No. 01-1208

In the Supreme Court of the United States

J.T. BRADLEY, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

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

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), protects the Food and Drug Administration's decisions to clear certain pedicle screw fixation systems for marketing on the ground that they are "substantially equivalent" to predicate devices already on the market.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-41) is reported at 264 F.3d 344. The opinion of the district court (Pet. App. 42-66) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 31, 2001. A petition for rehearing was denied on November 21, 2001 (Pet. App. 67-68). The petition for a writ of certiorari was filed on February 15, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Petitioners claim that they suffered injuries from the implantation of orthopedic bone screws into the pedicles of their spines. They allege that the Food and Drug Administration (FDA) negligently cleared various pedicle screw fixation systems for marketing based on the conclusion that those devices were "substantially equivalent" to predicate devices already on the market. Seeking damages under the Federal Tort Claims Act (FTCA), 28 U.S.C. 2671 *et seq.*, petitioners filed suit against the United States. The district court and the court of appeals both concluded that the discretionary function exception to the FTCA bars petitioners' claims.

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, regulates food, drugs, cosmetics, and medical devices, and authorizes the FDA to enforce its requirements. The Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, supplement the FDCA's medical device requirements. Under the MDA, medical devices are classified into one of three classes based on the risks to health that the devices pose and the controls that are necessary to provide reasonable assurance of the devices' safety and effectiveness. 21 U.S.C. 360c(a) (1994 & Supp. V 1999). Class I devices present the smallest risks to health and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful. They are subject to both general controls and additional "special controls" that the FDA may impose. 21 U.S.C. 360c(a)(1)(B). Class III devices present the greatest risks to health and therefore are subject to the strictest regulation. 21 U.S.C. 360c(a)(1)(C)(ii)(II). All devices

first marketed after 1976 are initially deemed to be Class III devices. 21 U.S.C. 360c(f)(1) (1994 & Supp. V 1999).

Before a Class III device may be introduced into the market, a manufacturer generally must obtain a "premarket approval" (PMA) from the FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, a prospective manufacturer must submit information to the FDA that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a) and (c); 21 U.S.C. 360e(d) (1994 & Supp. V 1999); 21 C.F.R. Pt. 814. "The PMA process is ordinarily quite time consuming because the FDA's review requires an 'average of 1,200 hours [for] each submission.'" *Buckman Co.* v. *Plaintiff's Legal Comm.*, 531 U.S. 341, 344-345 (2001) (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 477 (1996)).

A grandfathering provision permits Class III devices that were on the market before the MDA's enactment to remain on the market until the FDA initiates and completes a rulemaking requiring the submission of a PMA. 21 U.S.C. 360e(b)(1)(A). In order to prevent grandfathered manufacturers from monopolizing the market, the MDA allows other manufacturers to distribute competing devices if they show through a premarket notification process that they are "substantially equivalent" to predicate devices already on the market. 21 U.S.C. 360e(b)(1)(B). That premarket notification process is known as the "Section 510(k) process," which refers to the section of the FDCA codified at 21 U.S.C. 360(k) (1994 & Supp. V 1999). A device is "substantially equivalent" to a grandfathered device if it "has the same intended use as the predicate device," 21 U.S.C. 360c(i)(1)(A) (Supp. V. 1999), and the FDA finds that it "has the same technological characteristics as the

predicate device," or that it "has different technological characteristics," but the information submitted "demonstrates that the device is as safe and effective as a legally marketed device." 21 U.S.C. 360c(i)(1)(A)(ii) (Supp. V 1999). See *Buckman*, 531 U.S. at 345 (describing Section 510(k) process).

2. Petitioners are individuals who had bone screw devices implanted in the pedicles of their spines. Alleging that they suffered injuries because of those devices, petitioners filed thousands of individual suits against the manufacturers of the devices. Among other things, petitioners alleged that various manufacturers made fraudulent representations to the FDA concerning the intended uses of the devices and that the devices were thus improperly given market clearance. See *Buckman*, 531 U.S. 346-347. Although the Third Circuit initially held that petitioners' "fraud-on-the-FDA" claims could proceed, see *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (1998), this Court recently held that the claims "conflict with, and are therefore impliedly pre-empted by, federal law." *Buckman*, 531 U.S. at 348.

