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

CHIEF JUSTICE REHNQUIST delivered the opinion of the Court.

Respondent represents plaintiffs who claim injuries resulting from the use of orthopedic bone screws in the pedicles of their spines. Petitioner is a consulting company that assisted the screws' manufacturer, AcroMed Corporation, in navigating the federal regulatory process for these devices. Plaintiffs say petitioner made fraudulent representations to the Food and Drug Administration (FDA or Agency) in the course of obtaining approval to market the screws. Plaintiffs further claim that such representations were at least a "but for" cause of injuries that plaintiffs sustained from the implantation of these devices: Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured. Plaintiffs sought damages from petitioner under state tort law. We hold that such claims are pre-empted by the Federal Food, Drug, and Cosmetic Act (FDCA), 52 Stat. 1040, as amended by the Medical Device Amendments of 1976 (MDA), 90 Stat. 539, 21 U. S. C. §301 (1994 ed. and Supp. IV).

I

Regulation of medical devices is governed by the two Acts just named. The MDA separates devices into three categories: Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices "presen[t] a potential unreasonable risk of illness or injury" and therefore incur the FDA's strictest regulation. §360c(a)(1)(c)(ii)(II). It is not disputed that the bone screws manufactured by AcroMed are Class III devices.

Class III devices must complete a thorough review process with the FDA before they may be marketed. This premarket approval (PMA) process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." §§360e(d)(2)(A), (B). Among other information, an application must include all known reports pertaining to the device's safety and efficacy, see §360e(c)(1)(A); "a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device," §360e(c)(1)(B); "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device," §360e(c)(1)(C); samples of the device (when practicable), see §360e(c)(1)(E); and "specimens of the labeling proposed to be used for such device," §360e(c)(1)(F). The PMA process is ordinarily quite time consuming because the FDA's review requires an "average of 1,200 hours [for] each submission." *Medtronic, Inc.* v. *Lohr,* 518 U. S. 470, 477 (1996) (citing Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100–34), p. 384 (1987);

Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 Food Drug Cosm. L. J. 510, 512–514 (1984)).

An exception to the PMA requirement exists for devices that were already on the market prior to the MDA's enactment in 1976. See 21 U. S. C. §360e(b)(1)(A). The MDA allows these "predicate" devices to remain available until the FDA initiates and completes the PMA process. In order to avoid the potentially monopolistic consequences of this predicate-device exception, the MDA allows other manufacturers to distribute (also pending completion of the predicate device's PMA review) devices that are shown to be "substantially equivalent" to a predicate device. §360e(b)(1)(B).

Demonstrating that a device qualifies for this exception is known as the "§510(k) process," which refers to the section of the original MDA containing this provision. Section 510(k) submissions must include the following: "Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 CFR §807.87(e) (2000); "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," §807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," §807.87(k); and "[a]ny additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," §807.87(l).

In 1984, AcroMed sought §510(k) approval for its bone screw device, indicating it for use in spinal surgery. See *In re Orthopedic Bone Screw Products Liability Litigation*,

159 F. 3d 817, 820 (CA3 1998). The FDA denied approval on the grounds that the Class III device lacked substantial equivalence to a predicate device. See *ibid.* In September 1985, with the assistance of petitioner, AcroMed filed another §510(k) application. "The application provided additional information about the . . . device and again indicated its use in spinal surgery. The FDA again rejected the application, determining that the device was not substantially equivalent to a predicate device and that it posed potential risks not exhibited by other spinal-fixation systems." *Ibid.* In December 1985, AcroMed and petitioner filed a third §510(k) application.

