

“WHAT DO I DO ABOUT THIS WORD, ‘UNAVOIDABLE’?”: RESOLVING TEXTUAL AMBIGUITY IN THE NATIONAL CHILDHOOD VACCINE INJURY ACT

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INTRODUCTION

The quote in the title of this Essay comes from Justice Breyer, expressing his frustration with the language of section 22(b)(1) of the National Childhood Vaccine Injury Act. Justice Breyer made this comment during the October 12, 2010, oral argument in *Bruesewitz v. Wyeth, Inc.*,¹ a case about the availability of state tort claims based on vaccine design defects. The question before the Court was whether that section expressly preempts such 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.”² The answer depends on whether, as the Supreme Court of Georgia held, a court must make a case-by-case determination whether a side effect was “unavoidable” before a claim is preempted,³ or whether, as the Third Circuit held, Congress made a categorical determination that all side effects occurring despite proper preparation and labeling are “unavoidable,” and that claims deriving from them are therefore preempted, eliminating all such design defect claims against vaccine manufacturers.⁴

Every court that has confronted this issue has found the language drafted by Congress to be, as Justice Ginsburg said, “certainly, to say the least, confusing.” This Essay seeks to clear up some of that confusion, arguing that the language of § 22(b)(1), when closely analyzed, calls for the categorical approach adopted by the Third Circuit. Rather than anticipating

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1. Oral Argument at p. 46, *Bruesewitz v. Wyeth, Inc.*, No. 09-152, available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/09-152.pdf

2. 42 U.S.C. § 300aa-22(b)(1).

3. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 140 (Ga. 2008).

4. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 245–46 (3d Cir. 2009), cert. granted, 130 S. Ct. 1734 (March 8, 2010).

a case-by-case analysis of unavoidability, the statute employs the word “unavoidable” as a term of art that establishes premises that when satisfied make a vaccine injury inherently “unavoidable.” This Essay argues Congress has demonstrated that it is willing to adopt this kind of categorical approach regarding the issue of unavoidability in other statutes. This Essay further argues that the text of § 22(b)(1), although muddled, supports a categorical approach, because it defines the premises that must be true in order for the conclusion of unavoidability to be reached.

I. THE PROBLEM

The Act created a National Vaccine Injury Compensation Program to handle claims against manufacturers for vaccine-related injuries. This program involves a no-fault scheme where claimants seek compensation from a “vaccine court.” If the claimant rejects the judgment of the vaccine court, she may pursue certain limited claims in state or federal court. The primary limit on such tort claims is that a claimant may not pursue a tort claim “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.” But what makes a side effect unavoidable? Looming in the background of this inquiry are thousands of potential lawsuits by parents of children with autism. These parents blame childhood vaccines for causing the disorder, but so far they have been turned away by the vaccine court because the court found the evidence linking vaccines to autism legally insufficient to establish causation.⁵

At the outset, it certainly seems that the statute’s failure to define the word “unavoidable” is an invitation for case-by-case analysis. The conclusion that an event is unavoidable can never be proven absolutely and is more properly labeled a judgment call. Judgment calls lend themselves very well to the close examination of circumstance. In the absence of a statutory definition, courts must examine the facts and circumstances of each case and consider the sum of nondecisive reasons in favor of an ad hoc conclusion as to whether a death was “unavoidable.” A court’s role is more limited, however, if the statute lists the premises that must be true in order to reach the conclusion at issue; in such a case, the court only determines whether those conditions are satisfied.

The inquiry then becomes whether § 22(b)(1) adopted such a categorical approach to the question of unavoidability. The Bruesewitz family argued before the Court that a categorical interpretation would “render[] the entire concept of unavoidability surplusage” because Congress could have left out the term and just said that claims based on design defects were preempted if the vaccine was properly manufactured and contained proper warnings. Both Justice Scalia and Justice Alito responded that this reading would in turn render the words following “unavoidable”—“even though the vaccine was properly prepared and was accompanied by proper directions and warnings”—mere surplusage. But both the word “unavoidable” and the words following it *do* serve a purpose: “unavoidable” is a term of art in tort law for

5. See, e.g., *Cedillo v. Sec’y of Health and Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010).

damages that are noncompensable.⁶ When it passed the Act, Congress employed this term of art to define which claims could not be brought outside of the vaccine court—i.e., those that were preempted. Furthermore, as discussed below, the words following “unavoidable” are premises that establish when an injury will be categorized as unavoidable.