In addition, petitioners asserted tort claims against the United States in which they alleged that the FDA improperly granted clearances under Section 510(k) for various bone screw devices. The United States moved to dismiss petitioners' claims on the ground that they are barred by the discretionary function exception to the FTCA, 28 U.S.C. 2680(a), and the district court granted the motion. Pet. App. 42-66. Consistent with a prior order dismissing petitioners' claims, the court explained that petitioners' current "allegations involve the FDA's exercise of discretion rather than the violation of any mandatory directive and [petitioners] continue to seek to inquire into the subjective decision

making involved in the 510(k) clearance process." *Id.* at 44.

3. The court of appeals affirmed the district court's dismissal of the claims against the United States. Pet. App. 1-41. The court of appeals first rejected petitioners' attempt "to get around the discretionary function exception" by arguing that the FDA had engaged in intentional or criminal misconduct. *Id.* at 33. The court found that the "complaints do not appear to allege that the FDA's behavior amounted to intentional or possibly criminal misconduct." *Id.* at 34. Even assuming that petitioners had alleged "intentionally improper or criminal behavior" by the FDA, the court emphasized that such conduct would not generally "constitute[] the type of 'negligent or wrongful act or omission' for which the FTCA grants a waiver of sovereign immunity." *Id.* at 35. Finally, the court noted that the most pertinent state law analogue for petitioners' claims is an action "for some type of intentional tort of fraud or deceit," which "is explicitly exempted from the FTCA's waiver of sovereign immunity." *Id.* at 36 & n.21 (citing 28 U.S.C. 2680(h)).

The court next addressed petitioners' claims that the FDA acted negligently. Employing the two-part test for application of the discretionary function exception set out in *Berkovitz* v. *United States*, 486 U.S. 531, 536-537 (1988), the court first considered whether the challenged FDA decisions involve "an element of judgment or choice." Pet. App. 36-39 (quoting *Berkovitz*, 486 U.S. at 536). The court concluded that the FDA's substantial equivalence determinations under the Section 510(k) process involve judgment or choice because FDA regulators "must decide what data and other information is relevant, what is reliable, and how much is sufficient." *Id.* at 39.

The court also held that the FDA's decisions under the Section 510(k) process satisfy the second part of the *Berkovitz* test—they involve judgment "of the kind that the discretionary function exception was designed to shield." Pet. App. 37 (quoting *Berkovitz*, 486 U.S. at 536). In so holding, the court rejected petitioners' argument that "the § 510(k) process involves merely scientific tasks rather than the exercise of policy-based discretion." *Ibid.* The court noted that the Section 510(k) process requires the FDA to balance considerations such as safety and efficacy, and thus the FDA's judgments under that process "reflect policy choices." *Id.* at 40. Finally, the court held that the district court did not abuse its discretion in denying petitioners' requests for discovery. *Ibid.*

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. Accordingly, review by this Court is not warranted.

1. a. The FTCA is a limited waiver of sovereign immunity for certain tort actions against the United States. See 28 U.S.C. 1346(b), 2674. The discretionary function exception, which immunizes the United States from tort liability for discretionary policy choices made by its employees, is a significant limitation on that waiver of immunity. Under the exception, courts may not hold the United States liable for "[a]ny claim * * * based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." 28 U.S.C. 2680(a).

An action comes within the exception if (1) "it involves an element of judgment or choice," and (2) the judgment "is of the kind that the discretionary function exception was designed to shield." *Berkovitz* v. *United States*, 486 U.S. 531, 536 (1988). The first step of the inquiry focuses on whether a "federal statute, regulation, or policy specifically prescribes a course of action" as to the decision at issue. *Ibid.* The second step of the inquiry focuses "on the nature of the actions taken and on whether they are susceptible to policy analysis." *United States* v. *Gaubert*, 499 U.S. 315, 325 (1991); see *United States* v. *S.A. Empresa de Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 814 (1984) (exception prevents "judicial 'second-guessing'" of decisions "grounded in social, economic, and political policy").

b. The court of appeals correctly applied the *Berkovitz* test in holding that petitioners' tort claims against the United States are barred. The court found that no specific, mandatory directives constrained the FDA's decisionmaking under the Section 510(k) process. Pet. App. 38-39. In addition, because "[t]he § 510(k) process requires judgment regarding what evidence is relevant, how well that evidence demonstrates safety and efficacy, and what weight should be given conflicting evidence and opinions," the court also held that the decisions made under the process are "susceptible to policy analysis" and involve judgment of the sort protected by the discretionary function exception. *Id.* at 40.

