twombly* pleading standard when it granted Respondent's Federal Rule of Civil Procedure 12(b)(6) Motion to Dismiss.

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STATEMENT OF THE CASE

A. Nature of the Case

Petitioners, Dan and LoEtta Cooks ("Cooks"), appeal the judgment of the United States Court of Appeals for the Thirteenth Circuit, which affirmed the lower court's dismissal of Cooks' claim for failing to plead facts sufficient to support a finding of proximate cause for defective design. Cooks filed Grace state law negligence and design defect claims asserting that their twelve-year-old daughter, Estella Marie Cooks ("Estella Marie") suffered side effects caused by three doses of a vaccine she received containing the preservative thimerosal. Respondent, Carolina Laboratories, Inc. ("Carolina"), produced the vaccines in question. Cooks contended that the National Childhood Vaccine Injury Act of 1986 (the "Act") did not preempt their state law design defect claims, because Estella Marie's side effects could have been avoided if the vaccine had contained a preservative other than thimerosal.

Two issues are before the Court in this case: first, whether the Act preempted Cooks' Grace state law design defect claims, and second, whether the Thirteenth Circuit properly applied the pleading standard in dismissing Cooks' complaint for failure to state a claim. Carolina respectfully requests that this Court reverse the Thirteenth Circuit's holding that the Act did not preempt Cooks' design defect claims. Carolina further requests that this Court affirm the Thirteenth Circuit's dismissal of the design defect claims, because the Cooks did not plead facts sufficient to warrant findings of negligence and strict liability against Carolina.

B. Course of Proceedings and Disposition in the Courts Below

On September 3, 2001, Cooks filed a petition for compensation with the National Vaccine Injury Compensation Program ("Vaccine Court") for Estella Marie's injuries, pursuant to 42 U.S.C. § 300aa-1. (R. at 1-2.) The Vaccine Court gave Cooks the choice either to (a) accept compensation under the Act, surrendering their tort rights, or (b) reject the judgment and pursue

tort damages in state or federal court. (R. at 2.) On November 5, 2003, Cooks withdrew their petition with the Vaccine Court, pursuant to 42 U.S.C. § 300aa-11(a)(2)(A). (R. at 2.) On January 14, 2004, the Clerk of the United States Court of Federal Claims entered a judgment of withdrawal, pursuant to 42 U.S.C. § 300aa-21(b). (R. at 2.)

On January 21, 2004, Cooks filed a civil action in the Wicked County Court of Common Pleas in the State of Grace for damages, pursuant to 42 U.S.C. § 300aa-21(a). (R. at 2.) Cooks alleged that Carolina negligently failed to conduct adequate safety tests to ensure that thimerosal was non-toxic and a harmless ingredient in vaccines. (R. at 2.) Cooks additionally alleged that Carolina was strictly liable for the vaccine's defective design because a safer alternative existed. (R. at 2.) Carolina removed the case to the United States District Court for the District of Grace based on diversity of citizenship under 28 U.S.C. § 1332(a) (2006). (R. at 2.)

Once in federal court, Carolina moved to dismiss Cooks' Complaint. (R. at 2.) Carolina asserted that the Act barred Cooks' design defect claims, because the vaccine at issue was produced in compliance with the federal government's specifications. (R. at 2.) In the alternative, Carolina moved to dismiss because Cooks failed to sufficiently plead their claims under Grace state law. (R. at 2-3.) The district court granted the Motion to Dismiss, holding that the Complaint contained sufficient factual support to sustain Cooks' claims, but the Act barred the claims. (R. at 3, 5.)

Cooks timely appealed the district court's dismissal of the claims. (R. at 9.) The Thirteenth Circuit reviewed *de novo* the district court's dismissal of the claims and held that the Act did not preempt Cooks' claims, because a vaccine manufacturer may be found civilly liable for vaccine-related injuries resulting from avoidable side effects. (R. at 9-11.) The court stated that whether a side effect is avoidable is a question of fact that must be decided by courts on a

case-by-case basis. (R. at 11.) However, the Thirteenth Circuit further held that Cooks' claims were not facially plausible under the *Twombly* pleading standard, in light of the recent decision in *Ashcroft v. Iqbal*, because the Complaint alleged mere conclusions of law. (R. at 12-13.) The Thirteenth Circuit affirmed the district court's judgment, holding that Cooks did not allege any facts that would warrant either a finding of design defect or that the defect was the proximate cause of Estella Marie's injuries. (R. at 13.)

Cooks submitted a Petition for Writ of Certiorari to the U.S. Supreme Court. (R. at 14.) The Court granted the petition, but limited the proceeding to the two issues mentioned above. (R. at 14.)

C. Statement of the Facts

Between March 1996 and October 1998, Estella Marie received three doses of Carolina's Diphteria and Tetanus Toxoids and Pertussis ("DTP") – Haemophilus influenzae type b ("Hib") combination vaccine. (R. at 1.) This vaccine contained thimerosal, an organic compound that is fifty percent mercury by weight. (R. at 1.) Cooks filed a suit against Carolina, claiming that as a result of the thimerosal contained in their vaccine, twelve-year-old Estella Marie has suffered neurological injuries, including developmental delays, learning disabilities, social delays and deficits, impairment of motor skills, gastrointestinal illness, and immune system dysfunction. (R. at 1.)

SUMMARY OF THE ARGUMENT

The Thirteenth Circuit erred in holding that the Act did not expressly preempt all design defect claims and that courts must determine on a case-by-case basis whether a vaccine is unavoidably unsafe. States have historically exerted control over the health care of their citizens. However, in the past century, the federal government has stepped to the forefront, regulating and controlling the vaccine industry. The Act solidified this control, creating a task force and federal agencies to oversee the safety and design of vaccines. The federal government is the first and last word on vaccines. Before a vaccine hits the market, the federal government must approve its formulation , as well as monitor the vaccine manufacturers themselves. Thus, the Thirteenth Circuit erred in holding that design defect claims must be evaluated on a case-by-case basis to determine the safety of the vaccine at issue. Only federal agencies, not courts, can make this determination.

The Act expressly preempts vaccine manufacturers from all product liability claims except two: manufacturing design and failure to warn. The legislative history supports that design defect claims were never meant to be brought before a court. Design defect claimants have an appropriate recourse in the compensation program provided by the Act.

However, the Thirteenth Circuit properly dismissed Cooks' Complaint, because their allegations were nothing more than threadbare, conclusory recitals of the claims asserted. Threadbare and conclusory allegations do not meet the pleading standard of Federal Rule of Civil Procedure 8(a)(2). Although a plaintiff is not required to plead with specificity, a plaintiff must plead sufficient facts for a reviewing court to infer, based on its judicial experience and common sense, that the plaintiff is plausibly entitled to relief. Cooks' Complaint does not meet this standard.

Carolina respectfully asks this Court to reverse the ruling of the Thirteenth Circuit that the Act does not preempt state law. Carolina also respectfully asks this Court to affirm the Thirteenth Circuit's dismissal of Cooks' Complaint, because Cooks failed to offer any well-pleaded factual allegations that would plausibly entitle the Cooks to relief.

ARGUMENT

I. Cooks' design defect claims are preempted by the Act, which evinces congressional intent to expressly preempt all design defect claims.

Congressional purpose is " 'the ultimate touchstone' in every preemption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). To determine this purpose, courts scrutinize the statutory text. *Id.* at 486 (internal citation omitted). If further clarification is needed, courts review the statute's legislative history, historical context, and caselaw interpreting the statute. *Id.* The plain language of the Act states that design defect claimants must seek relief through the compensation program created through the Act itself, and not in the courts. The legislative history and historical context explain the reasoning behind this. Vaccines are both inherently safe and dangerous. Although vaccines can cause dangerous side effects, the benefits of vaccine administration far outweigh the risks. To protect those injured by the side effects of vaccines and the vaccine industry itself, Congress implemented the Act to provide a compensatory recourse for victims, to limit the liability of vaccine manufacturers for unavoidable injuries, and to outline the expansive control of the federal government over the vaccine industry. *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994. The clear intent of the Act was to preempt all design defect claims.

Federal law, including federal statutes, can preempt state law. *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). The preemption doctrine stems from the Supremacy Clause of the Constitution, which provides:

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

U.S. CONST. art. VI (emphasis added).

The United States Supreme Court has recognized three ways in which federal laws can preempt state laws: express preemption, implied conflict preemption, and field preemption. *Hillsborough County, Fla.*, 471 U.S. at 713. Express preemption occurs when the plain language of the statute provides that federal law preempts a particular area of state law. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001). Implied conflict preemption occurs when the state law conflicts with federal law in a particular area. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79 (1990). Field preemption occurs when either (a) the "field [is] reserved for federal regulation," *United States v. Locke*, 529 U.S. 89, 111 (2000), or (b) "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," *English*, 496 U.S. at 79 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The Act expressly exempts design defect claims. But even if it did not, preemption could be inferred, given the federal government's extensive control over the vaccine industry.

A. The plain language of the Act expressly preempts all products liability claims involving "unavoidable side effects," except for those claims that a vaccine was improperly prepared or included improper directions or inadequate warnings.

The Act provides that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death," except for the reasons provided in subsections 221(b), 221(c), and 221(e). 42 U.S.C. § 300aa-22(a). Section 22(b)(1) provides: "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). This statutory language is analogous to that of the Federal Cigarette Labeling and Advertising Act, which provides, "no statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15

U.S.C. § 1334(b) (2006). In *Lorillard*, the United States Supreme Court held that this language constituted an express federal preemption of state law on cigarette packaging. 533 U.S. at 2414-15. Likewise, in the instant case, the Act's plain language preempts all state tort claims, except manufacturing defect and failure-to-warn claims. 42 U.S.C. § 300aa-22(b)(1); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 294 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004). Thus, the only recourse for any design defect claimant is through the compensation program created by the Act.

Cooks' Complaint alleges first that Carolina conducted inadequate tests to determine the safety of thimerosal as an ingredient of their DTP-Hib vaccine, and second that Carolina is strictly liable because a safer alternative than thimerosal existed. (R. at 2.) Both claims are design defect claims and are thus preempted by the Act. Cooks initially sought compensation in the Vaccine Court and then, upon the entry of judgment, filed a notice of withdrawal to pursue this tort remedy in the court system. (R. at 1-2.) Cooks' proper recourse was to accept the compensation awarded by the Vaccine Court, as the plain language of the Act provides. The legislative history of the Act underscores this principle, as seen in the report produced by the House Committee on Energy and Commerce ("Energy and Commerce Committee"). "If [vaccine-injured persons] cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings[,] [they] should pursue recompense in the compensation system, not the tort system." H.R. REP. NO. 99-908, at 24.

Vaccine manufacturing is by nature an unpredictable industry. Even if vaccine manufacturers produce a vaccine that meets all federal specifications, that vaccine can still cause unavoidable, injurious side effects. *See* H.R. REP. NO. 99-908, at 6 (stating "no 'perfect' or

reaction-free childhood vaccine [is] on the market"). Despite the potential risks of vaccine administration, vaccine administration is less risky than exposure to the diseases they prevent. *Id.* If held liable for all such side effects, vaccine manufacturers would be financially bereft and forced to withdraw from the vaccine industry, which would in turn lead to the threat of vaccine shortages. *Id.* at 7. As a preventive measure, Congress implemented the Act to encourage "a more stable childhood vaccine market." *Id.*

Congress incorporated into the Act language that precluded all other claims except those related to manufacturing design and failure to warn, as well as the language of Restatement (Second) of Torts section 402A, comment K. Congress intended to insulate these manufacturers from the liability that would otherwise inevitably result from vaccine production. H.R. REP. NO. 99-908, at 26. "In such a case, the plaintiff is almost invariably a young child, often badly injured or killed, and free from wrongdoing. And, even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense." *Id.* By precluding liability where the side effects "were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings," 42 U.S.C. § 300aa-22(b)(1), the Act gives vaccine manufacturers a safe harbor. If they adhere to the extensive federal regulations concerning vaccine preparation and labeling, they should not have to fear being brought to court and financially drained by an injured claimant. It is uncontested that Carolina produced a vaccine that included no defect in its preparation or manufacturing, and that the vaccine at issue provided adequate warnings. (R. at 2.). Thus, Carolina is in full compliance with all federal regulations and should not be subject to liability for the injuries sustained by the claimant.

B. Even if the Act does not expressly preempt all design defect claims, such claims are preempted by the federal government's extensive regulatory and supervisory role in the vaccine industry, as evidenced by the provisions in the Act, as well as the Act's legislative history and historical context.

Although states have historically protected the health of their citizens, the federal government has historically sought to prevent the transmission of infectious diseases both internationally and between states. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 235 (3d Cir. 2009), *cert. granted*, 78 U.S.L.W. 3082 (U.S. Mar. 8, 2010) (No. 09-152); H.R. REP. NO. 99-908, at 5. With the passage of the Act, the federal government continues this commitment to public health, and specifically, to protect its citizens from childhood diseases through vaccination. H.R. REP. NO. 99-908, at 5.

The Act's twin goals are "to achieve optimal prevention of infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. With this statement of purpose, Congress pledged the federal government's support and control of the vaccine industry. This purpose comes into sharper focus in the Act's legislative history. The U.S. Supreme Court has stated the report of the particular bill's committee is the "authoritative source for finding the Legislature's intent." *Garcia v. United States*, 469 U.S. 70, 76 (1984) (internal citation omitted). The Energy and Commerce Committee has jurisdiction over matters relating to public health and quarantine, including the Act. Committee on Energy and Commerce, http://energycommerce.house.gov (About the Committee – Jurisdiction) (last visited March 9, 2010). Thus, in considering the Act's legislative history, this Court should look predominantly to the Energy and Commerce Committee Report, the 1986 House Report 99-908, H.R. REP. NO. 99-908 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

The Energy and Commerce Committee Report states that the federal government's control of childhood vaccinations is "one of the most spectacularly effective public health initiatives this country has ever undertaken" but that tort claims have challenged "the Nation's ability to maintain this level of success." H.R. REP. NO. 99-908, at 4. Concerned about the impact of these tort claims, which drove up the cost of vaccines, caused some vaccine manufacturers to withdraw from the market, and ultimately led to decreased access to vaccines, the Energy and Commerce Committee sought to reevaluate the federal government's role in vaccine activities. *Schafer*, 20 F.3d at 4; H.R. REP. NO. 99-908, at 5. To this end, it established a "comprehensive and fair compensation system" that would, in some cases, "change most" vaccine-related state laws. H.R. REP. NO. 99-908, at 25.

The Act establishes extensive federal control over the vaccine industry. The Secretary of Health and Human Services "has the responsibility to promote the development and use of improved, safer childhood vaccines." *Id.* at 30. The Director is required to supervise the safety tests of vaccines via other federal agencies. 42 U.S.C. § 300aa-2(a)(3). The Act appoints an advisory committee comprised of "physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations" to, among other things, recommend ways for the Director to ensure the safety of vaccines. 42 U.S.C. § 300aa-2(a)(5). By these provisions, the federal government supersedes the states in control of the vaccine industry. The states' secondary role is to keep the federal government abreast of research to aid the federal government in its control of the vaccine industry. "State government has become an important adjunct in carrying out the Federal government's responsibility to prevent the spread of infectious diseases." H.R. REP. NO. 99-908, at 5.

