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284 Ga. 384

S07G1708. AMERICAN HOME PRODUCTS CORPORATION et al. v. FERRARI et al.

Carley, Justice.

Appellees Marcelo and Carolyn Ferrari, individually and on behalf of their minor son, brought suit against several vaccine manufacturers, including Appellants, alleging that their son suffered neurological damage caused by vaccines made with the preservative thimerosal, which contained the toxic substance mercury. Appellees' claims under Georgia law included strict liability and negligence. They specifically alleged that Appellants could and should have manufactured children's vaccines without thimerosal before Appellees' son was vaccinated in 1998.

The trial court granted partial summary judgment in favor of Appellants, ruling that Appellees' design defect claims were preempted by the National Childhood Vaccine Injury Compensation Act of 1986, 42 USC § 300aa-1 et seq. (Vaccine Act). Section 300aa-22 (b) (1) of the Vaccine Act reads as follows:

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.

On appeal, the Court of Appeals summarized the parties' arguments as follows:

[Appellants] argue that the Vaccine Act bars [Appellees'] design defect claims because "any vaccine-related injury would be deemed 'unavoidable' if the vaccine was properly prepared and accompanied by proper warnings." [Cit.] [Appellants] essentially equate FDA [Food and Drug Administration] approval with a determination that side effects are "unavoidable." [Cit.] [Appellees], on the other hand, assert that design defect claims are barred only if the side effects are determined on a case-by-case basis to be "unavoidable." They argue that their child's injuries could have been avoided if the defendants had used a mercury-free preservative for multi-dose vials of their vaccines or if they had simply manufactured single-dose vials that did not require a preservative.

Ferrari v. American Home Products Corp., 286 Ga. App. 305, 308 (650 SE2d

585) (2007). The Court of Appeals determined that two alternative readings of

42 USC § 300aa-22 (b) (1) exist:

One reading is that vaccine injuries are "unavoidable" and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings. The other reading is that design defect claims are preempted only if the side effects are determined to be unavoidable on a case-by-case basis.

Ferrari v. American Home Products Corp., supra at 311. The Court of Appeals held that, despite clear legislative history favoring the first reading, Bates v. Dow Agrosciences, 544 U. S. 431, 449 (III) (125 SC 1788, 161 LE2d 687) (2005) imposes

“a duty to accept the reading (of the Vaccine Act) that disfavors pre-emption,” and we cannot resort to an examination of legislative history to discern Congress’s intent. [Cit.] Because two plausible, alternative readings of the Vaccine Act exist, we must conclude that the trial court erred by finding that [Appellees’] design defect claims are preempted.

Ferrari v. American Home Products Corp., supra at 312 (1). We granted certiorari to consider this ruling. Although the Court of Appeals erred in holding that Bates precludes the use of legislative history, we nevertheless affirm the judgment of the Court of Appeals because a full examination of both the text of 42 USC § 300aa-22 (b) (1) and the congressional intent behind it shows that the Vaccine Act does not preempt all design defect claims, but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were unavoidable.

1. “Except as provided in subsections (b), (c), and (e) [of § 300aa-22] State law shall apply to a civil action brought for damages for a vaccine-related injury or death.” 42 USC § 300aa-22 (a). Thus, in construing subsection (b) (1), “we are presented with the task of interpreting a statutory provision that expressly pre-empts state law.” Medtronic v. Lohr, 518 U. S. 470, 484 (III) (116 SC 2240, 135 LE2d 700) (1996). Although this subsection “preempts state law to the extent stated, the [Vaccine] Act, by expressly reserving state courts a role with respect to claims made under the Act, does not preclude state courts from adjudicating issues raised regarding it ([cit.]).” Militrano v. Lederle Laboratories, 769 NYS2d 839, 843 (Sup. Ct. 2003), aff’d, 810 NYS2d 506 (App. Div. 2006).

