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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

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BUCKMAN CO. *v.* PLAINTIFFS' LEGAL COMMITTEE

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

No. 98–1768. Argued December 4, 2000– Decided February 21, 2001

Respondent represents plaintiffs claiming injuries caused by the use of orthopedic bone screws in the pedicles of their spines. Petitioner assisted the screws' manufacturer in securing approval for the devices from the Food and Drug Administration (FDA or Agency), which has regulatory authority under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Devices Amendments of 1976 (MDA). While the screws are in a class that normally must go through a time-consuming process to receive premarket approval (PMA), they were approved under an exception, known as the §510(k) process, for predicate devices– devices that were already on the market when the MDA was enacted– and for devices that are "substantially equivalent" to predicate devices. The §510(k) application filed by petitioner and the manufacturer sought clearance to market the screws for use in arm and leg bones, not the spine. Claiming that the FDA would not have approved the screws had petitioner not made fraudulent representations regarding their intended use, plaintiffs sought damages under state tort law. The District Court dismissed these fraud-on-the-FDA claims on, *inter alia,* the ground that they were pre-empted by the MDA. The Third Circuit reversed.

Held: The plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, the FDCA, as amended by the MDA. Pp. 5–11.

(a) The relationship between a federal agency and the entity it regulates is inherently federal because it originates from, is governed by, and terminates according to federal law. Because petitioner's FDA dealings were prompted by the MDA and the very subject matter of petitioner's statements were dictated by that statute– and in contrast to situations implicating "federalism concerns and the his-

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toric primacy of state regulation of [health and safety matters]," *Medtronic, Inc.* v. *Lohr,* 518 U. S. 470, 485— no presumption against pre-emption obtains in this case. The conflict here stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and the Agency uses this authority to achieve a delicate balance of statutory objectives that can be skewed by allowing state-law fraud-on-the-FDA claims. While the §510(k) process lacks the PMA review's rigor, the former does set forth a comprehensive scheme for determining substantial equivalence with a predicate device. Other provisions give the FDA enforcement options that allow it to make a measured response to suspected fraud upon the Agency. This flexibility is a critical component of the framework under which the FDA pursues its difficult (and often competing) objectives of regulating medical device marketing and distribution without intruding upon decisions committed by the FDCA to health care professionals. Pp. 5–8.

(b) State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives. Complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants, who might be deterred from seeking approval of devices with potentially beneficial off-label uses— an accepted medical practice in which a device is used for some other purpose than that for which the FDA approved it— for fear of being exposed to unpredictable civil liability. Conversely, applicants' fear that their disclosures to the FDA will later be judged insufficient in state court might lead them to submit information that the Agency neither needs nor wants, thus delaying the comparatively speedy §510(k) process, and, in turn, impeding competition and delaying the prescription of appropriate off-label uses. Respondent's reliance on *Silkwood* v. *Kerr-McGee Corp.,* 464 U. S. 238, is misplaced. *Silkwood* was based on traditional state tort law principles, not on a fraud-on-the-agency theory, and, unlike *Silkwood,* there is clear evidence here that Congress intended that the MDA be enforced exclusively by the Federal Government. In addition, the MDA's express pre-emption provision does not bar the ordinary working of conflict pre-emption principles. *Geier* v. *American Honda Motor Co.,* 529 U. S. 861, 869. And although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not stand for the proposition that any FDCA violation will support a state-law claim. Pp. 8–11.

159 F. 3d 817, reversed.

REHNQUIST, C. J., delivered the opinion of the Court, in which

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O'CONNOR, SCALIA, KENNEDY, SOUTER, GINSBURG, and BREYER, JJ., joined. STEVENS, J., filed an opinion concurring in the judgment, in which THOMAS, J., joined.