SIMPSON THACHER
REPORT FROM WASHINGTON

To read the decision in *Bruesewitz v. Wyeth,* please click here.

The Supreme Court Hears Express Preemption Case Relating to Alleged Vaccine Design Defect

October 13, 2010

INTRODUCTION

The United States Supreme Court heard oral argument yesterday in *Bruesewitz v. Wyeth,* No. 09-152, in which the Court is poised to address the preemptive scope of Section 22(b)(1) of the National Childhood Vaccine Injury Act of 1986 ("the Act"). Under the Act, design defect claims against vaccine manufacturers are expressly preempted "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 warning." 42 U.S.C. § 300aa-22(b)(1). The Court is expected to determine whether — absent allegations that the vaccine was improperly prepared or unaccompanied by proper directions and warning — this provision preempts vaccine design defect claims categorically. The questions asked during the argument suggest that several of the Justices are disinclined toward Plaintiffs' position and inclined toward a broader interpretation of the Act's preemption provision.

BACKGROUND

Plaintiffs-Petitioners Russell and Robalee Bruesewitz claim that poor design of the vaccine TRI-IMMUNOL ("DPT") by the manufacturer, Defendant-Respondent, Wyeth, Inc. ("Wyeth"), injured their daughter Hannah.

On April 1, 1992, when she was six months old, Hannah received her third injection of DPT, a vaccine designed to reduce pertussis (or "whooping cough") infections. Shortly thereafter, Hannah began experiencing persistent seizures, which, Plaintiffs claim, left her lethargic, developmentally stunted, and displaying autistic-like symptoms. Plaintiffs contend that Hannah's injuries could have been avoided had Wyeth used an alternative design called ACEL-IMUNE ("DTaP").

Plaintiffs submitted their case before the Vaccine Court, an Office of Special Masters created by Congress in the Act to adjudicate vaccine-related claims. The Vaccine Court found that Hannah's injuries, residual seizure disorder and encephalopathy, were not listed on the Act's Injury Table for DPT, and therefore denied Plaintiffs' claim for damages. The Injury Table provides a list of specific illnesses, disabilities, injuries, and conditions associated with each vaccine, for which compensation may be available under the National Vaccine Injury Compensation Program. 42 U.S.C. § 300aa-14.

Plaintiffs then sued Wyeth in Pennsylvania state court based on claims for strict liability for design and manufacturing defects. Plaintiffs also alleged that Defendant "negligently failed to produce a safer vaccine despite knowledge of the existence and feasibility of such safer alternatives" and "negligently failed to warn of the actual dangers associated

The Report From Washington is published by the Washington, DC office of Simpson Thacher & Bartlett LLP.

with the particular batch DPT." *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 435 (E.D. Pa. 2007).

Shortly after removing the case to federal court based on diversity jurisdiction, Defendant moved for summary judgment on the grounds that the Act preempts Plaintiffs' state law claims. Although the United States District Court for the Eastern District of Pennsylvania initially denied Defendant's motion without prejudice, the court granted Defendant's motion for summary judgment on all counts after completion of discovery. The district court concluded that, in essence, Plaintiffs' suit alleged a design defect, and that Section 22(b)(1) of the Act preempts all such claims. The district court reasoned that, "allowing case-by-case inquiries into whether a particular vaccine is unavoidably unsafe would do nothing to protect vaccine manufacturers from suit from design defects, since such an inquiry would require a finder of fact to consider the manufacturer's design against a purported safer alternative." 508 F. Supp. 2d at 445. Addressing Congress's intent in passing the Act, the court found that "the Vaccine Court's no-fault compensation scheme reflects the other side of the balance Congress struck between the policy of widespread distribution of childhood vaccines and the need to compensate those injured affecting that policy." *Id*.

The Third Circuit agreed on appeal, holding that Plaintiffs' design defect claims were expressly preempted by the plain language of the Act. The Court of Appeals rejected Plaintiffs' argument that Section 22(b)(1) shields manufacturers from design defect claims only when a vaccine's harmful side effects could not have been prevented through a safer design. Looking to "the language, structure, and purpose" of the Act, and using legislative history to aid its interpretation, the court concluded that Section 22(b)(1) guards vaccine manufacturers in absolute terms against all possible design defect claims. Specifically, the court held that the "evidence indicates that Congress weighed the various concerns related to the pertussis vaccine and concluded that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine." *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 251 (3d Cir. 2009). The Third Circuit continued: "Even if Congress did not intend to prohibit all design defect claims against vaccine manufacturers, the legislative history indicates that it intended to preempt the specific claims at issue here" given the numerous references in the legislative debates to the DPT vaccine and its potential dangers.