In addition to overseeing the research and development of safe vaccines, the federal government also directly regulates vaccine manufacturers. First, the United States Food and Drug Administration (the "FDA") regulates the licensing of vaccine manufacturers and the individual vaccines. 21 C.F.R. § 600 *et seq.* But the FDA's role does not stop there. The FDA continues its control of the vaccine industry past the initial licensing process, imposing rigid standards on the manufacturers for each batch of vaccines, requiring reporting on the manufacturing process, safety tests, and submitting to periodic federal inspections of the facilities. *Id.* For instance, vaccine manufacturers must report to the federal government any injuries sustained by children as a result of vaccine administration. *Id.*; H.R. REP. NO. 99-908, at 4. The manufacturers must also keep records on vaccine production. H.R. REP. NO. 99-908, at 4. Manufacturers are not allowed to make subsequent changes to the vaccine design or labeling without FDA approval. *Id.* By entrusting the FDA with such a broad sweep of authority over the vaccine industry, Congress intended the federal government to be the first and last word in vaccine safety.

This Court should not give credence to the House Committee on the Budget Report ("Budget Report"). Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203 (101 Stat. 327) (codified at 26 U.S.C. §§ 4131-4132 (Supp. 1988)). The Budget Report pertains to the funding of the Act and makes no reference to the statutory provisions before this Court. In addition, the Budget Report was produced after the implementation of the Act in conjunction with Act amendments. This Court should not consider this report to be relevant in its determination, as subsequent legislative history "form[s] a hazardous basis for inferring the intent of an earlier [Congress]." *United States v. Price*, 361 U.S. 304, 313 (1960). The only federal court of appeals that has heard a case similar to the instant case has refused to

acknowledge the notion of "dueling committee reports," recognizing the Budget Report was "issued by a committee which paid no role in the passage" of the Act. *Bruesewitz*, 561 F.3d at 250. This Court should similarly disregard the Budget Report.

C. Caselaw demonstrates that courts have consistently held that the Act preempts design defect claims.

The Third Circuit recently held that the Act preempts all design defect claims. *Id.* at 235. In *Bruesewitz*, the plaintiff sought compensatory relief in the Vaccine Court, claiming she had suffered regular seizures and developmental delay following the administration of a DPT vaccine. *Id.* at 236. The vaccine manufacturer had applied for an alternative, safer DPT vaccine, but the safer alternative was not commercially available by the time Bruesewitz was scheduled to receive her third dose of the DPT vaccine. *Id.* The Vaccine Court ruled she was barred from receiving compensation for her injury, which was not listed in the table of injuries for which compensation was available. *Id.* at 237. The plaintiff brought design defect claims against the vaccine manufacturer, claiming that her injuries could have been avoided if the vaccine manufacturer had produced an alternative vaccine. *Id.* at 238. The district court ruled that her design defect claims were preempted by the Act, which provided a statutory remedy while at the same time "provid[ing] an umbrella under which manufacturers would improve the safety of their products while remaining immune from design defect claims." *Id.* Interpreting the Act as intending to preempt certain claims, the Third Circuit examined the legislative history to determine whether the Act intended to preempt all design defect claims or only strict liability design defect claims. *Id.* at 246-47. In reaching its decision, the Third Circuit examined a factually similar case in which the Georgia Supreme Court reached a different decision. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236. The *Ferrari* court held that Congress could not have intended to bar all design defect claims, because the Act provides: "No vaccine

manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine *if* the injury or death resulted from side effects that were unavoidable," implying that courts must determine on a case-by-case basis whether the side effects at issue were avoidable. *Ferrari*, 668 S.E.2d at 240 (quoting 42 U.S.C. § 300aa-22(b) (emphasis added)). The Third Circuit viewed the *Ferrari* court holding as contrary to the Act's language, because the holding would not bar any design defect claims and would tax the resources of the court by requiring the court to determine whether each individual design defect claim included avoidable side effects. *Bruesewitz*, 561 F.3d at 246. The Third Circuit held that Congress intended to insulate vaccine manufacturers from liability for *all* design defect claims. *Id.* at 248-49.

In another case similar to the instant case, an infant plaintiff suffered regular seizures after he received a DTP vaccine. *Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 507 (N.Y. App. Div. 2006). The plaintiff brought, *inter alia*, a design defect claim, alleging that he would not have sustained an injury from the DTP vaccine if the vaccine manufacturer had used an alternate vaccine formulation. *Id.* The New York Supreme Court granted summary judgment to the vaccine manufacturer, holding that the Act preempted all design defect claims and that it was thus the province of the federal government, not state juries, to decide the safety of vaccines. *Id.* The New York Appellate Division (Second Department) affirmed this decision. *Id.* In the instant case, the lower court quotes the *Militrano* court's view that the wording of comment K of the Restatement (Second) of Torts section 402A "appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act." *Id.* at 508. (R. at 11.) However, the lower court does not reveal the context of this statement. The *Militrano* court was making a reference to the Energy and Commerce Committee Report and goes on to say that "the

balance of the House Committee's discussion of the issue clearly establishes Congress' determination that the Comment K defense bars *all such claims*." *Id.* (emphasis added).

Similarly, in 2007, the United States District Court for the Eastern District of Pennsylvania held that the Act preempted all design defect claims after examining both the statutory text and the legislative history. *Sykes*, 484 F. Supp. 2d at 301. The *Sykes* court relied on the decision in *Blackmon*, in which the United States District Court for the Southern District of Texas had held that the Act, "read against the background of products liability law," preempted all design defect claims. *Blackmon*, 328 F. Supp. 2d at 664. The *Blackmon* court stated that the safety of vaccines was for the federal government, not state juries, to determine. *Id.* at 665. In *Sykes*, the court stated that to allow state juries to decide the safety was vaccines would run counter to the policy underpinning the Act, conflict with the federal government's regulation of the vaccine industry, and render the language of the Act meaningless. *Sykes*, 848 F. Supp. 2d at 300-01. The court said that if juries made this determination, "the manufacturers would again be subjected to the unpredictability and expense of the tort system, and companies would be dissuaded from remaining or entering the vaccine market." *Id.* Caselaw demonstrates the courts' shared view that Congress intended the Act to bar all design defect claims.

D. Because of the federal government's extensive control and expertise in the vaccine industry, courts should not determine on a case-by-case basis whether a vaccine is "unavoidably unsafe."

The Act provides for extensive federal regulation and control over the vaccine industry. Since the implementation of the Act in 1986, the federal government has played a primary role in vaccine safety and design. Thus, the federal government is in a better position than the courts to determine whether a vaccine is "unavoidably unsafe" and should subject the manufacturer to liability for its design. If courts determine the safety of a particular vaccine on a case-by-case basis, they will take on a time-consuming, cost-increasing task that will tax their already

compromised judicial resources. Vaccine manufacturers likely will also be subjected to greater liability and pressure to conduct more extensive research than that required by the federal government, which will wreak havoc on the vaccine industry and, in turn, potentially lead to more extensive federal regulation than that already provided in the Act. Thus, this Court should reverse the holding of the lower court and hold, as the district court did, that the Act preempts Cooks' design defect claims.

II. Cooks did not plead facts sufficient to sustain their design defect claims under the current pleading standard.

This Court should affirm the Thirteenth Circuit's ruling that Cooks' Complaint was deficient, because Cooks did not allege sufficient facts to plausibly suggest entitlement to relief. Even if Cooks had asserted sufficient facts, the Thirteenth Circuit's ruling would have been proper. The Thirteenth Circuit correctly applied the pleading standard established by the United States Supreme Court in *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007). The court does not have to assume the truth of conclusory allegations, and only plausible claims for relief can survive a motion to dismiss. *Id.* at 550-51; *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).

A. The U.S. Supreme Court defined the standard for pleading claims in federal court in *Bell Atlantic Corp. v. Twombly* and clarified the standard in *Ashcroft v. Iqbal*.

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint include "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). Although the rule contains the terms "short" and "plain," the rule still requires a "showing," rather than a generalized claim of relief. *Twombly*, 550 U.S. at 556 n.3. At the pleading stage, allegations must plausibly suggest entitlement to relief in order to meet "the threshold requirement of Rule 8(a)(2) that the plain statement possess enough heft to show that the pleader is entitled to relief." *Id.* at 557. Detailed factual allegations are not necessary to survive a Rule

12(b)(6) motion to dismiss, but a plaintiff's obligation to provide the basis for entitlement to relief "requires more than labels and conclusions" because a "formulaic recitation of the elements of a cause of action" will not suffice. *Id.* at 555.

Rule 8 does not open the door to discovery for plaintiffs who provide nothing more than conclusions in their complaints. *Iqbal*, 129 S.Ct, at 1950. If a complaint only provides factual information that is just uniform to the defendant's liability, it fails to show that the pleader is plausibly entitled to relief. *Id.* at 1949 (citing *Twombly*, 550 U.S. at 557). A complaint cannot survive if it simply offers "naked assertions devoid of further factual enhancement." *Id.* "Threadbare recitals of the elements of a cause of action" that are supported by conclusory statements will not suffice to show that a pleader is entitled to relief. *Id.* Courts apply a two-prong test when reviewing the sufficiency of a complaint under a motion to dismiss. *Id.* at 1950. First, courts must identify mere conclusory allegations. *Id.* Second, courts must identify the well-pleaded factual allegations, assume their authenticity, and determine whether they plausibly give rise to an entitlement to relief. *Id.* Applying this test is a context-specific task that "requires the reviewing court to draw on its judicial experience and common sense. *Id.* Therefore, a well-pleaded allegation will be accepted as true, but if a more likely explanation exists, such as FDA studies conducted on thimerosal-containing vaccines that do not reveal any causal links to neurological injuries, a reviewing court can find that the well-pleaded allegations do not plausibly show entitlement to relief. *Id.* at 1952.

1. <u>The *Twombly* Pleading Standard</u>

Twombly was a complex case that involved whether local telephone companies were violating antitrust law by agreeing not to compete with each other and thereby restraining trade. *Twombly*, 550 U.S. at 550. The antitrust law alleged to have been violated was section 1 of the

Sherman Act, and liability under the Sherman Act involves some type of contract or conspiracy evidencing restraint of trade or commerce among the several States. *Id.*

In *Twombly,* the respondents alleged that the petitioners, Regional Bell Operating Companies or Incumbent Local Exchange Carriers ("ILECs"), were restraining trade amongst themselves, causing each ILEC to inflate charges for local telephone and internet service. *Id.* at 551. The respondents specifically alleged that the petitioners were involved in parallel conduct in their individual service areas to impede the growth of upstart of Competitive Local Exchange Carriers, (CLECs), showing that some form of agreement existed between the parties. (Compl. ¶ 47.) In their complaint, the respondents were attempting to show that because the ILECs were not competing in other markets than their own, they must have made an agreement not to do so. *Twombly*, 550 U.S. at 551.

The Court found that the complaint's allegations were nothing more than legal conclusions couched as factual allegations. *Id.* at 555-556. The Court held that alleging parallel conduct, without more, was not enough to state a claim under the Sherman Act because it did not necessarily suggest that an agreement had been made between the telephone companies. *Id.* at 556. The Court stated that parallel conduct without more does not suggest conspiracy, and mere conclusory allegations of an agreement are not sufficient to show illegal conduct. *Id.* at 557. The Court stated that without factual enhancement, parallel conduct is a naked assertion that stops just short of the line between possibility of relief and plausibility of entitlement of relief. *Id.* at 557.

The Court held that the "nub" of the complaint was nothing more than an allegation of parallel conduct without more, which by itself did not cross the line from possibility to plausibility. *Id.* at 566. The Court noted that it was not establishing a heightened pleading

standard, but found that the claim should be dismissed since it failed *in toto* to make the respondents' entitlement to relief plausible. *Id.* at 569 n.14.

2. The *Twombly* standard as explained by the *Iqbal* Court

In *Iqbal*, the Court had to determine whether the United States Attorney General and the Director of the FBI were civilly liable to a detainee who was arrested in the aftermath of the September 11 attacks on the World Trade Center in New York City. Iqbal brought suit against the government challenging the constitutionality of their policy employed to amass potential suspects in the investigation of the September 11 attacks. *Iqbal*, 129 S. Ct. at 1942. The core of Iqbal's suit arose from the FBI's alleged treatment of him during his incarceration because of his race, religion, or national origin. *Id.*

The complaint alleged that then-Attorney General John Ashcroft and then-Director of the FBI Robert Mueller had developed and implemented a policy that held post-September 11 detainees in highly restrictive conditions of confinement until they were cleared by the FBI. *Id.* Iqbal also alleged that Ashcroft was the principal architect of the policy, and that Mueller was instrumental in its adoption. *Id.* Additionally, Iqbal alleged that while he was detained, he was "kicked in the stomach, punched in the face, and dragged across his cell without justification." *Id.* at 1944. Moreover, he further claimed he was stripped and body cavity searched "when he posed no safety risk to himself or others," and that he was forbidden from praying because the officers in charge declared that "there would be no prayers for terrorists." *Id.* The Court noted that the allegations against Ashcroft and Mueller were the only ones of any significance to this case before the Court. *Id.* Ashcroft and Mueller raised the defense of qualified immunity and moved to dismiss the claims. *Id.* at 1948. They contended that the complaint failed to state sufficient allegations to show their involvement in the clearly established unconstitutional

conduct of subjecting a detainee to beatings and unjustified searches. *Id.* at 1944. The Court held that Iqbal's pleading was insufficient under the *Twombly* standard. *Id.*

In assessing *Twombly*, the Court found that a well-pleaded complaint should contain sufficient factual matter to make claims plausible instead of only possible. *Id.* at 1949. The Court found that a claim is factually plausible when the factual content gives rise to a reasonable inference that the defendant is liable for the misconduct alleged. *Id.* The Court also explained that the reviewing court must embark on a context-specific task employing judicial experience and common sense when determining whether a complaint contains enough facts to withstand a motion to dismiss. *Id.* at 1950. First, "a court considering a motion to dismiss may begin by identifying allegations that, because they are mere conclusions, are not entitled to the assumption of truth." *Id.* Second, "when there are well-pleaded factual allegations, a court should assume there veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.*

The Court explained its application of the two-pronged approach found in *Twombly*, and then applied that analysis to Iqbal's complaint. *Id.* at 1950-51. Under the first prong of its analysis, the Court rejected the assertion that Ashcroft and Mueller subjected Iqbal to harsh conditions of confinement based solely on his race, religion, or national origin, finding the allegations were a formulaic recitation of the elements of unconstitutional discrimination. *Id.* at 1951. The Court compared the allegations to the conclusory allegations in *Twombly*, and stated that the conclusory nature of Iqbal's allegations was what caused them to be disentitled to the presumption of truth, because no matter how they were worded, the allegations were still only conclusions that did not show that he was plausibly entitled to relief. *Id.*

Moving to the second prong, Iqbal had alleged that "the FBI, under the direction of Mueller, arrested and detained thousands of Arab Muslim men as a part of its investigation of the

events of September 11." (Compl. ¶ 47.) In addition, Iqbal had alleged "the policy of holding post-September 11 detainees in highly restrictive conditions of confinement until they were cleared by the FBI was approved by Ashcroft and Mueller in the weeks following September 11, 2001." (Compl. ¶ 69.) The Court held that because the race, religion, and national origin of those suspected in the September 11 attacks was Arab Muslim, a justifiable policy directed to arrest and detain similar situated individuals likely would have a disparate impact on Arab Muslims. *Iqbal*, 129 S. Ct. at 1951. The Court ruled that the arrests were lawful in an effort to detain those illegally in the United States who potentially had links to Al-Qaeda regardless of the disparate impact, because the purpose was to detain those responsible for the September 11 attacks. *Id.* The Court stated that Iqbal needed more factual content to push his claim of purposeful discrimination "across the line from conceivable to plausible." *Id.* at 1952.

