

Dear Clients & Friends,



We are pleased to present you with the Summer 2015 Edition of the Reminger Co., LPA Product

Liability Group Newsletter. The attorneys in our group continue to achieve success in defending our clients. The Results section in this newsletter highlights some of our successes in both motion practice and in trial.

We are also happy to share with you that our Product Liability Litigation Practice Group was ranked as Metropolitan Cleveland Tier 1 by *U.S. News and World Report's* 2015 Rankings. for the second consecutive year in a row. We are very proud of this distinction as it is based on client feedback and directly reflects our clients' satisfaction and approval of our work.

In an effort to keep our clients abreast of legal issues, we include in this newsletter an article on vaccines and products liability. We hope that you find this information useful even if it does not directly impact your business.

We are thankful for our relationships with our clients and for the opportunities you have provided in allowing us to continue to serve your legal needs. We wish each of you an enjoyable summer and look forward to the opportunity to work with you in the future.

Sincerely,

Michael Gilbride and Robert Yallech
Products Liability Practice Group
Co-Chairs

Recent Results

Summary Judgment

January, 2015: the court granted summary judgment our client, the designer and manufacturer of a radio remote control that operated a 10-ton overhead crane. The defendant brought our client into a product-liability action and asserted claims for indemnity and contribution. The defendant claimed that the defective design and manufacture of the remote control caused the accident in which the plaintiff was injured – an alleged “runaway” crane that moved without any human command to the remote control – and which exposed the defendant to liability.

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newsletter

Vaccines and Products Liability

By Joseph McCoy and Robert Yallech



I. INTRODUCTION.

Vaccines are one of the greatest success stories in public health.


Through use of vaccines, we have eradicated smallpox and nearly eliminated wild polio virus. The number of people who experience the devastating effects of preventable infectious diseases like measles, diphtheria, and whooping cough is at an all-time low. To ensure the continued success of vaccines in the United States, it's crucial to make sure that vaccines are safe.

Before vaccines are approved by the Food and Drug Administration (FDA), they are tested extensively by scientists to ensure they are effective and safe. Vaccines are the best defense we have against infectious diseases; however, no vaccine is actually 100% safe or effective for everyone because each person's body reacts to vaccines differently.¹

Controversy surrounding vaccines is nothing new. From the time that the English doctor Edward Jenner discovered the vaccine for smallpox in 1796, the public has been divided regarding the efficacy and

safety of vaccines. The Church has objected to vaccines on the basis that it interferes with the Lord's design, economists have expressed concern that vaccines will lead to unsustainable population increases, and satirists have produced cartoons showing cows' horns sprouting from the heads of recently vaccinated children.²

The Supreme Court of the United States entered the vaccine debate in 1905 when it decided *Jacobson v. Massachusetts*, holding that a “well-ordered society” must be able to enforce “reasonable regulations” in responding to “an epidemic disease which



threatens the safety of its members.” The Court—in an opinion authored by Justice John Marshall Harlan—upheld the authority of states to enforce compulsory vaccination laws, reasoning that the freedom of the individual must sometimes be subordinated to the common welfare.³ Today, all 50 states have laws requiring the vaccination of school children for many diseases, although exceptions are allowed for medical as well as religious reasons.

Recently, in response to the alleged “revived anti-vaccination movement,” many political leaders and health care experts publicly encouraged parents to have their children vaccinated. While concerns about unvaccinated children are seemingly heightened, another side of the vaccination issue has not attracted the same level of media scrutiny: what happens when someone claims that a vaccine caused injury? With all the recent headlines involving vaccinations, it might be beneficial for the products liability practitioner to know the answer to that question. As this article explains, the answer is somewhat complicated because of the “National Childhood Vaccine Injury Act,” (the “NCVIA”) and the United States Supreme Court’s response to the NCVIA in *Bruesewitz, et al. v. Wyeth LLC, et al.*⁴ Thanks to the NCVIA and *Bruesewitz*, answering the question of what happens when a vaccine allegedly causes injury now involves determining when state tort law is preempted by the NCVIA.

