

CoMeD Inc.

14 Redgate Court,
Silver Spring, MD 20905-5726

Friday, 2 April 2010

To All:

The text following this page is an abbreviated statement on this lay person's views on the underlying legal issues in ***Bruesewitz v. Wyeth***, a "trial by jury preemption case" involving a purportedly vaccine-damaged child and his family's right to pursue a trial by jury as provided in Section 300aa-23 of the "National Vaccine Injury Compensation Program" (NVICP) as set forth in Title 42 of the United States Code (42 U.S.C.) in Sections 300aa-10 through 300aa-34.

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This statement, titled "***Bruesewitz v. Wyeth: A layperson's abbreviated views: The 7th amendment to the Constitution of the USA, the National Vaccine Injury Compensation Program (NVICP) [42 U.S.C. § 300aa-10 et seq.], and Wyeth's absolute, nondischargeable duty to prove that its vaccine was safe***", begins on the next page.

REVIEWER'S INTRODUCTORY REMARKS

First, to "*simplify*" this response, this reviewer's remarks are in a "Georgia" font except, when he quotes from or refers to:

- a. The pending U.S. Supreme Court Case documents or sections from filed documents filed appertaining thereto, the text will be in a "Times New Roman" font
- b. The Constitution of the United States of America, or any US statute or regulation, the text will be in a "Verdana" font, and
- c. Other sources, the quotations will be in an "Arial Narrow" font.

Finally, should anyone find any significant factual error for which they have published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and appropriately revise his views.

Respectfully,

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Paul G. King, PhD,
CoMeD Science Advisor
33A Hoffman Avenue
Lake Hiawatha, NJ 07034-1922
Email: drking@gti.net
Tel. 1-973-997-1321, after 19:00 Eastern Time
[To whom all inquiries should be directed]

***Bruesewitz v. Wyeth: A layperson's abbreviated views:
The 7th Amendment to the Constitution of the USA,
the National Vaccine Injury Compensation Program
(NVICP) [42 U.S.C. § 300aa-10 et seq.], and
Wyeth's absolute, nondischargeable duty to prove
that its DTP vaccine was safe***

The case that the United States Supreme Court has agreed to hear is:

"No. 09-152

In the Supreme Court of the United States

RUSSELL BRUESEWITZ, ROBALEE BRUESEWITZ,
PARENTS AND NATURAL GUARDIANS OF
HANNAH BRUESEWITZ, n MINOR CHILD AND
IN THEIR OWN RIGHT,
Petitioners,

v.

WYETH, INC. F/K/A WYETH LABORATORIES, WYETHAYERST
LABORATORIES, WYETH LEDERLE, WYETH
LEDERLE VACCINES AND LEDERLE LABORATORIES,
Respondents.

THE QUESTION BEFORE THE COURT

Simplistically, the question presented to the Supreme Court to answer has been framed as:

"Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 (Act) expressly preempts certain design defect claims against vaccine manufacturers '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).

Did the Third Circuit err in holding that Section 22(b)(1) preempts all vaccine design defect claims, regardless of whether the vaccine's side effects are unavoidable?"

THIS LAYPERSON'S SIMPLE ANSWER

Based on:

- ◆ The Seventh Amendment to the Constitution of the United States of America, which plainly grants every citizen the right to trial by jury in civil matters where there is a controversy and the amount in question exceeds 20 dollars;
- ◆ The plain provisions of the NVICP, which clearly place 42 U.S.C. Section 300aa-22 as an issue to be decided within a civil trial under Amendment 7 to the Constitution of the United States of America in 42 U.S.C. Section 300aa-23; and
- ◆ The absolute nondischargeable duty that respondent Wyeth, a drug maker and the manufacturer of the vaccine in question, has to prove its drug, a biological drug product, or any component thereof¹, is safe to all of the applicable safety standards, including, but not limited to, those set forth in 21 CFR § 610.15(a),

the short answer to the question before the Court is:

Yes, the Third Circuit erred because, *as enacted by Congress*, 42 U.S.C. Section 300aa-22 is clearly only intended to be considered in the first phase of a trial by jury afforded to the petitioners under the Seventh Amendment to the Constitution of the United States of America as provided for in “42 U.S.C. § 300aa-23. Trial”.

Nowhere else in the National Vaccine Injury Compensation Act (42 U.S.C. §§ 300aa-1 through 300aa-34) or the National Vaccine Injury Compensation Program (NVICP) [42 U.S.C. §§ 300aa-10 through 300aa-34] does the language set forth address the use, or applicability, of Section 300aa-22.

Moreover, the absolute, nondischargeable duty that the respondent Wyeth has to prove safety precludes any pre-trial finding that seeks to interpose itself between respondent Wyeth and respondent Wyeth's duty to prove, during the first phase of

¹ 21 U.S.C. § 321(g)(1) “The term ‘drug’ means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)” (emphasis added).

the civil trial, that respondent Wyeth met the “Standards of Responsibility” set forth in 42 U.S.C. § 300aa-22, including those set forth in § 300aa-22(b) which states:

“(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.**

(2) For purposes of paragraph (1), a **vaccine** shall be **presumed** to be **accompanied by proper directions and warnings** if the vaccine manufacturer shows that it complied *in all material respects* with all *requirements* under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (**including regulations issued under such provisions**) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless ...” (emphasis added).

Further, in this section of the NVICP, “*including regulations issued under such provisions*” encompasses respondent Wyeth’s providing:

- ◆ Scientifically sound and appropriate toxicological proof that the Thimerosal used as a preservative in the Wyeth DTP vaccine in question was proven to be “*sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, ...*” and
- ◆ Satisfactory toxicological evidence that the vaccine’s adjuvant, a polymeric hydroxylaluminum compound present in this DTP vaccine, was proven to “*not affect adversely the safety ... of the product*”².