Because no factual allegations existed to show Ashcroft's and Mueller's discriminatory states of mind, the pleadings did not meet the requirements of Federal Rule of Civil Procedure 8 to show entitlement to relief. *Id.* The Court held that Iqbal would have to plead more facts to suggest that Ashcroft and Mueller did more than employ a policy to keep suspected terrorists in the most secure situation possible until cleared of terrorist involvement. *Id.* In conclusion, the Court declared that the *Twombly* standard applied universally to all civil proceedings – not only antitrust suits. *Id.* at 1953.

3. Courts have dismissed complaints in similar products liability cases for failing to provide sufficient factual information to meet the plausibility standard as stated in *Twombly* and *Iqbal*.

To survive a Rule 12(b)(6) dismissal, a plaintiff must allege "more than labels and conclusions," and formulaic recitations of the elements of a cause of action" will not be enough. *Ivory v. Pfizer, Inc.*, No. 90-0072, 2009 WL 3230611, at *1 (W.D. La. Sept. 30, 2009). A

plaintiff armed with mere conclusions will not award the plaintiff with the keys to discovery. *Id.* at *2. A court is not required to accept conclusory allegations as true. *Lewis v. Abbott Labs.*, No. 8 Civ. 7480(SCR)(GAY), 2009 WL 2231701, at *1 (S.D.N.Y. July 24, 2009). When a court has decided that there are well-pleaded factual allegations, the court will assume their veracity and then resolve whether those allegations plausibly give rise to an entitlement to relief. *Id.* The factual allegations must be sufficient to raise the right to relief above the speculative level. *Heck v. Am. Med. Sys., Inc.*, No. CCB-07-2101, 2008 WL 1990710, at *2 (D. Md. Apr. 30, 2008). The plaintiff must show more than a sheer possibility that the defendant has acted unlawfully. *Frey v. Novartis Pharms. Corp.*, 642 F. Supp. 2d 787, 791 (S.D. Ohio 2009). If the plaintiff pleads factual content that allows the court to draw a reasonable inference that the defendant is liable for the transgressions alleged, the claim is facially plausible. *Id.*

a. *Ivory v. Pfizer*

In *Ivory*, the court was faced with deciding whether Pfizer was liable to Ivory for problems she had while using Chantix, a smoking-cessation aid. *Ivory*, 2009 WL 3230611 at *1. Ivory filed suit against Pfizer asserting, among other things, a design defect claim. *Id.* Pfizer moved to dismiss pursuant to Rule 12(b)(6), because Ivory failed to plead the existence of an alternative design. *Id.* The court employed the standard of pleading and the standard for testing the sufficiency of a complaint from *Twombly* and *Iqbal*. *Id.* The court found that Ivory was obligated to plead more than labels and conclusions because a formulaic recitation of the elements of a cause of action are insufficient to withstand a Rule 12(b)(6) motion to dismiss. *Id.* Furthermore, the court stated, “a claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the

misconduct alleged." *Id.* A plaintiff who is armed with nothing more than legal conclusions cannot "unlock the doors to discovery." *Id.* at *2.

After articulating the standard, the court analyzed each cause of action. *Id.* at *2-8. For Ivory's design defect claim, the court granted Pfizer's Rule 12(b)(6) motion to dismiss because Ivory's complaint was devoid of any reference to an alternative design. *Id.* at *3. To establish a claim for design defect in that jurisdiction, Ivory was required to show that at the time the product left Pfizer's control there was an alternative design for Chantix capable of preventing her injuries. *Id.* In addition, she was required to show that (a) a possibility existed that Chantix's design would cause her injuries, and (b) the gravity of those injuries outweighed the burden on the manufacturer to adopt the alternative design. *Id.* The court ruled that Ivory failed "to even allege an alternative design existed, much less that any such design would have reduced the adverse effects or that the burden of adopting such design was less than the likelihood and gravity of the damages associated with Chantix as designed." *Id.* Because no factual allegations stated there was an alternative design and how it would apply, Pfizer's Rule 12(b)(6) motion was granted, dismissing the design defect claim. *Id.*

b. *Lewis v. Abbot Laboratories*

In *Lewis*, the court accepted the report and recommendation of the federal magistrate, who decided whether Abbot Laboratories was liable to Lewis for injuries she sustained as a result of ingesting Depakote, which she claimed was used to chemically restrain her. *Lewis*, 2009 WL 2231701, at *1-3. The district court stated that *Twombly* and *Iqbal* provided further support for the report and recommendations offered by the magistrate. *Id.* at *1. The court stated that the principle that a court must accept as true all of the allegations contained in a plaintiff's complaint is inapplicable to legal conclusions. *Id.* Additionally, the court found when a court has

decided that there are well-pleaded factual allegations, the court will assume their veracity and will then resolve whether those allegations plausibly give rise to an entitlement to relief. *Id.*

Lewis was a patient at St. Luke's Hospital in New York and was under the care of a physician who forcibly administered Depakote to restrain her. *Id.* at *2. Lewis claimed that Depakote causes many dangerous side effects and that it caused her to have Tardive Dyskinesia, a disorder that involves involuntary movements of the lower face. *Id.* Lewis sought compensation for injuries as a result of taking Depakote. *Id.* at *3. The magistrate judge found, reading Lewis' complaint as a whole, that she was attempting to plead that Depakote was inherently dangerous, and that its side effects outweighed its benefits. *Id.* The magistrate considered her to be pleading negligence and strict liability. *Id.* at *4.

For Lewis to be successful on a strict liability design defect claim against Abbot, she was required to show that (a) Depakote as designed was possibly harmful, (b) it was feasible to design Depakote in a safer manner, and (c) the defect was a substantial factor in causing her injuries. *Id.* The magistrate found that Lewis alleged that Depakote is inherently dangerous because it causes the following side effects: pancreas, liver, and kidney disease; blood disorders; hair loss; skin conditions; and brain damage. *Id.* Additionally, Lewis alleged that the "negative consequences of the high doses of Depakote outweigh the benefits the drug offers." *Id.* The magistrate held that these allegations were conclusory. *Id.* Moreover, the magistrate found that Lewis had not shown that a feasible alternative to the vaccine existed. *Id.* Therefore, Lewis did not meet her burden to allege sufficient factual information to show that Depakote was not reasonably safe. *Id.*

For Lewis to be successful on a negligence claim, she was required to show that (a) Abbot owed Lewis a duty to exercise reasonable care, (b) Abbot breached that duty by failing to

use reasonable care such that Depakote was rendered defective, (c) the defect was the proximate cause of Lewis' injuries, and (d) Lewis suffered loss or damage. *Id.* The magistrate did not specifically note that negligence was being discussed, but he included that failure to warn claims are similar to negligence theories. *Id.* at *5. Again, construing Lewis' complaint broadly, the magistrate found that she had not alleged enough factual information to warrant plausible entitlement to relief on a failure to warn or negligence claim. *Id.* Additionally, the magistrate stated that Lewis could not succeed on a negligence claim regarding a manufacturing flaw, because she did not assert a manufacturing flaw. Rather, she asserted conclusively that Depakote was defective. *Id.* Ultimately, the magistrate dismissed the claims, finding that Lewis had failed to provide sufficient facts to support a claim for negligence with regard to design, failure to warn, or manufacturing defect. *Id.* at *6-8.

c. *Heck v. American Medical Systems, Inc.*

Heck involved whether American Medical Systems was liable to Heck for an artificial urinary sphincter device alleged to be defective. *Heck*, 2008 WL 1990710, at *1. Initially, Heck's device was operational. *Id.* Later, it was not functioning properly, and Heck had another operation to remove it. *Id.* Heck brought suit as a result of the malfunctioning device, asserting that American was negligent in manufacturing the device and liable for furnishing a defective product. *Id.* In his complaint, Heck alleged that he suffered pain and discomfort because the device had a design defect. *Id.* Additionally, he claimed that he could not live a normal physical and emotional life without the pain and embarrassment of urinary retention. *Id.*

Citing the standard found in *Twombly*, the court found that the complaint should be dismissed. *Id.* at *4. The court stated that factual allegations must be sufficient to raise the right to relief above the speculative level. *Id.* at *2. The court further held that Heck had an obligation

to provide the grounds of his entitlement to relief which requires more than labels and conclusions. *Id.* Formulaic recitations of the elements of cause of action are inadequate. *Id.*

In reviewing Heck's allegations, the court found that it stated legally operative terms in a conclusory fashion. *Id.* The court took the language from the complaint and placed it under the microscope of *Twombly*. *Id.* Claiming that American was negligent in the manufacture of the device and that it was liable for the defective device was not sufficient to satisfy the *Twombly* standard. *Id.* The court ruled that a viable complaint must be substantiated with facts. *Id.* The court further found that Heck's negligence claim was also deficient, because Heck never alleged how American was negligent. *Id.* at *3. In conclusion, the court held that Heck's complaint failed to specify the facts that led him to believe that the device was defective or that American was negligent in manufacturing. *Id.*

d. *Frey v. Novartis Pharmaceuticals Corp.*

In *Frey*, the court determined whether Novartis was liable to Frey for injuries she sustained from ingesting Trileptal, a drug used to treat partial seizures in adults and children with epilepsy. *Frey*, 642 F.Supp.2d at 788-789. Employing the *Twombly* and *Iqbal* standards, the court dismissed the claims against Novartis, finding that Frey had done nothing more than plead threadbare recitals of legal conclusions and formulaic recitals of the elements of her claims. *Id.* at 795.

Frey claimed that she suffered from multi-organ hypersensitivity and other related complications because she ingested Trileptal. *Id.* at 790. Based on her allegations, she brought a claim for strict liability for defect in design under Ohio law. *Id.* Frey claimed that the risks created by Trileptal exceeded its benefits and that a practical and technically feasible alternative was available that would have prevented the harm alleged without substantially impairing

Trileptal's usefulness or intended purpose. *Id.* She also claimed that Novartis sold a drug whose risks were not known to the public. *Id.* at 792. Frey claimed that she could not be any more specific in her complaint without engaging in discovery. *Id.*

Nonetheless, the court found that Frey's strict liability design defect claim "must be dismissed" because she had not stated a plausible claim for relief. *Id.* at 795. The court noted that the Ohio statute clearly provided what a plaintiff must to show in order to plead a successful strict liability design defect claim. *Id.* at 792-795. The court stated that Lewis did nothing more than provide a formulaic recitation of the elements of the cause of action outlined in the statute. *Id.* at 795. The court ruled that Frey's allegations fell short of the *Twombly* pleading standard because she did not plead facts sufficient to support her claim. *Id.*

B. The Thirteenth Circuit correctly held that Cooks' Complaint did not contain sufficient facts to state a plausible claim for relief.

When the Thirteenth Circuit addressed the adequacy of the pleadings, it began by citing the pleading standard stated in *Twombly* and *Iqbal*. Following the principles of those decisions, the Thirteenth Circuit held that Cooks' Complaint was deficient under the *Twombly* standard and under the extrapolation of that standard in *Iqbal*. It is necessary at the pleading stage for allegations to plausibly suggest entitlement to relief in order to meet "the threshold requirement of Rule 8(a)(2) that the plain statement possess enough heft to show that the pleader is entitled to relief." *Twombly*, 550 U.S. at 556 n. 3; *Iqbal*, 129 S. Ct. at 1949. However, Cooks' Complaint does not rise to the required level of sufficiency, and the Thirteenth Circuit was correct to make that distinction. The *Iqbal* Court articulated the standard for reviewing complaints at the motion to dismiss stage. *Iqbal*, 129 S. Ct. at 1949. The Court stated that first, a court should identify the pleadings that are merely conclusory, because they are not entitled to an assumption of truth; and

second, a court should recognize the well-pleaded factual allegations, assume their authenticity, and determine whether they plausibly give rise to an entitlement to relief. *Id.*

1. Cooks' Complaint contains threadbare recitals and conclusory allegations that do not warrant an assumption of truth.

Looking at Cooks' Complaint, the Thirteenth Circuit found that Cooks first asserted that the thimerosal-containing vaccine injected into Estella Marie was "unreasonably defective because it contained dangerous levels of ethyl mercury, a substance known to defendants to have neurotoxic properties." (R. at 12.) As the Thirteenth Circuit correctly held, this sole allegation does not rise to the level of a well-pleaded factual allegation. As in *Iqbal*, the conclusory nature of the allegation is what disentitles it to an assumption of truth. Similarily, the *Lewis* court found that the plaintiff's mere statement that the drug in question was defective was a conclusory allegation. The conclusive nature of the allegations asserted and the conclusory statement that the thimerosal-containing vaccine was defective is why this allegation asserted by Cooks is insufficient. A conclusory allegation should be disregarded by a court, because it is not worthy of an assumption of truth, as stated in *Twombly* and *Iqbal*. To make the claim viable, Cooks should have stated why ethyl mercury is dangerous, or, better yet, how Carolina knew that it had neurotoxic properties. Unlike the plaintiff in *Heck*, Cooks has not stated how or why the thimerosal containing vaccine is defective. Because Cooks merely states that the thimerosal-containing vaccine is defective without showing why, the allegation that the thimerosal-containing vaccine is unreasonably defective should be disregarded.

Cooks next alleged that Carolina "failed to conduct adequate safety tests to determine whether thimerosal was safe and non-toxic to humans." This allegation contains no factual support to substantiate the claim. This allegation is comparable to the allegation of parallel conduct in *Twombly*, which was not sufficient to rise to the level of plausibility that would

substantiate a conspiracy. Neither is it sufficient to say that Carolina failed to conduct adequate safety tests because Cooks believed the thimerosal-containing vaccine was defectively designed. Also comparable to *Ivory*, Cooks has not alleged how the product is defective or specified how Carolina's safety tests would have had an effect on Estella Marie's injuries. Like the plaintiff in *Frey*, Cooks has failed to support this threadbare conclusion.

The third conclusory allegation in Cooks' Complaint was as follows: "The unreasonably dangerous and defective products described were a substantial contributing cause of" Estella Marie's injuries. (R. at 12.) This allegation is merely conclusory, because it claims that the defect was the proximate cause of Estella Marie's injuries, but it does not state why or how. Under *Twombly* and its progeny, this is an unsupported, insufficient allegation. Thus, it is not a well-pleaded factual allegation. Like the plaintiffs in the other cases, Cooks was required to plead more than labels and conclusions, because a formulaic recitation of the elements of a cause of action were insufficient to meet the plausibility standard set forth in *Twombly* and reiterated in *Iqbal*.

If this Court were to find that there were other allegations upon which the Thirteenth Circuit could have relied, it is still readily apparent that any other allegations that can be found are conclusory in nature. For example, the Thirteenth Circuit does not necessarily mention the claim that there was a safer alternative to the product in question. However, Cooks should have asserted what the safer alternative was and not a mere conclusory allegation that an alternative existed. The *Ivory* court held that merely stating that a safer alternative existed is a conclusory allegation that warranted a dismissal of the claims. The same was true in *Lewis*, *Heck*, and *Frey*. The failure to allege what the safer alternative was and how it would reduce the possible adverse effects of the thimerosal-containing vaccine versus the effect on the usefulness of the vaccine is

dispositive. Cooks has not shown that a safer alternative existed or how an alternative would have prevented Estella Marie's injuries. Therefore, his threadbare recital should be viewed as conclusory, failing to satisfy the plausibility standard.