Of particular note, the Court of Appeals disagreed with the Georgia Supreme Court's recent decision in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008). In that case, Georgia's highest court held that if Congress had intended to preempt all design defect claims, it could have achieved that result by omitting the words "that were unavoidable" such that the provision would prevent liability "if the vaccine was properly prepared and was accompanied by proper directions and warnings." 668 S.E.2d at 240. The Third Circuit did not find the *Ferrari* Court's reading of the Vaccine Act to be compelling, however, concluding it was "contrary to the structure of the Act because it does not bar any design defect claims." 561 F.3d at 246. Recognizing that two interpretations of the language of Section 22(b)(1) are possible, the Third Circuit found that "a 'clear and manifest' expression of congressional intent supports" interpreting the section expressly to preempt all design defect claims. *Id*.

SUMMARY OF THE ARGUMENT

Before the Supreme Court yesterday, Plaintiffs claimed: "it's clear what Congress was intending was to enact a national defense, but not to displace State law completely." Chief Justice Roberts replied: "I would have thought the argument would go the other way: That because they set up a compensation scheme, that was a good sign that they didn't want to allow State law claims."

"If ['unavoidable'] simply means unavoidable with some other vaccine, you could always avoid them if you have a vaccine that is significantly less effective."

JUSTICE SCALIA

Plaintiffs also maintained that the Third Circuit misconstrued the word "unavoidable" in Section 22(b)(1), and thereby adopted a policy that exposes children to unnecessary safety risks. Certain Justices pressed Plaintiffs on their interpretation of "unavoidable." Justice Alito asked what need there was for the clause "even though the vaccine was properly prepared and was accompanied by proper directions and warnings" if the term "unavoidable" was intended to carry its ordinary meaning. Justice Scalia observed: "[i]f ['unavoidable'] simply means unavoidable with some other vaccine, you could always avoid them if you have a vaccine that is significantly less effective."

Justice Ginsburg then inquired as to the standard proposed by Plaintiffs, asking whether Plaintiffs' position was that, "[i]f there is a safer alternative, it must be pursued regardless of cost." Plaintiffs responded that there is a "reasonableness standard."

Justice Breyer asked Plaintiffs to respond to the argument submitted by the American Academy of Pediatrics, among other organizations, that, if Plaintiffs' position were adopted, judges and juries would be making decisions as to what design should be used instead of the FDA and other specialized agencies, which could result in driving certain vaccines from the market and lead to the death of numerous children. Plaintiffs dismissed these concerns, noting that 99 percent of the people who go through Vaccine Court accept the judgment of that body and the few who do not may nonetheless abandon their state law claims given the difficulty of proving causation or the availability of an alternative design. Responding to Plaintiffs' contention that juries ultimately would side with manufacturers if their vaccines were more efficient than the alternatives, Justice Kennedy noted: "you assume that there is no [cost] or burden to the manufacturers who defend these suits to assess settlement offers. This is a . . . tremendous expense."

"[Y]ou assume that there is no [cost] or burden to the manufacturers who defend these suits to assess settlement offers. This is a . . . tremendous expense."

JUSTICE KENNEDY

Defendant, on the other hand, argued that the Act was intended to preempt design defect claims, a reading supported by the "wave of tort litigation that threatened to drive manufacturers out of the business of providing the vaccine" at the time of its enactment.

Justice Sotomayor asked Defendant why, if that was Congress's intent, the Act did not make the Vaccine Court exclusive. In response, Defendant pointed out that manufacturing defect and improper warning claims are still allowed, and that solely design defect claims are preempted.

Justice Sotomayor then questioned: "[W]hat is the motivation for manufacturers to voluntarily remove a drug that is causing harm to the public before the FDA acts?" Defendant responded that, under Section 27, the Secretary of Health and Human Services "shall have an affirmative mandate to promote safer vaccines and to reduce the number of side effects." Defendant also noted both that "there are grave consequences if a manufacturer withholds knowledge of adverse effects from the FDA," and that a manufacturer selling a drug that causes harm remains exposed to failure to warn claims.

Justice Ginsburg asked Defendant about alternative statutory constructions: "[Congress] could have said simply that no vaccine manufacturer may be held civilly liable if the vaccine is properly prepared and accompanied by proper directions and adequate warnings. . . . Congress didn't make that statement. They were asked to amend the statute to make that statement, and they didn't." Defendant acknowledged that Congress could have drafted the text differently, but that the "best way to read the two clauses together" is to conclude that design defect claims are preempted.

