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PRESS RELEASE

WRF Prevails in FDA Pediatric Rule Case

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Washington, DC—WRF's Food & Drug Practice secured a major victory last week on behalf of three public interest groups when a federal judge overturned the Food and Drug Administration's (FDA) so-called "Pediatric Testing Rule."

The Association of American Physicians and Surgeons, Competitive Enterprise Institute and Consumer Alert, for whom WRF filed suit against the FDA, called the decision a "stunning victory." The court's decision marks the third major recent FDA-related success WRF's Food & Drug Practice has secured on behalf of its clients.

As a condition of approval for new drugs and biological products, the FDA's 1998 Pediatric Rule mandated that manufacturers test and reformulate their products for use in pediatric populations even where manufacturers did not wish a product to be used by children, did not promote the products to children and affirmatively disclaimed on the label use of the product by children. The lawsuit, *Association of American Physicians and Surgeons, Inc., et al., v. United States Food and Drug Administration, et al.,* filed in December 2000, asserted that the testing mandate "exceeds the FDA's statutory authority." The plaintiffs claimed that the rule was inconsistent with an incentive scheme that Congress established through the recent Best Pharmaceuticals for Children Act and the 1997 Food and Drug Administration Modernization Act (FDAMA) to encourage manufacturers to voluntarily test their products in pediatric populations. The groups asserted the rule would result in "further delays of life-saving medicines, and exposing children to unnecessary danger."

In the opinion issued October 17, 2002 by the U.S. District Court for the District of Columbia, U.S. District Judge Henry H. Kennedy, Jr. agreed. He went on to say, "Congress adopted an incentive scheme

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while the FDA adopted a command and control approach. The two schemes differ in almost every possible regard...far from complementing Congress's voluntary incentive scheme, the Pediatric Rule usurps it by superimposing an often-incompatible regime."

WRF Partner Andrew S. Krulwich, head of the firm's 12-lawyer Food & Drug and Product Safety Practice said, "The court's decision is a significant and welcome victory for our clients. The FDA had overstepped its authority. Our success in this suit comes on the heels of two other major FDA-related victories the firm has secured on behalf of the Washington Legal Foundation and Brown & Williamson Tobacco Corporation." Senior Partner Bert W. Rein led the WRF team that litigated the case.

In the case of *Washington Legal Foundation v. Friedman ,* U.S. District Judge Royce C. Lamberth ruled that the FDA's restrictions on certain communications concerning the "off-label" use of drugs and medical devices violated the First Amendment.

In June 2000, in an important victory for WRF client Brown & Williamson Tobacco Corporation , as well as other advertising and tobacco product manufacturers, the United States Supreme Court held that the FDA had exceeded the authority granted to it by Congress in attempting to regulate cigarettes and smokeless tobacco products as "drugs" and "medical devices."

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