In conclusion, Cooks' Complaint raised several allegations. However, each one was nothing more than a threadbare legal conclusion that did not plausibly suggest that Cooks was entitled to relief. Thus, Cooks' Complaint is deficient under the *Twombly* standard and must be dismissed for failure to state a claim upon which relief could be granted.

2. Cooks' Complaint contains no well-pleaded factual allegations that must be accepted as true; however, even if this Court finds to the contrary, Cooks' allegations do not plausibly give rise to an entitlement of relief.

Under the second part of the test, a court must accept the well-pleaded allegations and engage in a context specific task to determine whether the remaining allegations can be found to show plausible entitlement to relief. However, Cooks is left with no allegations for the Thirteenth Circuit to review. Therefore, the Thirteenth Circuit was not afforded an opportunity to closely examine the remaining well-pleaded allegations and draw upon its judicial experience and common sense to determine whether Cooks was plausibly entitled to relief. Nonetheless, this Court may review those allegations in a different light and determine that they could have been seen as well-pleaded factual allegations, but even if it were to construe those claims liberally, they still do not suggest plausible entitlement to relief.

Looking at the first allegation that the Thirteenth Circuit considered again liberally, a careful internet search or a trip to the library would have easily unraveled the mystery of how thimerosal is not dangerous as Cooks alleged. According to the FDA's website, studies of thimerosal-containing vaccines were conducted in 1999 and were concluded in 2001, revealing that the "maximum cumulative exposure to mercury from vaccines in the recommended

childhood immunization schedule was within acceptable limits U.S. Food and Drug Administration, Thimerosal in Vaccines, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm (last visited Mar. 9, 2010). The record stated that Estella Marie's injuries were sustained from vaccines she received between 1996 and 1998. If the FDA conducted a study that led to the conclusion that thimerosal was safe in 1999 through 2001, then the vaccines Estella Marie received from 1996 to 1998 were most likely also safe. Furthermore, thimerosal is not known to be neurotoxic and studies from 2001 to 2004 have shown that there was no link between thimerosal and neurological disorders such as those Estella Marie suffers. *Id.*

Reviewing the second allegation, this Court should find that this allegation, even if considered well-pleaded, would not satisfy the plausibility standard, because given more likely explanations, thimerosal-containing vaccines have been tested and were safe for humans. Although it cannot be shown that the thimerosal-containing vaccines were actually tested by Carolina, it is absurd to think otherwise. Thimerosal has been in existence as a preservative in a wide range of vaccines since 1931. *Id.* Thimerosal is normally found in vaccines at the rate of 0.01%, meaning that there are 25 micrograms of thimerosal in a 0.5mL dose of the vaccine. *Id.* The FDA website states that thimerosal tests have been conducted on both animals and humans. *Id.* A study has shown that rats could withstand a dose of 45mg of thimerosal. *Id.* When studying infants that had received shots containing thimerosal, it was shown that the ethyl mercury contained in thimerosal was removed quickly from the body through the stool and was not toxic to the infants. *Id.* Therefore, this conclusory allegation cannot be accepted as true.

An analysis of the third allegation yields the same result. If this Court viewed the third allegation liberally, it would find that the allegation cannot be substantiated. The FDA website

notes that weak associations, if any, have been made to thimerosal-containing vaccines causing neurological injuries. *Id.* Therefore, a reviewing court could use its judicial experience and common sense to draw the inference that thimerosal was not a proximate cause of Estella Marie's injuries in light of these FDA tests. Furthermore, Cooks has not cited to or made reference to any study or fact that declared the thimerosal-containing vaccine a proximate cause of Estella Marie's injuries. Consequently, this third allegation should also be dismissed given the more likely explanation found on the FDA's website.

Once more, if this Court found another allegation that the Thirteenth Circuit could have analyzed, this Court could still find that Cooks has not satisfied the plausibility requirement of *Twombly* and *Iqbal*. Through judicial experience and common sense, this Court should find that if a safer alternative existed, Cooks would and should have pleaded it. Moreover, another simple internet search or trip to the library could have provided Cooks with the information that would have shown that a safer alternative to the exact shot Estella Marie received did not come into existence until it was produced by Merck in 1999. *Id.* Cooks is possibly attempting to plead that because a safer alternative exists now, it existed then, but that is still conclusory. The exact safer alternative is not provided in the Complaint initially. They may also say that because vaccine manufacturers have discontinued thimerosal-containing vaccines that a safer alternative must have existed or at least Carolina allegedly knew it did. However, it was not until 2001 that a progressive movement took place to remove thimerosal from all vaccines used in America, with the exception of the influenza vaccine. *Id.* The reason for the removal was that the FDA decided to reduce the exposure of infants and pregnant women to mercury found in vaccines, because mercury is harmful in significant amounts. *Id.*

C. Cooks' Complaint should be allowed to survive a 12(b)(6) motion to dismiss because the sufficiency of a motion to dismiss does not turn on the controls of the discovery process.

In *Twombly*, *Iqbal*, and *Frey*, the plaintiffs asserted that they should be afforded with the opportunity to engage in discovery because they cannot offer specific facts that would allow them to adequately support their claims. It is true that this case does present what appears to be an information asymmetry problem, but that does not mean that Cooks should not engage, at the very least, an internet search or a simple trip to the library.

In *Twombly*, the Court specifically stated that the cost of modern discovery and the abuses that may stem from such expansive discovery outweigh the burdens of requiring the plaintiff to provide well-pleaded facts to support their allegations. *Twombly*, 550 U.S. at 558. The same should be applied to Cooks. Cooks should not be allowed to engage in a fishing expedition in hopes that they will find some evidence to support their claims. It is true that discovery may shed some light on the allegations alleged, but as *Twombly* notes, the plaintiff should be armed with more than unsubstantiated conclusory allegations before being given the keys to discovery.

Iqbal reiterates the principle that Cooks should not be allowed to engage in discovery simply because the claims are conclusory. In *Iqbal*, the plaintiff argued that he should be afforded with cabined discovery. *Iqbal*, S. Ct. at 1953-54. However, the Court found that to be unwise since his claims did not meet the level required by Rule 8. *Id.* at 1954. Since he had not met the standard of Rule 8, the Court said he was not entitled to discovery regardless of whether is cabined or not. Here, that should be also applied. It is tragic that Estella Marie has suffered from severe injuries. However, the law states that conclusory allegations do not rise to the requisite showing as required by Rule 8. Therefore, Cooks should not be given an opportunity to engage in discovery – cabined or otherwise.

In *Frey*, the plaintiff made the same plea. The plaintiff claimed, much like Cooks will, that she could not allege "the scientific makeup of the drug that is defective for a specific reason without conducting discovery." It is most likely true that neither Frey nor Cooks possesses the skill to chemically analyze the drugs in question and plead how they are scientifically defective. However, that is not what the Court requires. The Court requires at a minimum that the plaintiff plead enough facts to rise above a speculative level that the plaintiff is plausibly entitled to relief. *Twombly*, 550 U.S. at 555; *see also Iqbal*, 129 S. Ct. at 1949. Cooks should not be afforded an opportunity to engage in discovery, especially since a simple internet search or a trip to the library could have provided them with the information necessary to file a sufficient pleading, or better yet allowed them accept the judgment of the Vaccine Court, since it is unlikely that thimerosal can be linked to neurological injuries.

CONCLUSION

The Act preempts Cooks' design defect claims. The language of the Act itself, as well as the legislative history and historical context, support this. The federal government exerts extensive control over the vaccine industry that supersedes that of the states. With the Act, Congress expanded the control of the federal government over every aspect of vaccine production and safety. Thus, since the Act was implemented in 1986, the federal government has largely controlled the vaccine industry. With its extensive experience regulating the industry, the federal government is the sole authority on vaccine safety and development to protect its citizens.

The *Twombly*/*Iqbal* standard is clear: to survive a motion to dismiss, plaintiffs must arm themselves with more than threadbare recitals of the cause of action and conclusions. Here, Cooks has failed to provide the necessary facts to show that they are entitled to the relief they seek. Their Complaint does not contain a scintilla of factual support to allow this Court to draw upon its well of judicial experience and vast amount of common sense to find that Cooks is plausibly entitled to relief. Furthermore, public policy does not warrant that Cooks should be allowed to proceed because he has not met the threshold requirements of the standard of pleading.

Consequently, this Court should reverse the finding the state laws are not preempted by the Act. Additionally, this Court should affirm the decision to dismiss because Cooks' Complaint is devoid of any well-pleaded facts that would show plausible entitlement to relief.

APPENDIX

1. U.S. Constitution Art. VI:

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

2. 42 U.S.C. § 300aa-1 (2006):

> The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

3. 42 U.S.C. § 300aa-2(a)(3) (2006):

> (a) The Director of the Program shall have the following responsibilities:
> (3) Safety and efficacy testing of vaccines
> The Director of the Program shall, through the plan issued under section 300aa-3 of this title, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

4. 42 U.S.C. § 300aa-2(a)(5) (2006):

> (a) The Director of the Program shall have the following responsibilities:
> (5) Production and procurement of vaccines
> The Director of the Program shall, through the plan issued under section 300aa-3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

5. 42 U.S.C. § 300aa-22(a) (2006):

> (a) General rule: Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

6. 42 U.S.C. § 300aa-22(b)(1) (2006):

> (b) Unavoidable adverse side effects; warnings
>
> > (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

7. 28 U.S.C. § 1332(a) (2006):

> (a) The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between
>
> > (1) citizens of different States;
> > (2) citizens of a State and citizens or subjects of a foreign state;
> > (3) citizens of different States and in which citizens or subjects of a foreign state are additional parties; and
> > (4) a foreign state, defined in section 1603(a) of this title, as plaintiff and citizens of a State or of different States.
>
> For the purposes of this section, section 1335, and section 1441, an alien admitted to the United States for permanent residence shall be deemed a citizen of the State in which such alien is domiciled.

8. 15 U.S.C.A § 1334(b) (2006):

> (b) State regulations: No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

9. FED. R. CIV. P. 8(a)(2):

> (a) Claim for Relief. A pleading that states a claim for relief must contain:
>
> > (2) a short and plain statement of the claim showing that the pleader is entitled to relief;

10. FED. R. CIV. P. 12(b)(6):

> (b) How to Present Defenses. Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:
>
> > (6) failure to state a claim upon which relief can be granted;

11. H. R. REP. NO. 99-908 (1986):

HEALTH PROGRAMS
DATES OF CONSIDERATION AND PASSAGE
Senate August 12, October 18, 1986
House October 17, 1986
Senate Report (Labor and Human Resources Committee) No. 99–380,
Aug. 6, 1986 [To accompany S. 1744]
Cong. Record Vol. 132 (1986)
Related Reports:
Senate Report (Labor and Human Resources Committee) No. 99–225,
Dec. 18, 1985 [To accompany S. 1848]
Senate Report (Governmental Affairs Committee) No. 99–506,
Sept. 30, 1986 [To accompany S. 1209]
House Report (Energy and Commerce Committee) No. 99–908,
Sept. 26, 1986 [To accompany H.R. 5546]
House Report (Energy and Commerce Committee) No. 99–903,
Sept. 26, 1986 [To accompany H.R. 5540]
House Report (Energy and Commerce Committee) No. 99–154,
June 3, 1986 [To accompany H.R. 2417]
Senate Report (Labor and Human Resources Committee) No. 99–229,
Jan. 22, 1986 [To accompany S. 1762]
Much of Title III of this Public Law was derived from H.R. 5546. House Report (Energy and Commerce Committee) No. 99–908, Sept. 26, 1986 [to accompany H.R. 5546] is set out:

HOUSE REPORT NO. 99–908
September 26, 1986

1 The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5546) to amend the Public Health Service Act to establish a National Vaccine Program for the development of new vaccines and the improvement of existing vaccines and a program to compensate the victims of vaccine-related injuries and deaths, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

* * * * *

3 PURPOSE AND SUMMARY

H.R. 5546, the 'National Childhood Vaccine Injury Act of 1986', creates a new system for compensating individuals who have been injured by vaccines routinely administered to children. The system consists of two separate, but related parts and concerns only the actions of those injured by specified childhood vaccines and the manufacturers of such vaccines.

Part A of the system amends the Public Health Service Act to establish a Federal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity. All individuals injured by a vaccine administered after the date of enactment of the legislation are required to go through the compensation program. Judgments and awards entered under the compensation program must be expressly rejected

before other remedies may be pursued. Funding for the program is provided through a tax to be placed on designated childhood vaccines.

Part B of the system deals with the additional remedies that are available to vaccine-injured persons should they elect to reject a judgment and award made under the compensation program and to take action directly against a vaccine manufacturer. Under such circumstances, an individual may file a civil action for damages relating to a vaccine injury just as he or she may have done prior to the enactment of the legislation. Under Part B of the system, however,***4** several new substantive and procedural requirements are established for the recovery of these damages.

H.R. 5546 contains several other provisions not pertaining to the issue of compensation for vaccine-injured persons, but very much linked to the related questions of vaccine development, safety, and effectiveness. The bill makes mandatory—for the first time—the reporting of injuries resulting from routine childhood vaccines to Federal officials. It requires the Secretary to develop and distribute parent information materials on these vaccines and on the diseases ***6345** they prevent. Vaccine manufacturers are required to keep records on the production, testing, and handling of their products and to report any potential problems to appropriate Federal agencies within a 24-hour period. A new authority to recall hazardous vaccines is provided for the Secretary. Finally, the legislation requires the Secretary to perform a number of studies on various childhood vaccines and on the sufficiency of their warnings and labels.

The bill also establishes a National Vaccine Program to oversee and carry out Federal vaccine-related research, testing, licensing, production, and distribution activities concerning all vaccines. The purpose of this program is to provide needed focus and direction at the Federal level on the development of both new and improved vaccines that can be used in this country and around the world. Under such a program, the Committee expects that a greater number of manufacturers will enter the vaccine market and that a greater number of vaccine products will become available to prevent disease, reduce reactions, and otherwise improve public health.

BACKGROUND AND NEED FOR LEGISLATION

Vaccination of children against deadly, disabling, but preventable infections diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease. Billions of medical and health-related dollars have been saved by immunizations. And, through the development of vaccines to prevent childhood diseases, significant scientific progress has been made in the development of vaccines to prevent other types of diseases. In brief, the Nation's efforts to protect its children by preventing disease have been—by every measure—a success.

In recent years, however, the Nation's ability to maintain this level of success has come into question. Previously unrecognized injuries associated with vaccines have become more widely known. While most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured. These children are often without a source of payment or compensation for their medical and rehabilitative needs, and they and their families have resorted in greater numbers to the tort system for some form of financial relief.

At least in part as a result of this increase in litigation, the prices of vaccines have jumped enormously. The number of childhood vaccine manufacturers has declined significantly. In certain areas, the level of immunization against some preventable diseases has decreased while the incidence of those diseases has increased. ***5** All of this has led to the Committee's re-

evaluation of all current vaccine and vaccine-related activities and, in turn, to a real concern about the future of Federal immunization initiatives.

H.R. 5546 is the result of the Committee's re-evaluation. It reflects five principal findings (the basis for which are discussed below) made by the Committee during its study of this issue:

6346 (1) The availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities.

(2) The Federal government has the responsibility to ensure that all children in need of immunization have access to them and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries.