II. THE NATIONAL CHILDHOOD VACCINE INJURY ACT.

1. Background facts.

During the late 1970’s and early 1980’s, several lawsuits were filed against vaccine manufacturers and healthcare providers by individuals who believed that they or their children had been injured by various vaccines.⁵ Many of the lawsuits asserted vaccines caused disabilities and developmental delays in children. Some of these lawsuits resulted in substantial verdicts, which led to a massive increase in vaccine related tort litigation. As liability and prices soared, several vaccine manufacturers stopped producing vaccines due to the fear of being sued, which resulted in a vaccine

shortage and a concern about the return of epidemic disease.⁶ Plaintiffs conversely complained that despite the increase in the number of lawsuits, obtaining compensation for legitimate vaccine inflicted injuries was too costly and difficult.⁷

Responding to these issues, Congress established the National Vaccine Injury Compensation Program in the Department of Health and Human Services. The goal of the program was to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals determined to be injured by certain vaccines. The program established a no-fault alternative to the traditional tort system for resolving vaccine injury claims and was “designed to work faster and with greater ease than the civil tort system.”⁸ Determining that the administration of vaccines was too important to national health to allow it to be rendered financially impossible by tort law, Congress passed the National Childhood Vaccine Injury Act (“NCVIA”) in 1986 in order to keep manufacturers of vaccines in the market while still providing compensation for vaccine related injuries.

2. Brief overview of the process under the NCVIA.

Under the NCVIA, a vaccine injury claim begins with the electronic filing of a petition with the United States Court of Federal Claims located in Washington, D.C., naming the Secretary of Health and Human Services as the respondent. Vaccine injury cases are assigned to a Special Master who makes the factual and legal findings, and must do so within (except for two limited exceptions) 240 days. Once a vaccine petition is filed, there are two phases of the claim: entitlement and damages. The Court of Federal Claims must review objections to the Special Master’s decision and enter a final judgment, again within a statutorily prescribed time period. Once the Court of Federal Claims has entered a final judgment, the claimant can either accept the court’s judgment and forgo a traditional tort suit for damages or reject the judgment and seek tort relief from the vaccine manufacturer.⁹

The NCVIA is intended to provide fast,

informal adjudication, which is made possible partly by the Vaccine Injury Table. The Table lists the vaccines the NCVIA covers, describes each vaccine’s compensable adverse side effects, and indicates how soon after the vaccination those side effects typically manifest themselves.¹⁰ Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation without needing to show causation. It is also possible for a claimant to recover for unlisted side effects as well as for side effects that occur at times other than those specified in the Table. In those situations, however, the claimant must prove causation.¹¹ Unlike in tort suits, claimants under the NCVIA do not need to show that the vaccine was defectively manufactured, labeled, or designed in order to recover.

3. The relationship between NCVIA and state tort law.

While providing an alternative to the state tort system, the NCVIA does not eliminate state tort claims regarding vaccine related injuries. To the contrary, 42 U.S.C. § 300aa-22(e) forbids any state from establishing or enforcing “a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.” The NCVIA does nevertheless provide significant tort-liability protections for vaccine manufacturers. These protections include the following:

- The NCVIA requires claimants to seek relief through the compensation program before filing suit for more than \$1,000.¹²
- Under the NCVIA, manufacturers are immunized from liability for failure to warn if they have complied with all regulatory requirements (including but not limited to warning requirements) and have given the warning either to the claimant or the claimant’s physician.¹³
- Under the NCVIA, manufacturers are immunized from liability for punitive damages absent failure to comply with regulatory requirements, “fraud,” “intentional and wrongful withholding of

information,” or other “criminal or illegal activity.”¹⁴

The most important protection the NCVIA provides vaccine manufacturers—at least for purposes of the Supreme Court’s decision in *Bruesewitz*—is found in 42 U.S.C. § 300aa-22(b)(1):

(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.