While the language of subsection (b) (1) indicates that Congress intended to preempt some state law, we are nonetheless required to

“identify the domain expressly pre-empted” by that language, [cit.] Although our analysis of the scope of the pre-emption statute must begin with its text, [cit.], our interpretation of that language does not occur in a contextual vacuum. Rather, that interpretation is informed by two presumptions about the nature of pre-emption. [Cit.] First, because the States are independent sovereigns in our federal system, ... Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has “legislated ... in a field which the States

have traditionally occupied,” [cit.], we “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” [Cits.] ... [T]his assumption should apply ... to questions concerning the scope of its intended invalidation of state law, [cit.] ... That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety. Second, our analysis of the scope of the statute’s pre-emption is guided by [the] oft-repeated comment ... that “(t)he purpose of Congress is the ultimate touchstone” in every pre-emption case. [Cits.] As a result, any understanding of the scope of a pre-emption statute must rest primarily on “a fair understanding of congressional purpose.” [Cit.] Congress’ intent, of course, primarily is discerned from the language of the pre-emption statute and the “statutory framework” surrounding it. [Cit.] Also relevant, however, is the “structure and purpose of the statute as a whole,” [cit.], as revealed not only in the text, but through the reviewing court’s reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law. (Emphasis in original.)

Medtronic v. Lohr, supra at 484-486 (III) (with five Justices joining this part of the Supreme Court’s opinion).

The Court of Appeals viewed Bates as having drastically changed this traditional preemption analysis, so as to make the presumption against preemption irrebuttable and to require examination of the statutory language alone. Ferrari v. American Home Products Corp., supra at 310. “However, Bates does not require a court to automatically accept a plausible interpretation

of a statute which disfavors preemption.” Bruesewitz v. Wyeth, 508 FSupp.2d 430, 444 (V) (B) (2) (a) (E.D. Pa. 2007). Bates quotes from the above-quoted portion of Medtronic which sets forth the presumption against preemption, without any indication of disapproval. Furthermore, “Bates itself relies on the congressional intent behind [the statute before it] when applying the rule [disfavoring preemption]. [Cit.]” Bruesewitz v. Wyeth, supra. See also Bates v. Dow Agrosciences, supra at 452 (III), fn. 26 (examining legislative history).

It therefore appears that the Court of Appeals took “one part of the Bates ruling out of its context, and [gave] it broader scope than is appropriate.” Bruesewitz v. Wyeth, supra. Nevertheless, a majority of seven Justices in Bates “gave the most explicit statement yet of the presumption against preemption in a product preemption case” and “fully demonstrated its commitment to the presumption against preemption except in the narrowest of circumstances.” J. Eggen, “The Normalization of Product Preemption Doctrine,” 57 Ala. L. Rev. 725, 762-763 (III) (B) (2006).

2. Only two federal district courts and one state other than Georgia have considered in published opinions whether 42 USC § 300aa-22 (b) (1) preempts all claims that a vaccine was defectively designed. Bruesewitz v. Wyeth, supra;

Sykes v. Glaxo-SmithKline, 484 FSupp.2d 289, 297 (V) (B) (E.D. Pa. 2007) (same court as Bruesewitz); Blackmon v. American Home Products Corp., 328 FSupp.2d 659, 662 (II) (B) (S.D. Tex. 2004); Militrano v. Lederle Laboratories, 769 NYS2d, supra at 843-846, aff'd, 810 NYS2d, supra at 508. Each of these cases held that all such claims are preempted. However, every case correctly recognized that Congress modeled subsection (b) (1) after comment k to § 402A of the Restatement (Second) of Torts. “Section 402A is a general section providing for strict products liability.” Militrano v. Lederle Laboratories, 769 NYS2d, supra at 844. Comment k excepts from strict liability the seller of

[u]navoidably 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.... 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 ... drugs, vaccines, and the like

Restatement (Second) of Torts § 402A cmt. k. The phrase “properly prepared, and accompanied by proper directions and warning” refers to an absence of manufacturing or warning defects and, thus, comment k distinguishes the three fundamental types of products liability: defects in design, manufacturing, and packaging or marketing. Sykes v. Glaxo-SmithKline, supra at 300 (V) (B) (3);

Blackmon v. American Home Products Corp., supra at 664 (II) (B). See also Banks v. ICI Americas, 264 Ga. 732, 733 (1) (450 SE2d 671) (1994) (“There are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects. [Cit.]”).