(3) Private or non-governmental activities have proven inadequate in achieving either of these goals.

(4) Current economic conditions have resulted in an unstable and unpredictable childhood vaccine market, making the threat of vaccine shortages a real possibility.

(5) Because of their cost-effectiveness, the Federal government has an interest in the development, distribution, and use of vaccines, including those designed to prevent non-childhood diseases.

Childhood Diseases and Immunization Programs

Since the early days of this Nation's history, the Federal government has had the responsibility to prevent the spread of infectious diseases from other countries into the United States and between States within its own borders. In meeting this responsibility, the Federal government has assumed—for more than a generation now—a leadership role in providing immunizations against childhood diseases. Through Federal support, State and local health agencies are able to plan, develop, and conduct programs to immunize children against polio, measles, mumps, rubella (German measles), diphtheria, pertussis (whooping cough), and tetanus. This role, repeatedly reaffirmed by the Congress, assures that the country maintains a consistent national policy in protecting our children against preventable diseases. (For a more detailed description of the Federal government's historical involvement with childhood immunization programs, see Part II, *Childhood Immunizations*, a report prepared by the staff of the Subcommittee on Health and the Environment (Comm. Print 99–LL).)

Over the years, State government has become an important adjunct in carrying out the Federal government's responsibility to prevent the spread of infectious diseases. Today, State immunization laws require that virtually all children be vaccinated against each of the seven common childhood diseases before they enter school. Near-universal compliance with these laws has resulted in the dramatic reduction in the incidence of these diseases. Indeed, polio, diphtheria, and tetanus have essentially been eradicated as childhood diseases in this country. Great progress has been made in eliminating measles as a native disease and efforts have been intensified to hasten the elimination of the other childhood diseases as well.

Compensation for vaccine-related injuries

In the past, the medical problems that can be associated with the vaccines that are given to children have sometimes been overlooked.***6*** More recently, however, information has become available about the potential hazards of these vaccines and about the serious—and sometimes deadly—consequences they can have. This is ***6347*** particularly true with regard to the pertussis vaccine which is most commonly administered as part of a series of immunizations

known as DPT (diphtheria, pertussis, tetanus). Severe reactions to the other vaccines have been reported as well.

While it is true that some children, because of their physical condition, are more likely to react to a vaccine, vaccine reactions are not completely forseeable. There is today no 'perfect' or reaction-free childhood vaccine on the market. A relatively small number of children who receive immunizations each year have serious reactions to them. But it is not always possible to predict who they will be or what reactions they will have. And since State law requires that all children be immunized before entering school, most parents have no choice but to risk the change—small as that may be—that their child may be injured from a vaccine.

Despite these possibilities, public health officials, private physician groups, and parent organizations have repeatedly stated that it is safer to take the required shots than to risk the health consequences of contracting the diseases immunizations are designed to prevent. As a result and in light of the overall success of immunication programs, the Federal government continues to support States and local efforts to provide immunizations to children and States continue to require that children be vaccinated as a condition for entering school.

But for the relatively few who are injured by vaccines—through no fault of their own—the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.

This approach has also been ineffective for the manufacturers of childhood vaccines. This has become especially true in more recent years as the number of lawsuits—particularly those concerning the DPT vaccine—has increased. (For a more detailed discussion of the litigation experience of manufacturers, see Part IV of the Subcommittee's report, *Childhood Immunizations*, which presents the results of the Subcommittee's survey of the manufacturers on this subject). Manufacturers have become concerned not only with the problems of time and expense, but with the issue of the availability of affordable product liability insurance that is used to cover losses related to vaccine injury cases. Whether current problems with liability insurance arise from a crisis in the tort system or from a particularly bad downturn in the business cycle of the insurance industry has been and remains a matter of great controversy. Nevertheless, there is little doubt that vaccine manufacturers face great difficulty in obtaining insurance. This lack of insurance was the stated reason for one manufacturer to withdraw temporarily from the vaccine market in 1984. Others have suggested that they may follow a similar course of action. This factor, coupled with the ***6348 *7** possibility that vaccine-injured persons may recover substantial awards in tort claims, has prompted manufacturers to question their continued participation in the vaccine market.

The loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country. Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine. Two States, Michigan and Massachusetts, produce their own DPT vaccine. Despite Congressional support, Federal vaccine stockpiles maintained by the Centers for Disease Control (CDC) have never reached CDC's recommended level of six-months' supply. Thus, the withdrawal of even a single manufacturer would present the very real

possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.

H.R. 5546

Thus, two overriding concerns have led to the development of this legislation: (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market. As further outlined below, H.R. 5546 establishes a new system for vaccine injury compensation which the Committee believes is fair, simple, and easy to administer. Just as important, the Committee believes that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood vaccine market will evolve.

In establishing this new system, however, the Committee recognizes the need for additional measures to help ensure that the Nation is able to maintain safe and reliable childhood vaccination programs and to continue these programs' great successes of the past. H.R. 5546 contains, therefore, a number of provisions concerning vaccine safety, production, and information. In addition, the bill calls for several studies to be completed on specified vaccines. These provisions, together with the new compensation system, should produce a much improved national childhood immunization initiative.

In light of the significant public health advances that have been made as a direct result of the development and use of childhood vaccines, the Committee believes that more emphasis should be placed on the research and production of other vaccines. Accordingly, H.R. 5546 establishes a National Vaccine Program to make better use of the scientific opportunities offered by both public and private vaccine research. It is the Committee's expectation that under this program substantial progress will be made toward the development and distribution of vaccines that will further enhance the public health of this country as well as countries around the world.

*****6349 *8*** SECTION—BY-SECTION ANALYSIS AND DISCUSSION

Section 1—Short Title and Table of Contents

TITLE I—VACCINES

Section 101—Amendment to the Public Health Service Act

Section 101 adds a new title, numbered Title XXI, to the Public Health Service Act. The following references (through Section 2133) refer to the provisions of that title.

TITLE XXI—VACCINES

Subtitle 1—National Vaccine Program

In March of 1985, the Oversight and Investigations Subcommittee conducted a hearing on vaccine development, in the context of a series of hearings on biotechnology. Witnesses described advances in biotechnology that could lead to the production of new and improved vaccines, as well as the lack of organization at the Federal in the promotion and use of vaccines.

In response to these hearings and other Subcommittee and Congressional activity, on March 6, 1986, Chairman John D. Dingell of this Committee and Chairman Orrin G. Hatch of the Senate Committee on Labor and Human Resources wrote to Dr. Samuel O. Thier, President of the Institute of Medicine (IOM) to seek assistance in formulating a new policy on vaccines. In that letter, the two chairmen requested that the IOM examine questions of research development, testing, supply, and use of vaccines.

The IOM responded by convening a national conference of 70 leading experts on vaccines and immunization. The conference proceedings were summarized in a paper prepared for the use of the Committee and published as Committee Print 99–II. Working groups discussed problems and policy alternatives in seven areas: research; development; clinical trials; licensing and quality control; production and procurement; distribution and use; and surveillance and monitoring.

Among the researchers at the IOM conference, the discussion focused on the continuing inadequacy of government and industrial investment in this extraordinarily cost beneficial area of preventive medicine. Despite a strong history of the Government assigning high priority to vaccines, based on analyses of the cost-effectiveness of immunization, these researchers were not sanguine that their work would be carried through to its public health application.

The participants in the IOM conference reported that many potentially promising research results are never developed as products. Clinical trials are expensive and thus potentially limit vaccine development. The U.S. system of licensure is not linked to the public health goal of preventing human infectious disease. Decisions to manufacture and sell vaccines are often based on the small U.S. vaccine market rather than a response to the public health need.

Federal programs have probably had their greatest effect on the distribution and use of vaccines in the U.S., but the number of vaccines and their use is far from optimal. Adult vaccines, which are ***6350 *9** not mandated by school attendance statutes in the States, are poorly used in the U.S. There was agreement that improved surveillance of vaccine use and effectiveness would improve all aspects of vaccine and immunication programs.

At the close of the IOM conference, the current chairman of an interagency working group in the Public Health Service responded that further collaboration and cooperation between the Centers for Disease Control, the National Institutes of Health, and the Food and Drug Administration would be productive. There has been coordination of the effort to develop an improved pertussis vaccine and to stabilize the supply of the current vaccine. However, there has been neither time nor resources to do similar planning on other vaccine issues.

The National Vaccine Program established in subtitle 1 is a response to a broadly accepted need to make better use of the scientific opportunities offered by vaccine research. Both industry and government can enhance their efforts through coordination and collaboration.

Section 2101—Establishment

This section mandates the Secretary of Health and Human Services to create a National Vaccine Program, to be administered by a Director, selected by the Secretary. The purpose of the Program is to achieve optimal prevention of naturally occurring human infectious diseases through immunization and to achieve optimal prevention of the adverse reactions to vaccines.

The program is not intended to address infectious diseases that might be caused by manmade biological warfare agents.

Section 2102—Program Responsibilities

Subsection (a).—This provision spells out the elements of the national Vaccine Program. These program responsibilities are implemented through the plan described in Section 2103 (discussed below), and by the Director and the small staff funded by an appropriation authorized by Section 2106(a) (discussed below). The responsibilities are as follows:

(1) *Vaccine Research.*—The National Vaccine Program Director shall, by providing direction to and coordinating the research activities of Federal agencies, assure that Federal resources used for vaccine research have the greatest beneficial effect in preventing human infectious diseases. The vaccine research referred to in this section includes those activities intended to enhance our fundamental knowledge about diseases, pathogens, vectors, adjuvants, and host responses and thus make safe vaccine development possible. Such research is currently conducted by or for the National Institutes of Health, the Centers for Disease Control, the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(2) *Vaccine Development.*—Vaccine development activities of Federal agencies are to be coordinated by, and receive direction from, the National Vaccine Program. Vaccine development entails research on particular vaccines to produce them in test batches for clinical trials and, if these are successful, to address the engineering problems of industrial level production. An understanding of ***6351 *10** the role of private research and private development activities will be essential for the National Vaccine Program to operate effectively.

(3) *Safety and Efficacy Testing of Vaccines.*—Clinical trials to establish safety and efficacy are now required for all vaccines. Difficulty in organizing clinical trials and their cost may deter the development of important vaccines. The National Vaccine Program will assure that clinical testing of vaccines proceeds efficiently, so that the basic public health goals of immunization programs can be met. The Director of the Program will provide direction for, and co-ordinate, the testing activities conducted and supported by Federal agencies. Information about private testing activities will be essential to improve the effectiveness of Federal programs.

(4) *Licensing of Vaccine Manufacturers and Vaccines.*—The Food and Drug Administration, under Section 351, now licenses vaccine manufacturers and vaccines. The National Vaccine Program will, by coordinating these licensure activities with other Federal agencies that are engaged in research, development, and clinical testing, seek to make the licensure program responsive to the public health priorities of immunization. The National Vaccine Program will assist the Food and Drug Administration to assign resources to vaccine licensure activities, so that these activities may best contribute to rapid licensure of important vaccines.

(5) *Production and Procurement of Vaccines.*—The National Vaccine Program will be responsible for determining the vaccine supply needs of the United States. The Program will attempt to coordinate agency activities to assure that an adequate supply of vaccines is produced by the public and private sectors and that the Federal agencies will have the resources needed to procure the vaccines needed to supplement state and local, public and private purchases to achieve optimal immunization of the Nation's population. In addition, the Program will coordinate and monitor the United States continued contribution to the United Nations' immunization program and assistance of other countries through foreign aid. International immunization activities have always resulted in public health and financial benefits for U.S.

citizens. Through the plan and resources available under Section 2100(b) (discussed below) the National Vaccine Program will ensure adequate vaccine production and procurement.

(6) *Distribution and Use of Vaccines*.—The Centers for Disease Control is the agency charged with Federal responsibility for vaccine distribution and use. By providing direction to the Centers for Disease Control and coordinating its activities with other Federal agencies under the Plan, the National Vaccine Program can enhance the effectiveness of immunization programs. The programs of assistance to State and local health departments and to health practitioners in distributing vaccine and encouraging public acceptance of immunizations and avoiding misuse of vaccines leading to adverse reactions would be coordinated with other Federal activities.

(7) *Evaluating the Need for and the Effectiveness and Adverse Effects of Vaccines and Immunization Activities*.—In addition to the five Federal agencies regularly involved in immunication activities, the surveillance and monitoring activities envisioned in Section ***6352 *11** 2102(a)(7) would involve the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, the Health Care Financing Administration, and the Veterans' Administration. By coordinating and providing direction to these agencies and cooperating with private institutios, the National Vaccine Program would create a national program of monitoring and surveillance of vaccines and immunization activities.

(8) *Coordinating Governmental and Non-Governmental Activities*.—The National Vaccine Program would constitute the central focus in the Federal government for gathering and analyzing information about non-government vaccine and immunization activities. Because of the success of immunization efforts, including vaccine research and development, is dependent on close collaboration and cooperation between government, industry, universities, and others, the National Vaccine Program will encourage the investment of non-government resources in a manner that they will complement government activities.

(9) *Funding Federal Agencies*.—Because effective cooperation between Federal agencies under the National Vaccine Plan depends on each agency's meeting goals set in the Plan, the Director is authorized under Section 2106 (discussed below) to make funds available for activities described under the Plan, to supplement funds otherwise available to such agencies for activities under the Plan. These funds would be made available during the year that the Plan is in force to make sure that the failure of one agency to meet an objective does not cripple the whole national vaccine effort.

Subsection (b).—In carrying out this Section the Director shall consult with each and every Federal agency with a role in vaccine or immunization activity. The Committee expects that the Director will choose to create an interagency committee to enhance communication and to facilitate this kind of consultation.

Section 2103—Plan

The National Vaccine Plan, which is to produced by January 1, 1987, and updated annually, will describe all vaccine and immunization activities of the Federal government. It will establish priorities for research, development, testing, licensing, production, procurement, distribution and effective use of vaccines. It will describe an optimal use of resources to carry out the priorities, and describe how each of the various department and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with the Plan's priorities.

The annual production of the Plan is to be an optimal use of resources to the ongoing process for coordinating and providing direction to collaborating agencies.

Section 2104—Report

So that the appropriate House and Senate committees may perform their oversight function with regard to the National Vaccine Program, the Director is to submit an annual report on the implementation of the program and the Plan. This Plan will provide Congress with information on progress in vaccine research, development, testing, licensing, production and procurement, distribution***6353 *12** and use, and monitoring and surveillance. Information about these activities from many agencies should be assembled in this report so that the Congress can understand the progress being made on vaccines and immunizations against human infectious diseases.

Section 2105—National Vaccine Advisory Committee

This section creates a national advisory committee to advise the Director of the Program. Recognizing the longstanding role of the National Academy of Sciences' Institute of Medicine in vaccine policy development, the Committee intends that the Director consult with the Academy in appointing the Advisory Committee. The Director shall select the Committee's membership from among a broad and representative range of individuals concerned with vaccines.

The Advisory Committee will make recommendations in four areas:

(1) How to assure the supply of safe and effective vaccines.

(2) Research priorities to enhance vaccine safety and efficacy.

(3) Implementation of the Program and content of the Plan and report.

(4) Important areas for government and non-government cooperation to be included in the Program, Plan or report.

Section 2106—Authorizations

This section makes two annual authorizations for five years. The first is for funds to support staff for the Program and to support its activities, including the Advisory Committee. The second is for funds to be made available to programs under the Plan, which during a fiscal year, require additional funding to meet the objectives spelled out in the Plan.

