

**Cl. 2—Supremacy of the Constitution, Laws, and Treaties**

determined by the FDA to be “substantially equivalent” to a device previously on the market, a situation of some import to at least some of the Justices.

Unanimously, the Court determined that a defective design claim was not preempted and that the MDA did not prevent states from providing a damages remedy for violation of common-law duties that paralleled federal requirements. But the Justices split 4–1–4 with respect to preemption of various claims relating to manufacturing and labeling. FDA regulations, which a majority deferred to, limited preemption to situations in which a particular state requirement threatens to interfere with a specific federal interest. Moreover, the common-law standards were not specifically developed to govern medical devices and their generality removed them from the category of requirements “with respect to” specific devices. However, five Justices did agree that common-law requirements could be, just as statutory provisions, “requirements” that were preempted, though they did not agree on the application of that view.<sup>40</sup>

Following *Cipollone*, the Court observed that, although it “need not go beyond” the statutory preemption language, it did need to “identify the domain expressly pre-empted” by the language, so that “our interpretation of that language does not occur in a contextual vacuum.” That is, it must be informed by two presumptions about the nature of preemption: the presumption that Congress does not cavalierly preempt common-law causes of action and the principle that Congress’s purpose is the ultimate touchstone.<sup>41</sup>

The Court continued to struggle with application of express preemption language to state common-law tort actions in *Geier v. American Honda Motor Co.*<sup>42</sup> The National Traffic and Motor Vehicle Safety Act contained both a preemption clause, prohibiting states from applying “any safety standard” different from an applicable federal standard, and a “saving clause,” providing that “compliance with” a federal safety standard “does not exempt any person from any liability under common law.” The Court determined that the express preemp-

<sup>40</sup> The dissent, by Justice O’Connor and three others, would have held preempted the latter claims, 518 U.S. at 509, whereas Justice Breyer thought that common-law claims would sometimes be preempted, but not here. *Id.* at 503 (concurring).

<sup>41</sup> 518 U.S. at 484–85. *See also id.* at 508 (Justice Breyer concurring); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288–89 (1995); *Barnett Bank v. Nelson*, 517 U.S. 25, 31 (1996); *California Div. of Labor Standards Enforcement v. Dillingham Construction, Inc.*, 519 U.S. 316, 334 (1997) (Justice Scalia concurring); *Boggs v. Boggs*, 520 U.S. 833 (1997) (using “stands as an obstacle” preemption analysis in an ERISA case, having express preemptive language, but declining to decide when implied preemption may be used despite express language), and *id.* at 854 (Justice Breyer dissenting) (analyzing the preemption issue under both express and implied standards).

<sup>42</sup> 529 U.S. 861 (2000).