² 21 CFR § 610.15(a) § 610.15 Constituent materials.

“ (a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, and in the

THE LAYPERSON’S ABBREVIATED ARGUMENT

Based on the Constitution of the United States of America, neither Congress nor the Court has the right to abridge the 7th Amendment thereto, which clearly, and without restriction, states:

“In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law”.

In recognition of this reality, when Congress enacted the National Vaccine Injury Compensation Program (NVICP) legislation (42 U.S.C. §§ 300aa-10 through 300aa-34), setting up the “vaccine court”, an administrative body and not a legal “Court of the United States” (where facts are tried), the Congress preserved the petitioners’ right to bring a civil action under Amendment 7 to the Constitution of the United States of America in 42 U.S.C. §300aa-11(a)(2)(A) where the statute plainly states:

“Sec. 300aa-11. Petitions for compensation

(a) General rule

(1)

(2)(A) No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for

combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume (v/v) glycerin. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. The amount of aluminum in the recommended individual dose of a biological product shall not exceed:

(1) 0.85 milligrams if determined by assay;

(2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or

(3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe and necessary to produce the intended effect are submitted to and approved by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing addresses in §600.2 of this chapter)” (emphasis added).

such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and -

(i) (I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section”. [Emphasis added.]

Thus, Congress clearly intended to preserve a person’s right for a civil action provided the person submitted a petition under the NVICP and either –

- ❖ **exhausted his or her administrative remedies (see 42 U.S.C. § 300aa-11(a)(2)(A)(i)) or**
- ❖ **elected to withdraw such petition under section 300aa-21(b) (see 42 U.S.C. § 300aa-11(a)(2)(A)(ii)).**

Furthermore, the issues surrounding § 300aa-22 are clearly remanded to the purview of the civil trial by jury in § 300aa-23, which states:

“CHAPTER 6A - PUBLIC HEALTH SERVICE – SUBCHAPTER XIX - VACCINES

Part 2 - National Vaccine Injury Compensation Program

subpart b - additional remedies

Sec. 300aa-23. Trial³

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

³ Consistent with the Seventh Amendment to the Constitution of the United States of America, the trial referred to here is clearly a trial by jury.

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in -

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible” (emphasis added).

Thus, because § 300aa-22 only has meaning within § 300aa-23, “Trial”, and nowhere else within the NVICP, no Court may legally grant summary judgment pursuant to any aspect of § 300aa-22 because Congress clearly placed it as the primary issue to be decided in the first phase of a civil trial by jury (see: § 300aa-23(b)):

“(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title” (emphasis added).

Therefore, all issues raised within § 300aa-22 are clearly issues to be decided at trial by jury and, because Amendment 7 to the Constitution of the United States of America requires that “*the right of trial by jury shall be preserved*”, no Court has the authority to preemptively impose its judgment in any fashion, be it summary or otherwise, before the constitutionally guaranteed “right of trial by jury” has been granted and the first phase of said trial by jury has been conducted as Congress clearly provided in § 300aa-23(b) or, before aforesaid “*first stage of such a civil action*”, the respondent has admitted that it is liable or has been found to be legally liable because of its on-going knowing failure to comply “*in all material respects* with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought” as set forth in 42 U.S.C. § 300aa-22(b)(2).

Furthermore, respondent Wyeth’s absolute, nondischargeable duty to prove the safety of its drug, a DTP vaccine in this instance, precludes respondent Wyeth from using the actions, or inactions, of the US Food and Drug Administration as any preemptive defense to respondent Wyeth’s proving in a jury trial that respondent Wyeth complied “*in all material respects* with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought” as set forth in 42 U.S.C. § 300aa-22(b)(2).

Therefore, respondent Wyeth’s proof of compliance with the safety requirements of 21 CFR § 610.15(a) is clearly a prerequisite for respondent Wyeth’s proof that it met its “Standards of Responsibility” under 42 U.S.C. § 300aa-22(b) based on:

- ◆ The preceding safety requirement for preserved biological drug products including respondent Wyeth’s DTP vaccine;
- ◆ The plain language of:
 - The 7th Amendment to the Constitution of the United States

- of America,
 - The NVICP sections 300aa-11, 300aa-21, 300aa-22 and 300aa-23,
 - The applicable statutes, and
 - The plain language used in 42 U.S.C. § 300aa-22(b)(2); and
- ◆ Respondent Wyeth’s *absolute, nondischargeable* duty to prove that it complied, “*in all material respects, with all requirements* under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (*including regulations issued under such provisions*)” applicable to the vaccine (*including the applicable plain CGMP safety regulations* set forth in 21 CFR § 610.15(a) for preserved and adjuvanted biological drug products such as respondent Wyeth’s DTP vaccine) and related to vaccine-related injury or death for which the civil action was brought (the lack of proper proof of: **a**) safety or **b**) a design that complied with the applicable laws and regulations for biological drug product safety *in all material respects*).

End of Argument

This Layperson's Background

Paul G. King, PhD, an Analytical Chemist with an MS in Inorganic Chemistry and a technical degree in Computer Programming and Systems Analysis, worked for corporations that, among their other activities, were engaged in the development and manufacture of drugs for about two decades.

During much of the latter part of that career and subsequently, Dr. King has been involved in understanding the drug regulations governing the manufacture of drugs, including vaccines and other biological drug products, in a manner that meets all of the applicable safety requirement minimums established by the US Food and Drug Administration.

In addition, he has thoroughly studied most of the provisions of the NVICP.

For more detailed information on the background of Dr. King, please visit his web site: <http://www.dr-king.com>.