Subtitle 2—National Vaccine Injury Compensation Program

Part A—Program Requirements

The bill establishes a compensation system for those persons injured by routine pediatric vaccines. The system is intended to be expeditious and fair. It is also intended to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury and without a demonstration that a manufacturer was negligent or that a vaccine was defective.

While the bill does not prohibit a vaccine-injuried person who has completed compensation proceedings from going on to court, the system is intended to lessen the number of lawsuits

against manufacturers. Toward this end, the bill requires that a person with an injury resulting from a vaccine that was administered after the enactment of this legislation file a compensation petition and go through the compensation program before proceeding with any litigation against a manufacturer. If, however, after compensation proceedings are complete, a vaccine-injured person elects to reject the system's findings and award and go on to court, he or she is free to do so.

***6354 *13** The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation.

The Committee also recognizes that because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law. The Committee anticipates that many of these persons will be compensated for their injuries under the compensation system.

Section 2110—Program Established

Section 2110 establishes the National Vaccine Injury Compensation Program ('the Program') for the administration of payments awarded to vaccine-injured persons. The Program is to be administered by the Secretary of the Department of Health and Human Services (HHS). The section also establishes that it is the ethical duty of an attorney consulted on matters of vaccine-injury to advise his or her client or potential client of the availability of compensation under the program.

Section 2111—Petitions for Compensation

Subsection (a)—General Rule.—Under the bill, a compensation proceeding is initiated by the filing of a petition for compensation with the U.S. district court for the district in which the petitioner resides or in which the injury occurred. This petition is also to be served upon the Secretary of HHS.

In its establishment of eligibility for compensation and its establishment of proceedings that must be completed before entering litigation, the bill divides vaccine-injured persons into three general groups: 1) those who were injured by a vaccine more than eight years before enactment of the legislation; 2) those who were injured by a vaccine that was administered before the enactment of the legislation, but less than eight years before; and 3) those who are injured by a vaccine that is administered after the enactment of the legislation.

Group One: As described below in Section 2116, those persons in the first group are not eligible for compensation under the system. As further described in Section 2122, the bill makes no changes from current law in such persons' legal rights or remedies.

Group Two: Those persons in the second group (i.e., those injured less than eight years ago but by a vaccine administered before enactment of the legislation) are eligible for compensation but are not required to enter the compensation system before pursuing tort litigation.

If such a person has pursued a civil action against a manufacturer before enactment of the legislation and no damages were awarded or the action was dismissed, he or she may file for compensation. The ability to make such an election under this Section is not intended to permit such a person to bring a civil action that would be barred by such State doctrines as res judicata, laches, or collateral estoppel. It is not intended that such a claimant would be permitted to file a

new civil action upon completion of the compensation proceedings; rather, this permissive entry is provided only to ***6355 *14** give these persons the opportunity for compensation under the nofault system.

If a person in the second group has a tort action against a manufacturer pending at the time of enactment, he or she may elect to maintain such an action or may, within two years of enactment or before judgment in the action (whichever comes first), elect to withdraw the action without prejudice and enter the compensation system. If such a person elects to maintain the civil action, he or she is permanently barred from entering the compensation system. If such a person elects to withdraw the civil action within the specified time, he or she may enter the system and may, at the conclusion of the compensation proceedings, elect to pursue whatever tort remedies may be available (although if a second civil action is to be filed, he or she must, of course, first reject the compensation findings and award).

If a person in the second group initiates a civil action against a manufacturer after the enactment of this legislation without first completing the compensation system, he or she may not enter the compensation system.

If a person in the second group has been awarded damages or has received a settlement for a civil action against a manufactuer, he or she may not enter the compensation system.

Group Three: Persons in the third group must complete the compensation proceeding and reject its judgment and its award before pursuing a civil action against a manufacturer for vaccine injury. This limitation does not apply to claims for under $1,000.

The bill also prohibits the act—by impleader, cross-claim, or separate suit or any other practice—of making a vaccine manufacturer a party to any civil action brought by a person in the third group before that person has completed a compensation proceeding.

If a civil action is initiated by a person in group three who has not completed the compensation proceeding and rejected its judgment and award, that civil action is to be dismissed. This dismissal of a civil action does not affect the person's ability to bring another civil action after completing the compensation proceeding and rejecting its judgment and award.

If a civil action is initiated and dismissed as described in the preceding paragraph, and if a petition for compensation is filed thereafter, the date of the filing of the civil action is to be considered the date of the filing of the petition for purposes of the time limitations set forth below in Section 2116. Such a petition must be completed within one year.

Subsection (b)—Petitioners.—A petition may be filed by any person (or his or her legal representative) who has been injured by a vaccine listed in the Vaccine Injury Table (‘the Table,’ discussed in Section 2114 below). Only one petition may be filed with respect to each administration of a vaccine. While this provision allows for the possibility of a separate recovery for each shot in a series of inoculations with the same vaccine, the Committee intends that such multiple awards be made only under the unusual circumstances in which separate and distinct injuries occur from individual administration. In most circumstances in which a vaccine has been given on more than one occasion and injuries have resulted, the Committee intends that a single petition encompass all requests***6356 *15** for compensation and that the limits of available compensation apply to this petition and that only in the most unusual circumstances should a petitioner be allowed to make more than one recovery and exceed the limitations on pain and suffering payments.

Subsection (c)—Petition Content.—A petition must contain a variety of materials necessary to make a finding that compensation is to be made. These materials include evidence that the person on behalf of whom the petition is filed (hereinafter referred to as ‘the petitioner’)—

received a vaccine listed in the Table or contracted polio from a recipient or oral polio vaccine;
met certain citizenship or location restrictions;
sustained or had significantly aggravated an injury listed in the Table;
sustained or had aggravated the injury within the time periods specified in the Table;
suffered residual effects for more than one year or died or incurred unreimbursable expenses of greater than $1,000; and
has not previously collected an award or settlement for the injury.

The petition should also contain all available relevant medical records and identification of any unavailable records. In addition, the petition should include documents necessary for the determination of the amount of the compensation award.

If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both of these cases, however, the petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. (Such a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table.) The Committee does not intend, however, to susgest that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed to be eligible for compensation without further showings of causation.

'Significant aggravation' is defined below in Section 2133. The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g. a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intends that the time periods set forth in the Table apply to the significant aggravation in order for causation to be deemed to exist (e.g., a significant deterioration of a ***6357 *16** seizure disorder after DTP vaccination must first become manifest within three days of the vaccination).

Section 2112—Court Jurisdiction

Subsection (a)—General Rule.—The district courts are to have jurisdiction over the compensation proceedings and such orders as are necessary to assure payment of awards.

Subsection (b)—Parties.—The Secretary of HHS is to be named as the respondent to all petitions for compensation. No other persons may intervene or otherwise be made a party to the compensation proceeding.

Within 30 days of receiving the petition, the Secretary is to publish a notice of the petition in the Federal Register. Upon such publication, any person may submit relevant, written information relating to evidence of other causes of the injury for which compensation is sought. If the petition is brought for an injury which is not listed in the Table or for an injury which is listed in the Table but which did not occur within the time period set forth in the Table, any person may submit relevant written information relating to the injury and its causation.

The Committee has endeavored to create a swift, uncomplicated compensation system and it is the Committee's intent that the submission of relevant evidence on these limited points be the sole self-initiated participation of persons other than the petitioner or the Secretary. While the Special Master may, as described below in Subsection (c), require the submission of evidence or require testimony, outside persons may not enter into the proceeding on their own.

Subsection (c)—Special Masters.—After the receipt of a petition, the district court is to designate a Special Master to serve as an adjunct to the court. The Master may require any evidence, require the submission of any information, require any testimony, conduct hearings, and prepare proposed findings of fact and conclusions of law and submit these findings to the court.

Information submitted to the Master may not be disclosed to anyone other than the petitioner or the Secretary without the express, written consent of the person who submitted the information. It is the Committee's intent that, in order to guarantee full cooperation with the Master, all materials remain confidential and that the parties themselves not redisclose individually identifiable materials shared with them as part of the proceedings. However, nothing in this section is intended to affect or modify any of the rules of discovery governing civil actions for damages should the petitioner decide to pursue his or her claim in tort after completion of the compensation proceeding.

Other than the discovery specifically described as the prerogative of the Master, there is to be no other discovery in a compensation proceeding. In order to expedite the proceedings, the power of the Special Master is intended to replace the usual rules of discovery in civil actions in Federal courts. Because the only issues relevant to the compensation proceeding are whether the petitioner suffered a compensable injury and, if so, the extent of compensable damages, there should be no need for a wider inquiry, which might be appropriate in a civil action raising other issues. Thus, while the ***6358 *17** Special Master may compel any testimony or appearance, neither party is given power to cross-examine witnesses, file interrogatories, or take depositions. In this regard, the Committee expects the Special Master to be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim.

Subsection (d)—Action by the Court.—If either party objects to the proposed findings of fact and conclusions of law of the Special Master, or if the court choose to do so on its own motion, the district court is to review the record of the proceedings and may order a remand or make a de novo determination.

If no objection is filed and if the court chooses not to review the proceeding, the court is to adopt the findings of the Special Master and is to render judgment on these findings. The entire proceeding—from date of filing through Special Master proceedings and court review—is to take place as expeditiously as possible and, in no case, should take more than one year. The Committee notes that much of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner.

Subsection (e)—Administration of Award.—As described below in Section 2115, awards are to be made on a periodic basis and for specific purposes. The award is to be administered by the Program, which is to audit the payment of compensation. A petitioner awarded compensation is to notify the Program of any changes which significantly affect the compensation to be paid. Thus, the petitioner has an affirmative duty to disclose to the Program if elements of compensation are no longer needed or if actual expenses are less than projected for that period.

Subsection (f)—Revision of the Award.—If a petitioner has been awarded compensation for projected unreimbursable expenses and he or she finds, during the period for which the payment was made, that the award is insufficient to meet these expenses, he or she may request the court to review the award and to increase the award or to revise the payment schedule or both. Thus, if medical costs rise more quickly than expected or if the petitioner's injury becomes more serious, he or she may ask for increased and more frequent payment.

Conversely, if the petitioner discloses a smaller need then projected or if the audit by the Program discloses that an item of compensation is no longer required or that compensation has been used improperly, the Program is to petition the court to revise the award.

The Committee does not anticipate that frequent adjustments or frequent audits will be necessary nor does the Committee intend the Program to become a free-for-service, third-party payor (i.e., an agency to reimburse only for direct and individual charges incurred on behalf of the petitioner) for future medical and rehabilitation services. Rather the Program should serve, within broad general guidelines of stewardship, as an administrator of the Fund, ensuring that awards are used as the Special Master and court judge find appropriate.

****6359 *18*** *Subsection (g)—Appeals*.—The judgment of the court is to be the final determination of the compensation petition, except that either the petitioner or the Secretary may request a review of the judgment by the court of appeals for the circuit in which the district court is located. If such an appeal is requested, the request is to be delivered to the other party within 60 days.

Section 2113—Determination of Eligibility and Compensation

Subsection (a)—General Rule.—Compensation is to be awarded if the court determines on the basis of the record as a whole that (1) the petitioner has demonstrated those matters required by Section 2111 above (e.g., receipt of vaccine, citizenship, time of initial onset of injury, etc.) and (2) there is not a preponderance of the evidence that the injury was caused by factors unrelated to the vaccine. The court may not make such a finding on the basis of the petitioner's claims alone, without other medical records or opinion.

In its determination that the injury was not caused by factors unrelated to the vaccine, the court may rely on evidence of other infections, traumas, or conditions but is not to include speculative or hypothetical matters or explanations. If the injury is not demonstrated to have been caused by other, defined illnesses or factors and the injury is demonstrated to have met the other requirements of Section 2111 and the Table, the injury is to be deemed to be vaccine-related.

The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines (discussed below in Section 2119) may propose to revise the Table, as provided below in Section 2114. Until such time, however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

Subsection (b)—Matters to be Considered.—In its determination of the petitioner's eligibility for compensation, the court is to consider all relevant medical and scientific evidence in the

record, including medical records and tests. None of this evidence is binding on the court, and the court should, of course, exercise its best judgment in evaluating whether the record satisfies the requirements for compensation. The court is specifically authorized to find that the record demonstrates that the time restrictions of the Table have been met even if some pieces of evidence omit references to time or incorrectly record them.

Subsection (c)—Record Defined.—The record refers to the compensation proceeding record.

****6360 *19** Section 2114—Vaccine Injury Table*

Subsection (a)—Initial Table.—The Vaccine Injury Table sets forth a list of vaccines, injuries, and time periods of initial onset of injuries. If a listed injury is first made manifest within the time period specified in the Table following the administration of the vaccine listed in the Table, the injury is to be considered compensable (unless there is other evidence to the contrary, as described above in Section 2113).

Each portion of the Table also includes a provision for complications or sequelae of listed injuries which occur within the specified time periods. Thus, for example, if anaphylactic shock occurs within 24 hours of the administration of a DTP vaccine (i.e., within the specified time period), that injury is compensable if other conditions are met. If kidney failure occurs as a complication of that injury, it too is compensable, regardless of when the initial onset of kidney failure occurs. If, however, anaphylactic shock occurs 48 hours after administration of the vaccine (i.e., outside the specified time period) and kidney failure follows, neither injury is compensable unless a demonstration of causation can be made (as provided above in Section 2111(c)(1)(C)(ii)). These provisions are added to emphasize that compensation is available not just for the acute vaccine reactions listed but also for those conditions which result from these reactions. These provisions are not intended to expand the filing periods specified below in Section 2116, and if a petition for compensation for the original listed injury is not filed within the time limits specified in that section, a petition for compensation for a complication may not be filed after that period. If an award has been made on a petition for a listed injury, a later complication may not supersede the prohibition of multiple petitions (described above in Section 2111(b)); rather a petitioner should petition for revision of the award under the provisions of Section 2112(f) (discussed above).

Subsection (b)—Qualifications and Aids toInterpretation.—Subsection (b) provides various descriptions and definitions that the Committee intends be used in interpreting the meaning of the Table. In addition, the subsection also restates in specific terms the general rule described in Section 2113 and provides that if the cause of an encephalopathy is an infection or another condition not related to the vaccine, the encephalopathy is not to be considered compensable. If, however, the court if unable to determine the cause of an encephalopathy, the encephalopathy is to be considered compensable if other conditions (including specified time of initial onset) are met.

Subsection (c)—Administrative Revision of the Table.—The Secretary is authorized to promulgate regulations making administrative revisions of the Table. Such regulations may add injuries to be compensated to the Table or may delete listed injuries from the Table. Such regulations may also modify the time periods set forth in the Table during which initial symptoms of an injury must occur. In promulgating such regulations the Secretary must provide for public hearing and comment.

In addition, the Advisory Commission on Childhood Vaccines (discussed below in Section 2119) or any other person may request ****6361 *20*** the Secretary to propose regulations to revise

the Table. Unless clearly frivolous, requests by persons other than the Commission shall be referred by the Secretary to the Commission for its recommendations. Following receipt of the Commission's recommendations or within 180 days of receipt of the request, the Secretary is to conduct a rulemaking proceeding on the request or publish reasons for not conducting such a proceeding.

Any modification made to the Table is to apply only to petitions filed after the modification is made.

Subsection (d)—Role of Commission.—In making revisions of the Table, the Secretary is to provide notice to and to consult with the Advisory Commission on Childhood Vaccines (described below in Section 2119).