However, both Sykes and Blackmon erroneously construed comment k to support its interpretation of 42 USC § 300aa-22 (b) (1) as rejecting a case-by-case determination of whether a certain side effect was unavoidable. In particular, Sykes v. Glaxo-SmithKline, supra at 302 (V) (B) (4), mistakenly held that such interpretation “mirrors this established area of tort law for unavoidably unsafe products” as set forth in comment k. “Comment k., however, has been interpreted in a variety of ways ..., and there has been a wide range of disagreement regarding its application.” Freeman v. Hoffman-La Roche, 618 NW2d 827, 835 (IV) (1) (a) (ii) (Neb. 2000). Only a few jurisdictions have held that any prescription drug is deemed unavoidably unsafe and, thus, that strict liability for defective design is barred. Freeman v. Hoffman-La Roche, supra at 836 (IV) (1) (a) (ii); Militrano v. Lederle Laboratories, 769 NYS2d, supra at 846. Most of the states, including Georgia, “that have adopted Comment k have applied it in a more limited fashion and on a case-by-case basis. [Cits.]” Bryant

v. Hoffmann-La Roche, 262 Ga. App. 401, 404 (2) (585 SE2d 723) (2003) (physical precedent, with one judge urging adoption of a design defect test in the Restatement (Third) of Torts, which test was neither adopted by Congress in the Vaccine Act nor in existence at the time). Indeed, even Bruesewitz understands comment k in this manner:

Comment k, therefore, suggests that the question of whether a particular vaccine is unavoidably unsafe – and therefore subject to the immunity from suit posited by comment k – is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, “in the present state of human knowledge.”

Bruesewitz v. Wyeth, supra at 445 (V) (B) (3). Thus, the court in Bruesewitz, despite its adherence to Sykes’ ultimate holding, was compelled to acknowledge Sykes’ misunderstanding of comment k. Bruesewitz v. Wyeth, supra at 445-446 (V) (B) (3) (“conclud[ing] that § 22 (b) is broader than comment k”).

3. An analysis of the language and intent of 42 USC § 300aa-22 (b) (1), unhindered by the mistakes of Blackmon and Sykes, shows that Congress not only adopted comment k, but understood that comment in the same way that Bruesewitz and the great majority of other courts came to understand it. Subsection (b) (1) borrows liberally from the language of comment k, and the

committee report on which Blackmon, Sykes, Bruesewitz, and Militrano rely states, without qualification, that “[t]his provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) ...” H.R. Rep. 99-908, at 25 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6366.

The text of subsection (b) (1) is most consistent with the majority understanding of comment k. Under that subsection, a vaccine manufacturer is not civilly liable “if the [vaccine-related] injury or death resulted from side effects that were unavoidable” The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable. In order to bar all liability for defective design and to permit liability only for manufacturing and warning defects, Congress could easily have omitted this clause, retained the last clause, and made the bar to civil liability conditional on proper preparation and warnings, so that subsection (b) (1) would simply state that a vaccine manufacturer is not civilly liable “if the vaccine was properly prepared and was accompanied by proper directions and warnings.” Thus, Appellants effectively “favor reading ... words out of the statute This amputated version ... would

no doubt have clearly and succinctly commanded the pre-emption of all state” tort claims for defective design. (Emphasis in original.) Bates v. Dow Agrosciences, supra at 448-449 (III).

As the statute is actually written, however, it is best understood as barring liability only for those side effects which were unavoidable by means other than proper manufacturing and packaging. Conversely, if such effects were avoidable by a feasible alternative design, liability is not completely barred. Accordingly, the last clause of subsection (b) (1) was necessary to ensure that its bar to liability would not apply to the manufacturing and packaging process, but only to side effects which were not avoidable by a safer design.

