SUPREME COURT OF THE UNITED STATES

No. 98–1768

BUCKMAN COMPANY, PETITIONER *v.* PLAINTIFFS' LEGAL COMMITTEE

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

[February 21, 2001]

JUSTICE STEVENS, with whom JUSTICE THOMAS joins, concurring in the judgment.

As the Court points out, an essential link in the chain of causation that respondent must prove in order to prevail is that, but for petitioner's fraud, the allegedly defective orthopedic bone screws would not have reached the market. The fact that the Food and Drug Administration (FDA) has done nothing to remove the devices from the market, even though it is aware of the basis for the fraud allegations, convinces me that this essential element of the claim cannot be proved. I therefore agree that the case should not proceed.[1]

– – – – – –

[1] Though my analysis focuses on the failure of the plaintiffs to establish a necessary element of their claim, that failure is grounded not in the minutiae of state law but in the details of the federal regulatory system for medical devices. Therefore, while this case does not fit neatly into our pre-existing preemption jurisprudence, it is accurate, in a sense, to say that federal law "preempts" this state-law fraud-on-the-FDA claim because the FDA has not acknowledged such a fraud and taken steps to remove the device from the market.

This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the §510(k) process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims.

If the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme. Cf. *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 495 (1996) (holding that the presence of a state-law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but "merely provides another reason for manufacturers to comply with . . . federal law"); *id.*, at 513 (O'CONNOR, J., concurring in part and dissenting in part) (same).[2]

– – – – – –

[2] Though the United States in this case appears to take the position that fraud-on-the-FDA claims conflict with the federal enforcement scheme even when the FDA has publicly concluded that it was defrauded and taken all the necessary steps to remove a device from the market, see Brief for United States as *Amicus Curiae* 24, 30, that has not always been its position. As recently as 1994, the United States took the position that state law tort suits alleging fraud in FDA applications for medical devices do not conflict with federal law where the FDA has "subsequently concluded" that the device in question never met the appropriate federal requirements and "initiated enforcement actions" against those responsible for fraudulently obtaining its ap-

Under the preemption analysis the Court offers today, however, parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process. I do not believe the reasons advanced in the Court's opinion support the conclusion that Congress intended such a harsh result. Cf. *Silkwood* v. *Kerr-McGee Corp.*, 464 U. S. 238, 251 (1984) (declining to infer that a federal statutory scheme that affords no alternative means of seeking redress preempted traditional state-law remedies). For that reason, although I concur in the Court's disposition of this case, I do not join its opinion.

– – – – – –

proval. Brief for United States as *Amicus Curiae* in *Talbott* v. *C. R. Bard, Inc.*, No. 94–1951 (CA1), reprinted in App. to Pet. for Cert. in *Talbott* v. *C. R. Bard., Inc.*, O. T. 1995, No. 95–1321, p. 84a.