Subsection (e)—Recommendation.—The Secretary is authorized to recommend to the Congress revisions of the Table to change the vaccines covered by the Table. As new vaccines are developed, licensed, or required by State law, the Committee intends that the Secretary make recommendations of modification as soon as possible. The Committee is especially interested at this time in receiving the Secretary's recommendations as to compensation regarding the Haemophilus influenzae vaccine, the Hepatitis B vaccine, and other vaccines in current use.

Section 2115—Compensation

Subsection (a)—General Rule.—Compensation awarded under the Program is to be paid from the Trust Fund (described below in Title II). In general, potential compensation is divided into four types—(1) medical and rehabilitative care, (2) death benefits, (3) lost earnings, and (4) pain and suffering benefits. Payment for projected medical and rehabilitative care is to be made on a periodic basis, not less frequently than annually; payment for all other forms of compensation may be made in a lump sum.

(1) Medical and Rehabilitative Care. Compensation may be awarded for a wide range of medical and rehabilitative care, ranging from diagnosis to special nutritional needs, from custodial care to clothing for incontinence or physical protection. The Committee recognizes that injured children often have special or unusual health care and education needs and has attempted to provide flexibility in compensation awards by its broad description of compensable care.

Subject to the limits of Section 2116 (described below) compensation may be made for actual past unreimbursed expenses, for actual unreimbursable expenses incurred from the time of judgment to the time of award, and for reasonable projected unreimbursable expenses. In dealing with already incurred expenses, the Committee intends that the Program pay only demonstrated, actual costs for which reimbursement cannot be obtained. Interest and inflation adjustments are not authorized for past expenses.

In dealing with prospective payments, as mentioned above, the Committee does not intend for the Program to become a fee-for-service, third-party payor for future medical and rehabilitation services. Flexibility for projected expenses and periodic payment is intended.

***6362 *21** (2) Death Benefits. Allowable death benefits for a vaccine-related death are set a level of $250,000.

(3) Lost Earnings. In the case of an adult who sustains a vaccine injury and whose earning capacity is impaired by the injury, the level of compensation for lost earnings is to be determined in accordance with accepted actuarial principles.

In the case of a child who sustains a vaccine injury, compensation for lost earnings is to be made only after the child attains the age of 18. At the age of 18, if the earning capacity of the injured person is determined to be impaired, the award is to be adjusted to include lost earnings

up to the level of the average weekly earnings of workers in the private, non-farm sector, with appropriate, specified offsets. If the earning capacity of the injured person improves, the petitioner is obligated (as provided in Section 2112, discussed above) to notify the Program and the lost earnings component of the award is to be reduced or eliminated. The Committee does not intend that the award be reduced because of other government benefits for which the injured person might be eligible.

(4) Pain and Suffering. Awards for pain, suffering, and emotional distress are authorized to be made at a level not to exceed $250,000 for each petition. As contrasted with the fixed death benefit, the award for pain and suffering is to be set at the discretion of the Master and of the court. The Committee does not intend that all petitions for which compensation is awarded be given this maximum level but rather that the Master consider the individual pain and suffering of the injured person, as well as the benefits conferred by other forms of compensation within the legislation.

Subsection (b)—Residential and Custodial Care and Service.—Any compensation award for residential and custodial care and service expenses is to be sufficient to allow the compensated person to remain living at home. This provision is not intended to prevent injured persons from receiving appropriate institutional care if they and their families request such services; neither is it intended to provide for the payment of family living expenses, the purchase of a home, or the construction of a major addition. The Committee intends that this provision allow for in-home medical, rehabilitative, and custodial care, and such modifications to existing physical facilities (such as bathroom facilities) as are necessary to ensure that injured persons are not required to be institutionalized for purely economic reasons.

Subsection (c)—Types of Compensation Prohibited.—Compensation under the Program may not include punitive or exemplary damages or any form of compensation (other than death benefits or lost earnings) that is not for the health, education, or welfare of the injured person.

Subsection (d)—Attorneys' Fees.—If the court awards compensation on a petition, the compensation is to include an amount to provide for reasonable attorneys' fees and other costs incurred in proceedings on the petition. If the court does not award compensation on a petition, it may, in its discretion, nonetheless make such an award for attorneys' fees and costs if it determines that the action was brought in good faith and that there was a reasonable basis for the claim for which the action was brought.

****6363 *22*** If, at the time of enactment of this legislation, a petitioner had a civil action pending and elected under the provisions of Section 2111 (described above) to withdraw the action and petition for compensation, the court may make an award for attorneys' fees and costs incurred in that action before enactment.

No attorney may charge a fee for services in connection with a petition other than the amount authorized by this section.

Matters to be demonstrated before compensation can be awarded are relatively narrow and well-defined. Traditional discovery, cross-examination, pleadings, and trial are not allowed in the proceeding on a petition. Because of the straightforward nature of the petition and the proceedings, the Committee does not anticipate that reasonable attorneys' fees will be large. (For example, attorneys' fees in a similar compensation program for black lung disease have proven to be well below those that might be expected in litigation and have, in almost all cases, been less than $15,000 in total.)

Conversely, however, the Committee does not intend that the limitation of fees to those included in the award act to limit petitioners' ability to obtain qualified assistance and intends

that the court make adequate provision for attorneys' time and that the court exercise its discretion to award fees in non-prevailing, good-faith claims.

Subsection (e)—Payment of Compensation.—Except for ongoing medical and rehabilitative expenses, compensation may not be paid until an election is made under Section 2121 (described below) to accept the compensation and to waive the right to bring a civil action against a vaccine manufacturer. Compensation for unreimbursable actual expenses for medical and rehabilitative care is to be paid from the date of judgment on a petition and is to cease if an election is made under Section 2121 (described below) to reject the compensation and to bring a civil action. Payment of compensation is to be exempt from Federal reduction orders.

Subsection (f)—Program Not Primarily Liable.—Payment of compensation is not to be made for items or services for which payment has been made or can be expected to be made by other public or private entities. Thus, if an insurance program or a health maintenance organization pays or is obligated to pay for health care services, the Program is not to pay for these same services.

Subsection (g)—Liability of Health Insurance Carriers, Prepaid Health Plans and Benefit Providers.—No health insurance policy may make benefits secondary to benefits under the Program. Similarly, no State or pre-paid health plan may make benefits secondary to benefits under the Program. Thus, the elimination of vaccine-related injuries from an insurance program or a health maintenance organization which would cover similar injuries or conditions which are not vaccine-related is not allowed.

Section 2116—Limitation of Actions

Subsection (a)—General Rule.—As described in Section 2111 (above), the bill divides vaccine-injured persons into three general groups: 1) those who were injured by a vaccine more than eight years before enactment of the legislation; 2) those who were injured by a vaccine that was administered before the enactment of the legislation but less than eight years ago; and 3) those who are *****6364 *23*** injured by a vaccine that is administered after the enactment of the legislation.

Persons in the first group are not eligible to receive compensation.

Persons in the second group must file a petition within two years of promulgation of regulations implementing the Program.

Persons in the third group who are seeking an award for injury must file a petition within three years of the first manifestation of the illness. Persons in the third group who are seeking an award for a death must file a petition within two years of the death or within four years of the first manifestation of the illness, whichever is earlier.

Subsection (b)—Effect of Revised Table.—If the Table is revised (as described above in Section 2114) and the effect of the revision is to make an individual eligible for compensation, that individual must file a petition within two years of the effective date of the revision. No compensation is to be provided, however, for an injury or death that occurred more than eight years before the date of the revision.

Subsection (c)—State Limitations of Actions.—If a petition is filed under the Program, the State statute of limitations is to be stayed with respect toa civil action for a vaccine-related injury or death. If, for example, a State law provides that a civil action must be brought within three years of the onset of an injury and if a petition is filed two and a half years after the onset of a vaccine-related injury and if—following the compensation proceedings—a petitioner then elects to initiate a civil action, the State limitation of actions is to be stayed for the duration of the

compensation proceedings and the petitioner, in this example, would have six months after the judgment on compensation in which to initiate a civil action under the State law. If, however, the State statute of limitations makes special provisions for minors such that actions need not be brought before the age of 18 and if the petitioner files for compensation at age three and, at age four, elects to reject the compensation judgment and initiate a civil action, then the State statute of limitations is unaffected and the civil action may be brought until the age of 18.

Section 2117—Subrogation

Subsection (a)—Generally Rule.—The Vaccine Injury Compensation Trust Fund (described below in Title II) is to be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation is paid. This right of subrogation does not, however, allow the Fund to recover an amount greater than the compensation paid. The court may refer the record of a compensation proceeding to the Secretary and to the Attorney General with recommendations as to subrogation.

While the Committee recognizes that other similar authorities of subrogation of rights of recovery are often unexercised, the Committee anticipates that the Secretary, in an effort to ensure the solvency of the Fund and to lower the surcharge necessary to continue the Fund, will vigorously pursue the rights of the government in this instance.

****6365 *24** *Subsection (b)—Disposition of Amounts Recovered*.—Amounts recovered under this authority are to be deposited in the Fund.

Section 2118—Increase for Inflation

The compensation set for death benefits and for maximum awards for pain and suffering under Section 2115 (described above) are to be increased to account for inflation. The civil penalty authorized under Section 2128 (described below) is to be similarly increased. This provision is adopted in an attempt to maintain these provisions at meaningful levels, rather than allowing them to become token amounts.

Section 2119—Advisory Commission on Childhood Vaccines

Subsection (a)—Establishment.—The Advisory Commission on Childhood Vaccines is to be established and is to be composed of nine members appointed by the Secretary. These members are to be health professionals, members of the general public, and attorneys. The Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control, the Commissioner of Food and Drugs are to be ex officio members.

Subsection (b)—Term of Office.—Members are to be appointed for three year terms, although initial members are to be appointed to staggered terms.

Subsection (c)—Meetings.—The Commission is to meet four times a year and at the call of the chair.

Subsection (d)—Compensation.—Standard compensation provisions are made for Commission members.

Subsection (e)—Staff.—The Secretary is to provide appropriate staff to the Commission.

Subsection (f)—Functions.—The Commission is established to advise the Secretary on the implementation of the Program, the modification of the Table, the improved safety of vaccines,

and the gathering of information on vaccine-associated injuries. The Commission to the Director of the National Institutes for Health on research on vaccine safety.

Part B—Additional Remedies

Part B modifies the requirements for the pursuit of remedies beyond the system for a vaccine injury or death. Should a petitioner choose to reject the judgment and award of the Special Master and the court, he or she is free to pursue whatever additional remedies may be available under applicable law. In so doing, however, the petitioner must proceed in accordance with specific trial procedures outlined below. Manufacturers defending against such actions may, in turn, raise certain presumptions and standards of liability, also outlined below.

Section 2121—Authority to Bring Actions

Subsection (a)—Election.—The provision sets forth the options available to the petitioner once the judgment of the district court regarding the petition for compensation has become final. At any point not later than 90 days from the date that a final judgment *****6366 *25*** has been entered, the petitioner may file an election in writing either to accept the court's judgment (whether it awarded compensation or not) or to file a civil action for damages for the vaccinerelated injury or death.

The election must be filed in writing even if the court has refused to award compensation In the event that the petitioner fails to file an election in writing within the 90-day period, he or she will be deemed to have accepted the court's judgment.

If a petitioner elects to receive compensation or is deemed to have accepted the court's judgment, he or she may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered.

Subsection (b)—Limitation of Actions.—After the petitioner has completed a proceeding for compensation and has made a timely election in writing not to accept the compensation award (or the judgment of the court denying compensation), the statute of limitations governing the filing of an action for damages arising from the vaccine-related injury or death will be that which is set forth in applicable State law. Under this provision, the petitioner must elect in writing within 90 days whether or not to accept the court's final judgment regarding compensation.

Should the petitioner properly elect to file a civil action for damages, he or she must then look to State law to determine the period within which such an action for damages must be filed. A number of States have statutes of limitations that are stayed during the period in which one is a minor. Except for the requirement (where applicable) that one file a petition for compensation within the proper time period as a prerequisite to filing a civil action for damages and the provision in Section 2116(c) (discussed above) that stays the statute of limitations during the pendency of a petition for compensation, nothing in this legislation is intended to affect these statutes of limitations—or any other provisions of State statutes of limitations—with respect to the filing of civil actions for damages for a vaccine-related injury or death.

Section 2122—Standards of Responsibility

Subsection (a)—General Rule.—This section establishes certain standards of responsibility with respect to civil actions brought for damages for vaccine-related injuries or death. In some cases, the standards will be the same or similar to existing State law; in others, the standards will

change most State laws. The Committee believes that the establishment of these standards of responsibility is appropriate in light of the availability of a comprehensive and fair compensation system. However, the establishment of these standards are the only new requirements that affect State law regarding actions for vaccine-realted injuries or death; all other aspects of State law remain unchanged.

Subsection (b)—Unavoidable Adverse Side Effects; Direct Warnings.—This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even through the vaccine was *****6367 *26*** properly prepared and accompanied by proper directions and warnings.

The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system. The vaccines addressed in this legislation certainly present the hardest case for the application of Comment K. In such a case, the plaintiff is almost invariably a young child, often badly injured or killed, and free from wrongdoing. And, even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense.

The Committee believes that this bill offers another, better, alternative. Part A establishes a no-fault compensation system that goes far beyond even the most expensive ruling issued by in a court in a vaccine case. Under this compensation system, vaccine-injured persons may obtain a full and fair award for their injuries even if the manufacturer has made as safe a vaccine as possible. Petitioners are compensated because they suffered harm from the vaccine—even a 'safe' one—not because they demonstrated wrongdoing on the part of the manufacturer.

Given the existence of the compensation system in this bill, the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should pursue recompense in the compensation system, not the tort system.

For purposes of this subsection, a vaccine is presumed to be accompanied by proper directions and warnings where the manufacturer demonstrates that it complied in all material respects with relevant Federal law governing the approval and labeling of the vaccine. This presumption may be overcome, however, but only upon a showing that the manufacturer engaged in fraudulent conduct or intentional and unlawful withholding of information in obtaining premarket approval for the vaccine from the Food and Drug Administration; *or* upon a showing that the manufacturer intentionally and wrongfully withheld information relating to the vaccine's safety or efficacy after it was approved; *or* upon a showing, by clear and convincing evidence, that the manufacturer failed to exercise due care notwithstanding its compliance with relevant Federal law.

In establishing this pesumption, the Committee intends to make clear its view that only those significant failures to warn or provide directions that clearly pertain to vaccine safety and that clearly arise from substantial wrongdoing on the part of the manufacturer ought to result in liability.

***6368 *27** *Subsection (c)—Direct Warnings*.—Subsection (c) addresses a line of cases in which vaccine manufacturers have been held liable for their failure to provide warnings directly to the injured party. (See, e.g., *Givens* v. *Lederle*, 556 F.2d 1341 (5th Cir. 1977), *Reyes* v. *Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) and *Davis* v. *Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968).) Its purpose is to establish the principle that no vaccine manufacturer is to be held liable for damages arising from a vaccine-related injury or death solely due to its failure to provide direct warnings to the injured party (or the injured party's legal representative). If the manufacturer provides an adequate warning and adequate directions to an intermediary such as a doctor, nurse, or pharmacist who can be expected to know about the product and its risks, and who is reresponsible for informing the ultimate recipient of a vaccine (or the recipient's legal representative), the manufacturer should not be held liable for any failure to warn or provide directions directly to a person (or a person's legal representative) who is injured from the vaccine. Thus, once the manufacturer provides adequate warnings and directions to such professionals, the manufacturer meets the requirements of this provision and fulfills its obligations under the law with respect to its duty to warn of potential vaccine risks or hazards.