4. This construction of 42 USC § 300aa-22 (b) (1) is bolstered by the previously cited 1986 committee report in the following explanation:

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.

H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. Militrano v. Lederle Laboratories, 810 NYS2d, supra, acknowledges that this wording “appears to

leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act” Indeed, that language alone refutes the Court of Appeals’ concession that there is “clear legislative history to the contrary” Ferrari v. American Home Products Corp., supra at 312 (1). Subsequent language in the 1986 committee report carries a similar implication, when it recognizes that the Vaccine Act established a “no-fault compensation system,” providing an award to vaccine-injured persons “even if the manufacturer has made as safe a vaccine as possible.” H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367.

This context must be considered when reading the following sentence on which Blackmon, Sykes, Bruesewitz, Militrano, and Appellants rely:

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 [they] should pursue recompense in the compensation system, not the tort system.

H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. This sentence includes both those persons who have been injured by vaccines which were as safely designed as possible and those injured by vaccines for which there was a safer feasible alternative design. Accordingly, the committee report does not use

language which indicates that use of the compensation system is mandatory. The immediately preceding sentence states that “[v]accine-injured persons will now have an appealing alternative to the tort system.” H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. Thus, Congress defended the new compensation system by assuming that it would attract even vaccine-injured persons who may be able to prove that the vaccine was not made as safe as reasonably possible. Such an assumption about a no-fault compensation system is certainly questionable, to say the least. However, the assumption is not relevant for its accuracy, but rather for its illumination of congressional intent. Upon considering Congress’ assumption regarding the compensation system for that proper purpose, we conclude that the sentence of the committee report on which Appellants rely means only that, in the committee’s opinion, if a vaccine-injured person does not have a claim for a manufacturing or warning defect, he should find the compensation system appealing even though he is authorized to attempt to prove the existence of a safer design in the tort system. Accordingly, that sentence does not mean that 42 USC § 300aa-22 (b) (1) preempts all design defect claims.

The Court of Appeals rejected the use of “subsequent legislative history” as “a hazardous basis for inferring the intent of an earlier Congress.’ [Cit.]” Ferrari v. American Home Products Corp., supra at 311, fn. 9. That subsequent legislative history consists of a report by the same committee which originally considered the Vaccine Act and which produced the 1986 report relied upon by Appellants and the courts. The subsequent committee report was issued in 1987, the year following passage of the Vaccine Act, and related to amendments to that Act which did become law. In these circumstances, the 1987 committee report is relevant to “shed[] light on allegedly ambiguous language” and “certainly constitutes a prophylactic against adopting a tortured reading of an otherwise plain statute.” Grapevine Imports v. United States, 71 Fed. Cl. 324, 335 (II) (C) (3) (2006). That report is strikingly clear and emphatic:

[T]he codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. Rep. 100-391 (I), at 691 (1987), as reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-365.

Furthermore, an amendment to the Vaccine Act which would have established “that a manufacturer’s failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.” H.R. Rep. 100-391 (I), at 691, 1987 U.S.C.C.A.N. at 2313-365. “Generally the rejection of an amendment indicates that the legislature does not intend the bill to include the provisions embodied in the rejected amendment. [Cits.]” 2A Sutherland Statutory Construction § 48:18 (7th ed.).

5. Our analysis is consistent with the structure and purpose of the Vaccine Act as a whole, as correctly summarized by the Court of Appeals:

Congress enacted the Vaccine Act “to prevent manufacturers from leaving vaccine production or significantly increasing their prices, while at the same time compensat(ing) victims of vaccine-related injuries quickly.” [Cit.] The Vaccine Act creates a no-fault compensation system for victims of certain vaccine-related injuries and requires injured parties to file a petition in the vaccine court. [Cits.] If the injured party is not satisfied with the outcome of the vaccine court process, he or she may pursue a traditional tort action, subject to certain restrictions imposed by the Vaccine Act. [Cits.]