> "AcroMed and [petitioner] split the . . . device into its component parts, renamed them 'nested bone plates' and [cancellous] bone screws' and filed a separate §510(k) application for each component. In both applications, a new intended use was specified: rather than seeking clearance for spinal applications, they sought clearance to market the plates and screws for use in the long bones of the arms and legs. AcroMed and Buckman claimed that the two components were substantially equivalent to predicate devices used in long bone surgery. The FDA approved the devices for this purpose in February 1986." *Ibid.*

Pursuant to its designation by the Judicial Panel on Multidistrict Litigation as the transferee court for *In re: Orthopedic Bone Screw Liability Litigation*, MDL No. 1014, the District Court for the Eastern District of Pennsylvania has been the recipient of some 2,300 civil actions related to these medical devices. Many of these actions include state-law causes of action claiming that petitioner and AcroMed made fraudulent representations to the FDA as to the intended use of the bone screws and that, as a result, the devices were improperly given market clearance and were subsequently used to the plaintiffs' detri-

ment. The District Court dismissed these "fraud-on-the-FDA" claims, first on the ground that they were expressly pre-empted by the MDA, and then, after our decision in *Medtronic*, on the ground that these claims amounted to an improper assertion of a private right of action under the MDA.[1] See 159 F. 3d, at 821.

A divided panel of the United States Court of Appeals for the Third Circuit reversed, concluding that plaintiffs' fraud claims were neither expressly nor impliedly pre-empted. We granted certiorari, 530 U. S. ___ (2000), to resolve a split among the Courts of Appeals on this question, see *Kemp* v. *Medtronic, Inc.,* 231 F. 3d 216, 233–236 (CA6 2000) (identifying split and holding such claims expressly pre-empted), and we now reverse.

II

Policing fraud against federal agencies is hardly "a field which the States have traditionally occupied," *Rice* v. *Santa Fe Elevator Corp.,* 331 U. S. 218, 230 (1947), such as to warrant a presumption against finding federal pre-emption of a state-law cause of action. To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law. Cf. *Boyle* v. *United Technologies Corp.,* 487 U. S. 500, 504–505 (1988) (allowing pre-emption of state law by federal common law where the interests at stake are "uniquely federal" in nature). Here, petitioner's dealings with the FDA were prompted by the MDA, and the very subject matter of petitioner's statements were dictated by that statute's provisions. Accordingly– and in contrast to

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[1] The District Court also determined that the plaintiffs' fraud claims failed for lack of proximate cause, see *In re Orthopedic Bone Screw Products Liability Litigation,* 159 F. 3d 817, 821 (CA3 1998), but that question is not presently before us.

situations implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety," *Medtronic,* 518 U. S., at 485– no presumption against pre-emption obtains in this case.

Given this analytical framework, we hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law.[2] The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.

As described in greater detail above, the §510(k) process sets forth a comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device. Among other information, the applicant must submit to the FDA "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use," 21 CFR §807.87(e) (2000), and a statement attesting to and explaining the similarities to and/or differences from similar devices (along with supporting data), see §807.87(f). The FDA is also empowered to require additional necessary information. See §807.87(l). Admittedly, the §510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device. Nevertheless, to achieve its limited purpose, the §510(k) process imposes upon applicants a variety of re-

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[2] In light of this conclusion, we express no view on whether these claims are subject to express pre-emption under 21 U. S. C. §360k.

quirements that are designed to enable the FDA to make its statutorily required judgment as to whether the device qualifies under this exception.

Accompanying these disclosure requirements are various provisions aimed at detecting, deterring, and punishing false statements made during this and related approval processes. The FDA is empowered to investigate suspected fraud, see 21 U. S. C. §372; 21 CFR §5.35 (2000), and citizens may report wrongdoing and petition the agency to take action, §10.30. In addition to the general criminal proscription on making false statements to the Federal Government, 18 U. S. C. §1001, (1994 ed., Supp. IV),[3] the FDA may respond to fraud by seeking injunctive relief, 21 U. S. C. §332, and civil penalties, 21 U. S. C. §333(f)(1)(A); seizing the device, §334(a)(2)(D); and pursuing criminal prosecutions, §333(a). The FDA[4] thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Agency.