Disagreements over the extent of the protection provided by subsection (b) is what led to the Supreme Court’s decision in *Bruesewitz, et al. v. Wyeth LLC*.

III. *Bruesewitz, et al. v. Wyeth LLC, et al.*

1. Background facts.

Russell and Robalee Bruesewitz filed a vaccine injury petition in the United States Court of Federal Claims, alleging that their daughter, Hannah, had suffered from residual seizure disorder and encephalopathy injuries as a result of being administered doses of a diphtheria, tetanus, and pertussis vaccine (“DTP vaccine”) manufactured by Lederle Laboratories. A Special Master denied their claims on various grounds, though they were awarded \$126,800 in attorney’s fees and costs. The Bruesewitzes elected to reject the unfavorable judgment, and they filed a lawsuit in Pennsylvania state court. Their complaint included the following allegations, all under Pennsylvania common law:

- the defective design of the DTP vaccine caused Hannah’s disabilities;
- the defendant manufacturer was subject to strict liability; and
- the defendant manufacturer was subject

to liability for negligent design.¹⁵

After the defendant removed the case to the United States District Court for the Eastern District of Pennsylvania, the District Court granted the defendant summary judgment on the strict liability and negligence design defect claims, holding that the Pennsylvania law providing those causes of action was preempted by 42 U.S.C. § 300aa-22(b)(1).¹⁶ The United States Court of Appeals for the Third Circuit affirmed, and the Supreme Court granted certiorari.¹⁷ The precise question the Supreme Court considered in the case was “whether a preemption provision enacted in the National Childhood Vaccine Injury Act of 1986 (NCVIA) bars state-law design-defect claims against vaccine manufacturers.”¹⁸

2. The majority’s holding.

The Court held that state law design defect claims are preempted by the NCVIA. Justice Scalia authored the majority opinion for the Court, Justice Brennan concurred, and Justices Sotomayor and Ginsburg dissented. As is typical of Justice Scalia, the majority opinion consisted of a close textual analysis of the statute at issue:

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.¹⁹

Justice Scalia reasoned that in this statutory text, “[t]he ‘even though’ clause clarifies the word that precedes it” and “delineates the preventative measures that a vaccine manufacturer must have taken for a side-effect to be considered ‘unavoidable’ under the statute.”²⁰ This means that as long as a vaccine was properly prepared and was accompanied by a proper warning, “any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable.”²¹ Justice Scalia explained that because “[a] side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine

not containing the harmful element,” the “language of the provision...suggests that the *design* of the vaccine is a given, not subject to question in the tort action.”²²

Justice Scalia justified the majority opinion with another textual argument: the statute fails to mention design defect liability while it specifically refers to liability for defective manufacture and defective directions or warnings. Citing a treatise on the law of torts as well as the third Restatement, Justice Scalia explained that “[p]roducts-liability law establishes a classic and well known triumvirate of grounds for liability: defective manufacture, inadequate directions or warnings, and defective design.” The specific references to liability for defective manufacture and defective directions or warnings makes the absence of liability for defective design more than a coincidence to Justice Scalia and the majority: “It seems that the statute fails to mention design-defect liability ‘by deliberate choice, not inadvertence....’ *Expressio unius, exclusion alterius.*”

The majority opinion found further support for its conclusion from the structure and regulations of the NCVIA. The regulations accompanying the NCVIA require a vaccine’s license to disclose the manufacturing method that must be followed as well as the directions and warnings that must supplement the product.²³ If a product deviates from the license, that deviation provides objective evidence of manufacturing defects or inadequate warnings, and manufacturers must obtain the Food and Drug Administration’s approval before modifying either the manufacturing method or the directions and warnings. More than 90 Food and Drug Administration regulations regulate the manufacturing process.