The court below in *Bruesewitz* did little to help the resolution of this problem when it unnecessarily complicated the issue. Rather than taking the language of the statute head-on, the Third Circuit held that the term “unavoidable” is not defined anywhere in the Act, and instead justified its conclusion that § 22(b)(1) is a categorical exclusion by referencing the Act’s structure, purpose, and legislative history. The Act’s structure and purpose are indeterminate, however, as noted in oral argument: the Act can be seen as designed to compensate those injured by vaccines, whose claims were largely denied in courts prior to the Act; and it can also be viewed as enacting a policy choice to protect manufacturers from large, uncertain tort liability, thereby keeping prices low and keeping manufacturers in the market. The legislative history is also of little guidance. One committee report suggests a categorical approach,⁷ while another suggests a case-by-case approach.⁸ Such conflicting aids to interpretation are in fact no aid at all.

Fortunately, logic and context allow a textual analysis of § 22(b)(1) to “stand[] on its own, without need of (or indeed any assistance from)” these interpretive devices.⁹ Congress set the conditions that must be true—proper preparation, warnings, and directions—in order to reach the conclusion of unavoidability. This categorical proposition precludes a case-by-case approach.

II. THE LOGIC OF UNAVOIDABILITY

“Unavoidable” describes an absolute state. This absolute state is a legal conclusion that can only be reached through logical reasoning. Three contrasting types of reasoning could lead to a conclusion of unavoidability. The first—reasoning from observation—is precluded because unavoidability, being in the form of a negative, requires an inordinate amount of observation before one can even come close to reaching an acceptable level of probable accuracy. This is what Kathleen Sullivan, attorney for Wyeth, described in oral argument as “shadowboxing against an infinite number of theories about how there could have been a safer vaccine.” Anyone who has been asked to prove a negative understands this difficulty.

Alternatively, the conclusion of unavoidability could be reached the same way that the conclusion of liability is reached: a court could look at facts, and then decide based on some legal standard whether some occurrence was unavoidable. This is classic case-by-case analysis; the approach which the *Bruesewitz* family asked the Court to adopt. A final way to reach this conclusion is to construct premises that, when true, definitionally yield

6. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

7. H.R. Rep. No. 99-908, pt. 1, at 26 (1986).

8. H.R. Rep. No. 100-391, pt. 1, at 691 (1987).

9. *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich LPA*, 130 S. Ct. 1605 (2010) (Scales, J., concurring).

the conclusion. This creates a shortcut around the time consuming, case-by-case analysis: legislators make the judgment that if a, b, and c are true, conclusion x necessarily follows. Whether that proposition is accurate in the absolute sense is of no consequence. It is accurate in the legal sense—because it passed both houses of Congress, was signed by the president, and is not unconstitutional. This truth in the legal sense is what matters. A court need only determine if the premises are true. This is the classic categorical approach—the approach sought by Wyeth, and the approach Congress adopted in § 22(b)(1): all events (injuries from side effects) that result from administration of any vaccine and satisfies the premises of the Act (proper preparation, proper directions, and proper warnings) are categorically “unavoidable.”

III. CONGRESS IS COMFORTABLE DEFINING THE TERM “UNAVOIDABLE”

Although finding that something is unavoidable may seem like a judgment call naturally made by courts, Congress and agencies are comfortable making the categorical determination that when certain premises are true, events will be categorized as “unavoidable.” For example, an animal cruelty statute called the “28-hour law,” which was drafted in a similarly poor and redundant fashion, allowed animals in transport to be confined for more than 28 hours only if off-loading was “prevented by storm or by other accidental or *unavoidable causes which cannot be anticipated or avoided by the exercise of due diligence and foresight.*”¹⁰ Courts interpreting this language have held that when a transporter meets the specified conditions that follow the term “unavoidable,” he is within the defined universe of “unavoidable” and therefore exempt from the requirement.¹¹ In other words, when the premises (exercise of due diligence and foresight) are true, the conclusion (excess confinement was unavoidable) follows. When the premises are not true, the conclusion does not follow.¹² The statute called for and the courts applied a categorical approach. There was no need for case-by-case analysis, and none was used. This situation is similar to the proper analysis of “unavoidable” under the Vaccine Act: when facts establish that a vaccine was properly prepared and was accompanied by proper directions and warnings (like establishing due diligence under the 28-hour law), there is no further inquiry needed as to whether the resulting outcome was unavoidable.