Ferrari v. American Home Products Corp., supra at 306. Accordingly, we must not “overstate the degree of uniformity and centralization that characterizes” the Vaccine Act. Bates v. Dow Agrosciences, supra at 450 (III). Having thoroughly examined both the text of 42 USC § 300aa-22 (b) (1) and the congressional intent behind that subsection and the entire Act, including the relevant legislative history, we hold that subsection (b) (1) clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe.

Even if the language of 42 USC § 300aa-22 (b) (1) is ambiguous, the legislative history hardly shows a “clear and manifest” congressional purpose to supplant state tort law with respect to claims of defective design. Thus, although the Court of Appeals mistakenly construed Bates to preclude reliance on any indication of congressional intent other than the statutory language, Bates would nonetheless apply to resolve any ambiguity in subsection (b) (1) against preemption.

Even if [Appellants] had offered us a plausible alternative reading of [that subsection] – indeed, even if its alternative were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors pre-emption.... The long history of tort litigation against manufacturers of [prescription drugs and vaccines] adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly. [Cit.]

Bates v. Dow Agrosciences, supra at 449 (III).

Our holding is not undermined by the “four conclusions” of Sykes v. Glaxo-SmithKline, supra at 301-303 (V) (B) (4), as utilized in Bruesewitz v. Wyeth, supra at 445 (V) (B) (3). First, 42 USC § 300aa-22 (b) (1) does not “protect vaccine manufacturers from suit [for] design defects.” Bruesewitz v. Wyeth, supra. Rather, it protects them from liability for unavoidable side effects. Second, the federal district court in Bruesewitz and Sykes failed to explain how the National Vaccine Program set up by the Vaccine Act will better promote the discovery of safer alternative designs if manufacturers are given a blanket tort immunity for design defects. See Bates v. Dow Agrosciences, supra at 450 (III); Militrano v. Lederle Laboratories, 769 NYS2d, supra (decisions favoring the majority view of comment k “emphasize that blanket immunity from tort liability would remove an incentive for developing safer designs

([cit.]”). Third, as discussed above, the legislative history does not show that Congress intended that the no-fault compensation system would balance the supposed elimination of design defect claims. Fourth, the district court did not cite any authority for its conclusion that FDA approval alone renders a vaccine unavoidably unsafe, and that conclusion is not compatible with the majority interpretation of comment k in the realm of prescription drugs. See Adams v. G.D. Searle & Co., 576 S2d 728, 733 (Fla. App. 1991) (cited in Bryant v. Hoffman-La Roche, supra) (“it seems likely to us that a drug manufacturer is in a better position to monitor the current state of knowledge and technology, as applied to its products, than is the FDA. We hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval. We therefore reject a blanket approach and decline to apply comment k to all prescription products.”); Christopher J. Albee & Dawn Kilgallen, Comment, Providing Blanket Comment K Immunity to All FDA Approved Ethical Drugs: The Defect in Grundberg v. Upjohn Co., 7 St. John’s J. Legal Comment 475 (1991).

The text of 42 USC § 300aa-22 (b) (1) is not directed towards any particular cause of action, but rather encompasses products liability claims based upon strict liability as well as negligence. Bruesewitz v. Wyeth, supra at 440 (V) (B), fn. 4; Sykes v. Glaxo-SmithKline, supra at 303 (V) (B) (5); Blackmon v. American Home Products Corp., supra at 666 (II) (B). Therefore, although the Vaccine Act provides for limited no-fault compensation, construing subsection (b) (1) as set forth in Bruesewitz, Sykes, Blackmon, and Militrano “would ‘have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry....’ [Cit.]” Doyle v. Volkswagenwerk Aktiengesellschaft, 267 Ga. 574, 576-577 (481 SE2d 518) (1997) (quoting Medtronic v. Lohr, supra at 487 (IV)). In the absence of any clear and manifest congressional purpose to achieve that result, we must reject such a far-reaching interpretation of 42 USC § 300aa-22 (b) (1), at least until the Supreme Court of the United States has spoken on the issue.

Judgment affirmed. All the Justices concur.

Decided October 6, 2008.

Certiorari to the Court of Appeals of Georgia – 286 Ga. App. 305.

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