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NEW SIXTH CIRCUIT DECISION ALLOWS CAUSE OF ACTION AGAINST DRUG MANUFACTURER FOR NEGLIGENTLY BRINGING PRESCRIPTION DRUG TO MARKET

On August 18, 2010, the United States Court of Appeals for the Sixth Circuit issued Wimbush v. Wyeth, __ F.3d __, 2010 WL 3256029 (C.A. 6 (Ohio)), a decision that highlights the urgent need for the U.S. Supreme Court to clarify overbroad preemption language in Wyeth v. Levine. The Wimbush decision holds that notwithstanding a new drug's approval by the FDA, a plaintiff may pursue her claim that a drug manufacturer was negligent in "ignoring the . . . consensus of authority of potential harms" and bringing the drug to market.

The drug at issue in Wimbush is Redux, a diet drug approved by the FDA in 1996 and taken off the market in 1997. The labeling approved by the FDA included a warning regarding the risk of primary pulmonary hypertension (PPH) associated with the use of all types of prescription weight loss drugs. After plaintiff's decedent succumbed to PPH, plaintiff sued the manufacturer of Redux, alleging a defective and negligent design, and negligence "for bringing Redux to market at all."

The Sixth Circuit affirmed summary judgment on plaintiff's defective design claim, and held that if Ohio's 2005 amendment to its product liability statute were retroactive, plaintiff's remaining claims would also be barred (the amendment superseded common law product claims). But because the amendment was not retroactive, plaintiff could assert her common law negligence claim that the manufacturer should have refrained from seeking approval of the diet drug. Assuming, without deciding, that Ohio recognizes such a common law claim, the Sixth Circuit held that it was not preempted by FDA approval.

The Sixth Circuit's condonation of state juries second-guessing FDA approval of a new drug follows in the footsteps of a series of recent federal circuit court decisions reading Wyeth v. Levine, 128 S.Ct. 1187 (2009) too broadly. Much of the misreading can be laid at the doorstep of the Levine decision itself, which purports to reject an "obstacle" preemption argument for reasons applicable only to the much broader "field" preemption argument. Levine distinguishes that Court's most recent (and most analogous) obstacle preemption authority, Geier v. American Honda Motor Co., 529 U.S. 861 (2000), for example, by characterizing the Levine defendant's argument as a field preemption argument that leaves no room for state regulation of pharmaceuticals. See Levine, 128 S.Ct. at 1200-1201 (distinguishing Geier):

> In such cases the Court has performed its own conflict determination, relying on the substance of state and federal law and not on agency proclamations of preemption. We are faced with no such regulation in this case, but rather with an agency's mere assertion that state law is an obstacle to achieving its objectives.

Following suit, the Wimbush decision rejects Geier with a single sweeping statement that the "conflicts" present in Geier "do not exist here

because the state duty urged by [plaintiff] does not create an obstacle to following the federal regulatory scheme."

Similarly, the Sixth Circuit cites a quote from Levine to apply a virtually insurmountable presumption against preemption: "'Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.'" Wimbush, citing Levine, 129 S.Ct. at 1200. Levine, in turn, was quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 167 (1989). As is apparent from the language quoted, which refers to state law operating in a "field" of federal interest, the Bonito passage was discussing (and rejecting) a field preemption argument – specifically, the argument that patent laws expressly or "by negative implication, deprive the states of the power to adopt rules for the promotion of intellectual creation within their own jurisdictions." 489 U.S. at 165. But the dispositive holding in Bonito applies a conflict analysis analogous to Geier's and finds a state law that conflicted with the "balance struck by Congress" to be preempted:

> Thus our past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws.

489 U.S. at 152. It is hard to imagine a clearer "balance struck by Congress" than the balance of risks and benefits that precedes FDA approval of a new drug for marketing. Yet a challenge to that very balance forms the core of the claim found to be viable in Wimbush.

The potential fallout from the new Sixth Circuit decision is foreshadowed in the Court's favorable citation to Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528 (6th Cir. 1993). The Tobin decision, which issued seven years before Geier, held that "a plaintiff in a product liability action may litigate an FDA finding that a drug is efficacious . . . ." 993 F.2d at 537. That is, while FDA approval "is evidence which the jury may consider" in a product liability claim asserted against a drug manufacturer, the jury may "weigh FDA approval as it sees fit, especially in a case where the plaintiff has presented evidence to support an articulable basis for disregarding an FDA finding – in this case the finding that Ritodrine was effective." Id. After the Tobin plaintiff obtained a verdict on her defective design claim by (among other things) calling a witness who participated in the proceedings of the FDA Advisory Committee that initially rejected the drug at issue, the Tobin Court concluded:

> We do not sit to review the findings of the FDA; our only role in this appeal is to decide if there was sufficient evidence on which the jury could base its verdict. . . . We find that there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market Ritodrine.

Id. at 540. Thus, according to Tobin, judges cannot second-guess the FDA, but juries can.

Nowhere in Levine does the U.S. Supreme Court explicitly or implicitly approve product liability claims that are dependent upon a jury finding that the FDA should not have approved a new prescription drug. The Sixth Circuit does express some qualms about doing so in Wimbush; they "admit that, until today, there is . . . no post-Levine court of appeals authority for the proposition that the Levine rationale extends beyond the realm of failure-to-warn claims to apply to all pre-approval state law claims," and clarify that they "do not pass upon whether there may be alternative bases for adjudicating these claims short of trial." The Court nevertheless sanctions a cause of action that allows a plaintiff to recover based on a jury's disagreement with the FDA's scientific judgment that a drug be approved for marketing. The best that can be hoped for is that decisions such as Wimbush hasten the U.S. Supreme Court's narrowing of Levine.

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