This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives. For example,

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[3] 18 U. S. C. §1001(a) (1994 ed., Supp. IV) provides: "[W]hoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; [or] makes any materially false, fictitious or fraudulent statements or representation; or makes or uses any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry; shall be fined under this title or imprisoned not more than 5 years, or both."

[4] The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: "[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U. S. C. §337(a).

with respect to Class III devices, the FDA simultaneously maintains the exhaustive PMA and the more limited §510(k) processes in order to ensure both that medical devices are reasonably safe and effective and that, if the device qualifies under the §510(k) exception, it is on the market within a relatively short period of time. Similarly, "off-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. See, *e.g.*, Beck & Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L. J. 71, 76–77 (1998) (noting that courts, several States, and the "FDA itself recogniz[e] the value and propriety of off-label use"). Indeed, a recent amendment to the FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U. S. C. §396 (1994 ed., Supp. IV). Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.

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. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants– burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking §510(k) approval of devices with potentially beneficial off-label uses for fear that such use

might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability. In effect, then, fraud-on-the-FDA claims could cause the Agency's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, see 21 U. S. C. §396 (1994 ed., Supp. IV), and even though off-label use is generally accepted.[5]

Conversely, fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Agency neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application. As a result, the comparatively speedy §510(k) process could encounter delays, which would, in turn, impede competition among predicate devices and delay health care professionals' ability to prescribe appropriate off-label uses.[6]

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[5] See Green & Schultz, Tort Law Deference to FDA Regulation of Medical Devices, 88 Geo. L. J. 2119, 2133 (2000) ("Physicians may prescribe drugs and devices for off-label uses"); Smith, Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act, 55 Food & Drug L. J. 245, 251–252 (2000) (discussing off-label use in terms of the "practice of medicine doctrine[, which] stands firmly for the proposition that regulatory efforts are directed primarily at device marketing by manufacturers, not device use by physicians"); Beck & Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L. J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize").

[6] In light of the likely impact that the fraud-on-the-FDA claims would have on the administration of the Agency's duties, we must reject respondent's contention that these claims "will . . . affect only the

Respondent relies heavily on *Silkwood* v. *Kerr-McGee Corp.,* 464 U. S. 238 (1984), which it reads to "creat[e] a virtually irrefutable presumption against implied preemption of private damage remedies predicated on an alleged conflict with a federal remedial scheme." Brief for Respondent 34. *Silkwood* is different from the present case, however, in several respects. Silkwood's claim was not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant. See 464 U. S., at 241. Moreover, our decision there turned on specific statutory evidence that Congress "disclaimed any interest in promoting the development and utilization of atomic energy by means that fail to provide adequate remedies for those who are injured by exposure to hazardous nuclear materials." *Id.*, at 257. In the present case, by contrast, we have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government. 21 U. S. C. §337(a).

Respondent also suggests that we should be reluctant to find a pre-emptive conflict here because Congress included an express pre-emption provision in the MDA. See Brief for Respondent 37. To the extent respondent posits that anything other than our ordinary pre-emption principles apply under these circumstances, that contention must fail in light of our conclusion last Term in *Geier* v. *American Honda Motor Co.,* 529 U. S. 861 (2000), that neither an express pre-emption provision nor a saving clause "bar[s] the ordinary working of conflict pre-emption principles." *Id.*, at 869.

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litigants and will not have the kind of direct impact on the United States, which preemption is designed to protect from undue incursion." Brief for Respondent 30 (citing *Miree* v. *DeKalb County,* 433 U. S. 25 (1977)).

We must also reject respondent's attempt to characterize both the claims at issue in *Medtronic* (common-law negligence action against the manufacturer of an allegedly defective pacemaker lead) and the fraud claims here as "claims arising from violations of FDCA requirements." Brief for Respondent 38. Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. See 518 U. S., at 481. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.

The judgment of the Court of Appeals is reversed.

It is so ordered.