Subsection (d)—Construction.—The provisions relating to an election made under Section 2121(a), as discussed above, are not intended to permit a petitioner to bring a civil action that would be barred by State doctrines of res judicata or collateral estoppel. Section 2111(a)(4) (above) permits a petitioner who received an adverse ruling from a court in a civil action brought against a vaccine manufacturer before the date of enactment of the legislation to file a petition for compensation. Nothing in this legislation, however, is intended to permit the filing of a new civil action upon completion of the proceeding for compensation if a final judgment denying recovery was entered in a previous civil action.

Subsection (e)—Preemption.—State statutes that effectively foreclose individuals from bringing civil actions from vaccine-related injuries or deaths or pre-empted by this subsection. The Committee intends for this preemption to apply even where a State has established a compensation system as an alternative to filing civil actions. It does not intend, however, to preempt statutes of limitations or other provisions of State law and practice that regulate the time or manner in which civil actions in general may be brought or maintained. Similarly, the Committee does not intend to preempt State statutes that limit damages, such as those that establish limitations or ‘caps' on awards for pain and suffering and mental anguish, in actions for personal injury or death.

Section 2123—Trial

Subsection (a)—General Rule.—Section 2123 provides for the trifurcation of civil actions against vaccine manufacturers for damages from a vaccine-related injury or death associated with the administration of a vaccine after the date of enactment of this subtitle which is not barred by any of the limitations contained in Section 2111(a)(2) (above).

***6369 *28** The purpose of this Section is not to bar in any way the introduction of otherwise admissible evidence concerning a vaccine-related injury or death in civil actions. Rather, its purpose is to establish rules for the timing of the introduction of such evidence in order to prevent irrelevant and prejudicial factors from unfairly influencing the outcome of trials. Thus, the legislation establishes three stages for the conduct of such civil actions.

Subsection (b)—Liability.—In the first stage of a trial for damages arising from a vaccine-related injury or death, the question of liability for such injury or death is to be determined separately, i.e., before any consideration of damages may be given to the issues of damages,

either general or punitive. Accordingly, this subsection requires that the court make a determination of liability before proceeding to consider questions of damages. Regardless of the court's evidentiary rulings under applicable law in this regard, the Committee urges courts to be diligent in addressing liability issues in a manner as free as possible from irrelevant and prejudicial factors (such as inflammatory material or documentation whose emotional impact can be exepected to overshadow necessary factual determinations).

Subsection (c)—General Damages.—Should the question of liability be decided against the defendant, the second stage of a civil action is to be held to determine the amount of damages, other than punitive damages, the defendant should be required to pay. In separating punitive damages from the first and second stages of a trial, the Committee intends to prevent the intorduction of evidence relating to the financial position of the vaccine manufacturer from these stages.

In establishing three separate stages of trial, the Committee does not intend, however, to bar the introduction of evidence respecting the defendant that is relevant either to the establishment of liability or the determination of damages simply because such evidence would establish the grounds for punitive damages as well. In establishing liability, for example, a plaintiff may demonstrate that the manufacturer produced a defective vaccine through clearly criminal behavior if that is what the evidence shows. The Committee also does not intend to limit plaintiffs to establishing liability by a preponderance of the evidence if they go further and can establish liability beyond a reasonable doubt.

Subsection (d)—Punitive Damages.—The third stage of a trial be held solely for the purpose of determining punitive damages where such damages are sought by the plaintiff and permitted by State law. Under this subsection, punitive damages are not to be awarded in cases arising from injuries or death associated with a vaccine if a determination is made that a vaccine manufacturer has complied with those specified provisions of the Public Health Service Act and the Food, Drug and Cosmetic Act relevant to vaccine safety. The Committee believes that punitive damages should be assessed only where particularly reprehensible, conscious behavior is involved. Where a manufacturer has attempted in good faith to comply with a government standard—even if the standard provides inadequate protection to the public—the manufacturer should not be assessed punitive damages absent evidence that it engaged in reprehensible behavior that directly resulted in the establishment of *****6370 *29*** maintenance of the standard's inadequacy. Section 2123(d)(2) sets forth the types of reprehensible behavior that would result in the imposition of punitive damages.

Subsection (e)—Evidence.—This provision bars the introduction into evidence in any civil action against a vaccine manufacturer of the existence of the Vaccine Injury Table (discussed in Section 2114 above), any finding of the district court or the Special Master appointed by the court, and the final judgment of the district court. Compensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of a tort proceeding and might confuse such civil actions.

Part C—Assuring a Safer Childhood Vaccination Program in the United States

The legislation mandates a number of procedures that must be followed for the maintenance of the safest and most effective childhood vaccination programs possible. While some of these procedures are already in place, others are not. Moreover, because current practices are not

mandatory, Federal officials may not be receiving all of the information that is needed to evaluate the safety and effectiveness of the various childhood vaccines.

Section 2125—Recording and Reporting of Information

Health care providers who administer the vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above) to keep permanent medical records on the administration of these vaccines, including information on the specific vaccine that was given. Both health care providers and vaccine manufacturers are also required to report to the Secretary on the occurrence within a 7-day period of any event set forth in the Table as well as the occurrence of any contraindicating reactions to the vaccine that are specified within the vaccine manufacturer's package insert. The reporting of these events is to begin within 90 days after the enactment of this legislation. Information concerning the nature of the reactions reported to the Secretary is to be made available to the public.

Section 2126—Vaccine Information

The Secretary must develop and disseminate within one year after the enactment of this legislation, information materials on the vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above). Such materials are to include information on the diseases these vaccines are designed to prevent, the potential adverse reactions to the vaccines, and the reporting mechanisms that should be followed when adverse reactions do occur. The materials are to be developed under a rulemaking procedure that includes sufficient opportunity for public comment. The Secretary is to disseminate the materials to health care providers who, in turn, are to distribute the information (or its equivalent) to the legal representatives of children receiving vaccines prior to the time such vaccines are administered.

****6371 *30** Section 2127—Mandate for Safer Childhood Vaccines*

The Secretary has the responsibility to promote the development and use of improved, safer childhood vaccines. In carrying out this mandate, the Secretary is to make appropriate use of each of the authorities concerning vaccine development, distribution, and use, including those relating to the activities of the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control, as well as the provisions of this legislation. Within two years after the date of enactment of this legislation, the Secretary is to report to the Congress on the actions that have been taken during this period to comply with this mandate.

Section 2128—Manufacturer Recordkeeping and Reporting

This section specifies the recordkeeping information that manufacturers are to prepare and maintain on the vaccines they produce as well as the reporting procedures they must follow upon the development of significant vaccine safety problems. These requirements are applicable both to the manufacturers of vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above) and to the manufacturers of any other vaccines which are mandated for use under State law. Section 2128 also provides for sanctions that are to be imposed on manufacturers and individuals who intentionally destroy, alter, falsify, or conceal the information that is to be provided under these requirements.

Part D—General Provisions

Section 2131—Citizens' Actions

Subsection (a)—General Rule.—Section 2131 provides standing to any person to bring an action in a district court of the U.S. against the Secretary where the Secretary has failed to perform any act or duty under this subtitle.

Subsection (b)—Notice.—Before bringing such an action under this Section, the person claiming a failure on the part of the Secretary to perform his or her duty must given written notice of intent to commence such an action. The purpose of requiring such notice is to permit the Secretary to come into compliance with this subtitle. Courts should consider the Secretary's good faith efforts to take substantial steps to come into compliance with this subtitle in issuing any final order against the Secretary.

Subsection (c)—Costs of Litigation.—In issuing any final order under this Section, a court may award costs of litigation (including reasonable attorney and expert witness fees) to any party (plaintiff or defendant) when appropriate. The Committee urges the courts to be judicious in awarding costs under this provision. Courts should be reluctant to give such awards to a plaintiff simply because he or she has demonstrated a technical violation of the law having little impact on any of its major purposes. Courts should, however, be reluctant to assess damages against unsuccessful plaintiffs where they have sought in good faith to compel the Secretary to perform his or her obligations under the law.

***6372 *31** *Section 2132—Judicial Review*

A petition for review of a regulation under this subtitle may be filed in a court of appeals within 60 days from the date of the promulgation of regulations or after such date if such petition is based solely on grounds arising after such 60th day.

Section 2133—Definitions

This section sets forth definitions that apply in Subtitle 2 of the legislation.

Subsection (1) defines the term ‘health care provider.’

Subsection (2) defines the term ‘legal representative.’ Because most individuals injured by vaccines are children, the Committee anticipates that legal representatives will be parties in the filing and processing of most petitions for compensation.

Subsection (3) defines the term ‘manufacturer.’ This section makes clear that the term is intended to be applied broadly to include public and private groups that manufacture, import, process, or distribute under their own label vaccines set forth in the Vaccine Injury Table (discussed in Section 2114 above). For purposes of recordkeeping and reporting (as well as the imposition of sanctions) under Section 2128 (above), the term includes any manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any state.

Subsection (4) defines the term ‘significant aggravation.’

Subsection (5) defines the term ‘vaccine-related injury or death.’

Subsection (6) defines the terms ‘Advisory Commission on Childhood Vaccines,’ ‘Vaccines Injury Table,’ and ‘National Vaccine Injury Compensation Trust Fund.’

Section 102—Related Studies

Subsection (a)—Review of Pertussis Vaccines and Related Illnesses and Conditions.—Within three years of the date of enactment of this legislation, the Secretary must complete a review of all relevant medical and scientific information on the nature, circumstances and extend of the relationship between vaccines containing pertussis and a specified list of illnesses and conditions.

Subsection (b)—Findings with Respect to Pertussis.—Within three years of the date of enactment of this legislation, the Secretary must make and publish in the Federal Register specific findings regarding the illnesses and conditions set forth in subsection (a) (above).

Subsection (c)—Revision of Table with Respect to Pertussis Vaccines.—At the time the Secretary publishes the findings required in subsection (b) (above), the Secretary must also propose such regulations as may be necessary to change the Vaccine Injury Table (discussed in Section 2114 above) in accordance with the findings made pursuant to subsection (b). The Secretary must promulgate such regulations no later than 42 months after the date of enactment of this legislation after providing an opportunity for a public hearing.

Subsection (d)—Review of MMR Vaccines and Related Illnesses and Conditions.—Within three years of the date of enactment of this legislation, the Secretary will complete a review of all relevant ***6373 *32** medical and scientific information on the nature, circumstances and extent of the relationship between vaccines containing rubella (including vaccines intended to prevent or confer immunity against measles, mumps, the rubella) and radiculoneuritis. Within this same time period, the Secretary is to make and publish in the Federal Register any findings regarding the relationship between rubella vaccines and radiculoneuritis. The Secretary is also required to propose such regulations as may be necessary to change the Vaccine Injury Table (discussed in Section 2114 above) in accordance with the Secretary's findings.

Subsection (e)—Pertussis and MMR Studies.—The Secretary is to arrange for studies with respect to vaccines containing pertussis and vaccines containing rubella (including MMR) in order to assist the Secretary in making the findings required in subsections (b) and (d) (above). The results of the studies are to be submitted to the House Committee on Energy and Commerce and the Senate Committee on Labor and Human Resources within 32 months of the date of enactment of this legislation. The studies must be made available to the public at the time they are submitted to the Secretary.

Section 103—Study of Other Vaccine Risks

Subsection (a)—Study.—Within three years of the date of enactment of this legislation, the Secretary is to arrange for a study of risks not studied under Section 102 (above) that are associated with the vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above). In addition, the Secretary is to establish guidelines respecting the administration of such vaccines including the circumstances under which such vaccines should not be administered, the circumstances under which administration of the vaccines should be delayed, as well as the groups, categories, or characteristics of potential recipients of such vaccines who may be at significantly higher risk of major adverse reactions to such vaccines than the general population of potential recipients.

Subsection (b)—Revision of Guidelines.—Not less than every three years, the Secretary is to review and revise the guidelines issued pursuant to subsection (a) (above). Should the Secretary find on the basis of such periodic reviews that no revision of the guidelines is necessary at that particular time, the Secretary shall publish that finding in the Federal Register.

Subsection (c)—Factors Affecting Guidelines.—This provision sets forth several factors that the Secretary must consider in establishing guidelines under subsection (a) (above).

Subsection (d)—Dissemination.—The Secretary is required to disseminate widely the guidelines establish under subsection (a) (above).

Section 104—Review of Warnings, Use Instructions, and Precautionary Information

Within one year of the date of enactment of this legislation, the Secretary is to review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines listed in the Vaccine Injury Table (discussed in Section 2114 above) and is to determine, by rule, whether such warnings, instructions ***6374 *33** and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines. If the Secretary should determine that any such warnings, instructions, or information is inadequate for this purpose, the Secretary must require the appropriate manufacturer or manufacturers to revise and reissue such warnings, instructions, or information as expeditiously as practical, but not later than 18 months after the date of enactment of this legislation.

Section 105—Recall Authority

Section 105 provides specific authority for the Secretary to seek the recall of any batch, lot or other quantity of a vaccine licensed under subsection (d) of Section 351 of the Public Health Service Act upon the Secretary's determination and issuance of an order (pursuant to Section 554 of the Administrative Procedure Act) indicating that the quantity of vaccine presents an imminent or substantial hazard to the public health.

The Committee understands that most recalls conducted by the Food and Drug Administration have been conducted on a voluntary basis even where no formal statutory authority for recall exists. The Committee does not intend this provision to displace existing voluntary procedures which have proven successful in protecting the public.

TITLE II—AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1954

Part I—National Vaccine Injury Compensation Trust Fund

Section 201—Establishment of National Vaccine Injury Compensation Trust Fund

Subsection (a)—In General.—The National Vaccine Injury Compensation Trust Fund (‘the Fund’) is established in the Treasury of the U.S. to include appropriated and credited amounts. There are appropriated to the Fund in amounts equal to the excise taxes of the vaccines covered by the Program (described below in Section 211) and to the amounts recovered by the Program in its rights of subrogation (described above in Section 2117). Expenditures from the Fund are for the purposes of the Program (described above in Title I, Subtitle 2, Part A).

Repayable advances to the Fund are authorized to be appropriated. These advances are, in essence, a loan to the Fund to carry out the Program. Such advances are to be repaid, with interest, to the general fund of the Treasury when the Secretary determines that the Fund has sufficient resources to do so.

The liability of the Federal government is limited to funds available in the Fund. Nothing in Title I of the bill is to be construed as authorizing the payment of any claim from any other source than the Fund. If at any time the Fund has insufficient funds to pay all claims payable, the claims shall be paid in full in the order in which they were determined.

Subsection (b)—Appropriation for Initial Funding of Trust Fund.—There is appropriated, as a repayable advance, $40 million for the initial establishment of the Fund, to remain available until expended.

****6375 *34** *Subsection (c)—Clerical Amendment*.—This subsection provides for an amendment to the table of sections.

Subsection (d)—Effective Date.—Except for subsection (b), the amendment made by this Section is to take effect on January 1, 1987. The amendment made by subsection (b) is to apply to fiscal year 1987.

12. RESTATEMENT (SECOND) OF TORTS § 402A (1965):

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or 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 the seller.

13. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965):

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