Design defects conversely, are not mentioned in the NCVIA or the Food and Drug Administration regulations, and Justice Scalia finds this absence profound: “[T]he lack of guidance for design defects combined with the extensive guidance for the two grounds of liability specifically mentioned in the Act strongly suggests that design defects were not mentioned because

they are not a basis for liability.”²⁴ Justice Scalia reasons that it makes sense that Congress intended to eliminate liability for design defects because design defect torts “have two beneficial effects: (1) prompting the development of improved designs, and (2) providing compensation for inflicted injuries.”²⁵ Because Congress accounted for both of these effects within the NCVIA with its generous compensation scheme and by directing the Secretary of Health and Human Services “to promote ‘the development of childhood vaccines that result in fewer and less serious adverse reactions,’” it makes sense that Congress intended to eliminate state tort liability for design defect claims.²⁶

3. The dissent’s argument.

Justice Sotomayor’s principal disagreement with the majority centers on the meaning of the word “unavoidable” in 42 U.S.C. § 300aa-22(b)(1). She would interpret the word “unavoidable” as a term of art incorporating comment *k* of the Restatement (Second) of Torts § 402A (1963-1964). The Restatement generally holds manufacturers strictly liable for harm caused to person or property when that harm is caused by “any product in a defective condition unreasonably dangerous to the user.”²⁷ Under comment *k*, “unavoidably unsafe products” are exempted from the strict liability rule. Justice Sotomayor argues that Congress was referring to comment *k* of the Restatement by using the word “unavoidable,” and therefore had no intention of preempting state law design defect claims.

Justice Scalia dispensed with the dissent’s

argument without considering “the finer points of comment *k*.”²⁸

Whatever consistent judicial gloss that comment may have been given in 1986, there is no reason to believe that § 300aa-22(b)(1) was invoking it. The comment creates a special category of “unavoidably unsafe products,” while the statute refers to “side effects that were unavoidable.” That the latter uses the adjective “unavoidable” and the former the adverb “unavoidably” does not establish that Congress had comment *k* in mind. “Unavoidable” is hardly a rarely used word.²⁹

IV. CONCLUSION

Regarding the question of what can be done about the unvaccinated child—the question so prominent in the news media today—this article is of no use. However, this article hopefully provides the products liability practitioner with some guidance in answering the question of what happens when an individual claims that a vaccine has caused some sort of injury. The NCVIA establishes an elaborate system for vaccine related claims to be adjudicated, and most claims must start in the United States Court of Federal Claims. Because of the NCVIA and *Bruesewitz*, all state tort law design defect claims are preempted.

¹See the Centers for Disease Control and Prevention, “History of Vaccine Safety,” http://www.cdc.gov/vaccinesafety/vaccine_monitoring/history.html (last accessed 3/19/15).

²See “The Return of the Vaccine Wars,” by David

Oshinsky.

<http://www.wsj.com/articles/the-return-of-the-vaccine-wars-1424463778> (last accessed 2/20/15).

³*Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

⁴131 S.Ct. 1068 (2011).

⁵Freed GL, Katz SL, Clark SJ., Safety of vaccinations: Miss America, the media, and public health. (<http://www.ncbi.nlm.nih.gov/pubmed/8968002>).

⁶Sing & William, *Supplying Vaccines: An Overview of the Market and Regulatory Context, in Supplying Vaccines: An Economic Analysis of Critical Issues*, 45, 51-52 (M. Pauly, C. Robinson, S. Sepe, M. Sing, & M. William eds. 1996).

⁷See Apolinsky & Van Detta, *Rethinking Liability for Vaccine Injury*, 19 Cornell J.L. & Pub. Pol’y 537, 550-51 (2010).

⁸*Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995).

⁹See 42 U.S.C. § 300aa.

¹⁰42 U.S.C. § 300aa-14(a); 42 CFR § 100.3 (current Vaccine Injury Table).

¹¹42 U.S.C. § 300aa-11(c)(1)(C)(ii).

¹²42 U.S.C. § 300aa-11(a)(2).

¹³See 42 U.S.C. § 300aa-22(b)(2), (c). The immunity does not apply if the plaintiff establishes by clear and convincing evidence that the manufacturer was negligent, or was guilty of fraud, intentional and wrongful withholding of information, or other unlawful activity.