Agencies, using power delegated from Congress, also define premises that lead to the conclusion that an event is “unavoidable.” One patent statute, for example, says, “[t]he Director may accept the payment of any maintenance fee . . . at any time after the six-month grace period *if the delay is shown* to the satisfaction of the Director *to have been unavoidable.*”¹³ The regulation interpreting this statute requires a patentee to show “that the delay *was unavoidable since reasonable care was taken* to ensure that the

10. Pub. L. No. 59-340, 34 Stat. 607–08 (codified as amended at 49 U.S.C. § 80502) (emphasis added).

11. See, e.g., *United States v. Boston & Maine R.R.*, 99 F.2d 635, 637 (1st Cir. 1938); *Chicago, Burlington & Quincy R.R. Co. v. United States*, 194 F. 342, 345 (8th Cir. 1912).

12. See *Boston & Maine R.R.*, 117 F.2d at 427.

13. 35 U.S.C. § 41(c)(1) (emphasis added).

maintenance fee would be paid timely. . . .”¹⁴ This regulation has been applied in a categorical fashion by courts: if the premise (reasonable care taken) is true, the conclusion (delay was unavoidable) will follow, and vice versa. In *Ray v. Lehman*, for example, the court noted, “the standard is unavoidable delay. . . . [I]n order to satisfy this standard, one must show that he exercised the due care of a reasonably prudent person.”¹⁵ Thus, in applying the phrase “unavoidable since reasonable care was taken,” the court only looks to see whether the premise is true. There are many other examples like this of agencies defining the premises that must be true for the conclusion of unavoidability to be reached.¹⁶

IV. “EVEN THOUGH” HAS A SPECIAL MEANING WHEN USED WITH “UNAVOIDABLE”

The primary difficulty of a textual analysis in this case arises because of the use of “even though” in § 22(b)(1). “Even though” is a subordinating conjunction. A subordinating conjunction joins a subordinate clause to a main clause and is used to indicate the relationship between the two clauses. Different subordinating conjunctions show different relationships. For example, they can be used to show cause or manner, indicate concession, fix a time, etc.¹⁷ In § 22(b)(1), as noted by the Third Circuit in *Bruesewitz*, “even though” connects the main clause, “side effects that were unavoidable”—which, were it not for the second clause, could stand alone as a complete thought—to the subordinate clause, “the vaccine was properly prepared and was accompanied by proper directions and warnings.” As discussed above, when congressional drafters choose a categorical approach, they do so by constructing premises that when true yield the conclusion: finding the truth of the premises leads to acceptance of the conclusion. Thus, for § 22(b)(1) to be categorical, one must show that “even though” connects the conclusion (in the main clause) to the premises (in the subordinate clause) in a relationship of causation; in other words, proper preparation, directions, and warnings leads to the conclusion that the side effect was unavoidable.

The problem is that “even though” is not usually used as a subordinating conjunction to show cause. The most appropriate subordinating conjunctions to show cause are words like “because,” “as,” and “since,”¹⁸ as was the case with the patent regulation discussed above (“unavoidable *since*”). The subordinating conjunction “even though,” on the other hand, is most properly used to indicate a relationship of concession between a main and a subordinate clause: the subordinate clause acknowledges something as true that makes the main clause appear to be an unexpected result. For example, the conjunction often appears in a definition that is conceded to be counterintuitive: “A veteran shall be considered as living with a spouse, *even*

14. 37 C.F.R. § 1.378(b)(3) (2010) (emphasis added).

15. 55 F.3d 606, 609 (Fed. Cir. 1995).

16. *See, e.g.*, 21 C.F.R. § 70.20; 7 C.F.R. § 457.167(11)(a); 50 C.F.R. § 22.26(a)(2).

17. *See* MARGARET SHERTZER, *THE ELEMENTS OF GRAMMAR* 46 (2001).

18. *Id.*

though they reside apart. . . .”¹⁹ The conjunction also often appears where there is a fact that is conceded to be relevant but should nonetheless be ignored: “Amounts received in respect of the services of a child shall be included in his gross income and not in the gross income of the parent, *even though* such amounts are not received by the child.”²⁰ Thus, the choice of the conjunction “even though” in § 22(b)(1) must be explained if a textual argument for a categorical approach is to be convincing.