"[W]hat is the motivation for manufacturers to voluntarily remove a drug that is causing harm to the public before the FDA acts?"

JUSTICE SOTOMAYOR

The United States, as amicus curiae, argued in its brief that the language, structure, purpose and history of Section 22 reveal that it preempts design defect claims against manufacturers. In addition, the Government pointed to the Act's overall structure to confirm Section 22's preemptive effect. Through the enactment of the Act, the Government argued, Congress had adopted "an affirmative and comprehensive national policy favoring development and widespread administration of childhood vaccines," and Section 22(b)(1) was indicative of "Congress's judgment that holding manufacturers liable for the design of their vaccines would unacceptably undermine the Act and its animating policy." At oral argument, the Government emphasized the role of the Centers for Disease Control and Prevention, noting that the agency recommends vaccines for routine administration. Justice Sotomayor asked: "At what documents do I look at to make a judgment that in fact, CDC is doing what I ask, that it is looking at the question of whether this is the most efficacious drug with the least adverse effects?" The Government confirmed that the "CDC makes that judgment and announces it in a reasoned, published announcement in its official journal . . . ."

On rebuttal, Plaintiffs downplayed the role of the CDC, stating: "I'm not aware that the CDC does the kind of granular comparisons that would go to the level of safety that is at issue in this kind of case." In response to a question by Justice Alito, Plaintiffs admitted that, under their theory, a lay jury would be permitted to use experts to argue that the CDC had erred in making a recommendation of one vaccine over another.

Justice Kagan did not participate in this case due to the involvement of the Office of the Solicitor General as amicus curiae.

IMPLICATIONS

In *Bruesewitz,* the Court is set to decide the scope of the Vaccine Act's express preemption of vaccine-related claims. If the Supreme Court adopts the Georgia Supreme Court's analysis in *Ferrari*, consumers will be able maintain actions against vaccine manufacturers by alleging that their injuries were caused by a design defect that created an avoidable risk. Critics of such a result argue that this approach would make the Act's preemption language meaningless with respect to almost any design defect claim, as such claims usually examine whether there was a safer alternative design. In addition, these critics argue, such an interpretation of the Act would hinder a uniform, nationwide immunization program by discouraging vaccine development and manufacture through enormous litigation cost exposures, and may also result in inconsistent results across states. On the other hand, if the Supreme Court adopts the Third Circuit analysis, vaccine manufacturers will be protected against the costly burden of civil litigation based upon alleged design defect. Opponents of such a result, however, argue that it would remove incentives for manufacturers to design the safest possible vaccines.

For further information about this decision, please feel free to contact members of the Firm's Litigation Department, including:

New York City:

Robert Bourque
212-455-3595
rbourque@stblaw.com

Mark Cunha
212-455-3475
mcunha@stblaw.com

David Ichel
212-455-2563
dichel@stblaw.com

Mary Elizabeth McGarry
212-455-2574
mmcgarry@stblaw.com

Joseph McLaughlin
212-455-3242
jmclaughlin@stblaw.com

Lynn Neuner
212-455-2696
lneuner@stblaw.com

Roy Reardon
212-455-2824
rreardon@stblaw.com

Palo Alto:

George Newcombe
650-251-5050
gnewcombe@stblaw.com

Washington DC:

Peter Bresnan
202-220-7769
pbresnan@stblaw.com

Peter Thomas
202-220-7735
pthomas@stblaw.com

UNITED STATES

New York
425 Lexington Avenue
New York, NY 10017
+1-212-455-2000

Los Angeles
1999 Avenue of the Stars
Los Angeles, CA 90067
+1-310-407-7500

Palo Alto
2550 Hanover Street
Palo Alto, CA 94304
+1-650-251-5000

Washington, D.C.
1155 F Street, N.W.
Washington, D.C. 20004
+1-202-636-5500

EUROPE

London
CityPoint
One Ropemaker Street
London EC2Y 9HU
England
+44-(0)20-7275-6500

ASIA

Beijing
3119 China World Office 1
1 Jianguomenwai Avenue
Beijing 100004
China
+86-10-5965-2999

Hong Kong
ICBC Tower
3 Garden Road, Central
Hong Kong
+852-2514-7600

Tokyo
Ark Mori Building
12-32, Akasaka 1-Chome
Minato-Ku, Tokyo 107-6037
Japan
+81-3-5562-6200

SOUTH AMERICA

São Paulo
Av. Presidente Juscelino Kubitschek, 1455
São Paulo, SP 04543-011
Brazil
+55-11-3546-1000