¹⁴42 U.S.C. § 300aa-23(d)(2).

¹⁵See *Bruesewitz v. Wyeth LLC*, 561 F.3d 233, 237. The complaint also made claims based upon failure to warn and defective manufacture. Because these claims were no longer at issue before the Supreme Court, they are not addressed here.

¹⁶*Id.* at 237-38.

¹⁷*Bruesewitz v. Wyeth LLC*, 131 S.Ct. 1068 (2011).

¹⁸*Id.*

¹⁹42 U.S.C. § 300aa-22(b)(1).

²⁰*Bruesewitz*, 131 S.Ct. at 1075 (emphasis in original).

²¹*Id.* (emphasis added).

²²*Id.* (emphasis in original).

²³42 U.S.C. § 262(a), (j); 21 C.F.R. §§ 601.2(a), 314.105(b) (2010).

²⁴*Bruesewitz*, 131 S.Ct. at 1079.

²⁵*Id.*

²⁶*Id.* citing 42 U.S.C. § 300aa-27(a)(1).

²⁷Restatement (Second) § 402A, p. 347.

²⁸*Bruesewitz*, 131 S.Ct. at 1077.

²⁹*Id.*

Recent Results (con’t).

Judgment Affirmed

December, 2014: Plaintiff appealed adverse trial court judgment in products liability personal injury claim

Defense Verdict

August, 2014: Arbitration defense of lemon law and breach of express warranty claim

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Hugh Bode

Products Liability Shareholder Spotlight



“Jurors want to do the right thing by making the correct decisions at trial.

I see myself foremost a teacher who delivers the persuasive understandable information they need to make those correct decisions.”

-Hugh Bode

Hugh Bode joined Reminger Co., L.P.A. in 1976 as a clerk-investigator. He now leads the firm’s Products Liability Department. Hugh specializes in the representation of manufacturers of motor vehicles, machinery, chemicals and consumer products. He has successfully tried over 130 jury trials in courts throughout Ohio and in many other states. He lists among his successes several of the most significant automotive products liability cases tried in the last 20 years.

In addition to trial work, Hugh also represents manufacturers before the U.S. Consumer Products Safety Commission and other administrative agencies. In that capacity he has formulated and managed nationwide corrective action campaigns.

Hugh is a Sustaining Member of the Products Liability Advisory Council. He has lectured on products liability issues to engineering students at The Ohio State University and executives at the European School of Management and Technology, Schloß Gracht.

Education

- J.D., Case Western Reserve University School of Law, 1978
- B.A., Northwestern University, 1975

Bar Admissions

- State of Ohio, 1978
- U.S. District Court, Northern District of Ohio, 1979
- U.S. Court of Appeals, Sixth Circuit, 1979
- U.S. District Court, Southern District of Ohio, 2002
- State of Kentucky, 2003

Honors and Recognitions

- Listed in Best Lawyers in America
- Recognized as a Super Lawyer in *Ohio Super Lawyers Magazine* from 2010 through 2015

Professional Memberships

- DRI
- Product Liability Advisory Council



Reminger's Product Liability Practice Group represents manufacturers, importers, and distributors of various products including automobiles, boats, medical devices, pharmaceuticals, and industrial machinery.



Nationally recognized, we serve major multi-national corporations as well as small market entrepreneurs. Members of this practice group are admitted to the bar in Ohio, Kentucky, West Virginia, Tennessee, Michigan and Indiana.

Our attorneys have successfully tried to verdict cases with 'bet the company' exposure and national media attention. Their technical expertise and advocacy abilities obtain outstanding results at trial, during discovery and in mediations and negotiations. They are known personally to the scientific community and are able to obtain the assistance of prominent, highly qualified consultants in the physical and material sciences.

In addition to the typical products case, our attorneys have appeared before the U.S. Consumer Product Safety Commission to address the broad based issues concerning product recalls and nationwide corrective action programs.

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