This strange use of “even though” can be explained, however, and it rests on the special nature of unavoidability. The premises put forward for a conclusion of unavoidability usually involve required precautions and an undesired event. When the premises are true—the required precautions have been taken—and the undesired event still occurs, the conclusion of unavoidability follows. Thus, the relationship between the premises and the conclusion of unavoidability is in the form of a concession: the required precautions have been taken and nonetheless the event occurs. The precautions taken make the occurrence of the undesired event a surprise; it is because the occurrence of the event, in the face of precautions, *is a surprise* that the label “unavoidable” is used in the first place. This inherent concession in reaching the conclusion that an event was “unavoidable” (the surprise that the undesired event occurred after precautions had been taken) explains the usage of “even though,” a concessionary subordinating conjunction, in § 22(b)(1). An injury or death from a vaccine side effect occurring after proper preparation, directions, and warnings is a surprise, and it is because such injury or death is not expected that the injury or death is categorically labeled “unavoidable.”

This explanation is confirmed by other instances where “even though” and “unavoidable” are juxtaposed. For example, under fish and wildlife regulations, a permit for programmatic (i.e., ongoing) eagle take (i.e., disturbance) will be granted when “the take is *unavoidable even though* advanced conservation practices are being implemented.”²¹ While no court has yet interpreted this regulation, the Department of the Interior has explained, in describing this rule, that the “even though” conjunction was used to show that the truth of the premises in the subordinating clause (“advanced conservation practices are being implemented”) *causes* the conclusion in the main clause (“take is unavoidable”), and hence a permit may be issued. The Department interpreted the statute allowing programmatic permits to be issued when “take is unavoidable even though advanced conservation practices are being implemented” to mean “[w]e can issue programmatic permits . . . based on implementation of ‘advanced conservation practices.’”²² Thus, the implementation of “advanced conservation practices” causes the take to fall under the umbrella of “unavoidable.” The “even though” language was used to show that the truth of the premises causes the conclusion, just as was done in § 22(b)(1).

19. 38 U.S.C. § 1521(h)(2) (emphasis added).

20. 26 U.S.C. § 73(a) (emphasis added).

21. 50 C.F.R. § 22.26(a)(2) (2010) (emphasis added).

22. 74 Fed. Reg. 46,841 (2009).

This usage of “even though” can also be found in the context of motor vehicle tort law. Many states label a motor vehicle accident “unavoidable” if it occurs even though ordinary care was used or no one was at fault. That is, the truth of the premise (ordinary care was used) causes the conclusion (the accident was unavoidable). In *Batts v. Capps*, for example, the Virginia Supreme Court analyzed a jury instruction defining the unavoidable accident doctrine: “the law recognizes that a collision between vehicles may be *unavoidable even though* the drivers are lawfully, properly and without negligence operating the same.”²³ It is the concession that due care was used (premise true), and still the accident happened, that causes the conclusion (accident unavoidable). In describing the law under which the above jury instruction was formulated, the court in *Batts* confirmed the concessionary nature of the analysis and the causative nature of “even though”: “Where there is a reasonable theory of the evidence under which the parties involved may be held to have exercised due care notwithstanding that the accident occurred, an unavoidable accident instruction is proper and should be submitted to the jury.”²⁴

CONCLUSION

The distinction between a categorical and case-by-case approach turns on the freedom given to courts. If a conclusion in the form of an ambiguous term such as “unavoidable” is left undefined, then it is up to courts to reason to conclusion by the gathering and aggregating of facts on a case-by-case basis. On the other hand, when Congress has outlined an approach by defining premises that, if true, will necessarily lead to the conclusion, courts are left only to apply that categorical proposition: they must determine if the premises are true; if they are, the conclusion follows. Congress has shown itself willing to set the premises of unavoidability and other instances of the phrase “unavoidable even though” show that it is used to set such premises. Once the somewhat muddled language of § 22(b)(1) is placed in this proper context, we can see that it creates just such a categorical proposition. When the premises defined by Congress are true—proper preparation, directions, and warnings—the conclusion must therefore follow—the side effect is unavoidable.

23. 191 S.E.2d 227, 228 (Va. 1972) (emphasis added).

24. *Id.*; see also *Sears v. Frost's Administrator*, 279 S.W.2d 776, 779 (Ky. 1955).