Petitioners do not seriously challenge the court of appeals' conclusions concerning the nature of the FDA's decisionmaking under the Section 510(k) process. Instead, petitioners argue (Pet. 3, 11-15) that "the FDA violated its own policies and procedures." Pet. 3. As in

the court of appeals, however, petitioners do not identify any specific directive that the FDA allegedly violated. Nor do petitioners explain why a violation of internal policies would necessarily strip respondent's actions of their discretionary character.

Petitioners argue that the FDA granted clearance for a certain device despite the manufacturer's "failure to provide sufficient or valid data to demonstrate that the device was substantially equivalent to, or as safe and effective as, a predicate device." Pet. 11. But the governing statutes and regulations give the FDA broad leeway in determining the quantity and quality of the data needed for substantial equivalence decisions. See 21 U.S.C. 360c(i)(1)(A) (Supp. V 1999) (requiring "appropriate clinical or scientific data if deemed necessary by the Secretary"); 21 C.F.R. 807.100(b)(2)(ii)(B) (same). Thus, the court of appeals correctly concluded that petitioners' argument "that the FDA violated statutory and regulatory provisions is, in reality, a claim that the FDA's judgment is wrong." Pet. App. 39.

Likewise, petitioners contend (Pet. 15) that the FDA violated a specific duty to take "appropriate regulatory action" to halt off-label uses of certain orthopedic bone screw devices in spinal surgeries. But the determination of what regulatory action is "appropriate" is clearly a discretionary judgment for the agency. As this Court recently recognized, the FDA has wide discretion in using the enforcement options at its disposal to combat suspected fraud, and it must be afforded sufficient "flexibility" to pursue many "difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349; see *id.* at 350 (discussing with approval the FDA's policy regarding off-label use). Moreover, it is well-established that an agency's decision not to take

enforcement action is generally not subject to review under the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985). Thus, the FDA's failure to take what petitioners believe was "appropriate" enforcement action against certain bone screw manufacturers cannot serve as the basis for tort liability under the FTCA. See *Moore* v. *Valder*, 65 F.3d 189 (D.C. Cir. 1995) (holding that prosecutorial decisions are generally protected under the discretionary function exception), cert. denied, 519 U.S. 820 (1996).

In addition, petitioners argue that decisions under the Section 510(k) process are not protected by the discretionary function exception because a substantial equivalence determination "requires only performance of scientific evaluation and not the formulation of policy." Pet. 13. The court of appeals also correctly rejected that argument. Pet. App. 39-40. The court explained that the Section 510(k) process implicates such considerations as safety and efficacy. *Id.* at 39. Thus, the court held that "[d]ecisions made in this context reflect policy choices and cannot be categorized as ministerial." *Id.* at 40.

The court of appeals' conclusion is supported by this Court's decision in *Gaubert*. The plaintiff in that case argued that the day-to-day "operational" decisions made by federal regulators who were running a bank were not protected under the discretionary function exception because the routine business decisions alleged to be improper (*i.e.*, hiring and firing consultants and mediating salary disputes) did not involve policy considerations. See *Gaubert*, 499 U.S. at 328. Emphasizing that "[d]iscretionary conduct is not confined to the policy or planning level," *id.* at 325, this Court rejected the argument that the government's actions

were not protected under the discretionary function exception simply "because they involved the mere application of technical skills and business expertise," *id.* at 331. Petitioners' argument that the FDA's determinations under the Section 510(k) process are not protected because they involve the application of scientific principles is similarly without merit. See also *GATX/Airlog Co.* v. *United States*, No. 99-36024, 2002 WL 598421, at *9 (9th Cir. Apr. 19, 2002) (holding that FAA's "equivalent strength" determinations in issuing airworthiness certificates were protected under the discretionary function exception despite arguments that such decisions involved "objective scientific standards").

Finally, petitioners point to no split of authority on the questions raised in the petition. In fact, petitioners do not cite any circuit court authority from outside the Third Circuit and principally argue that the Third Circuit's decision in this case deviates from prior Third Circuit precedent. Any such deviation, if it existed, would not warrant this Court's review. See *Wisniewski* v. *United States*, 353 U.S. 901 (1957) (per curiam).

2. Also contrary to petitioners' contentions (Pet. 15-19), the court of appeals correctly affirmed the district court's decision not to permit discovery on petitioners' claims of intentional or criminal wrongdoing by the FDA. The court of appeals found that the "complaints do not appear to allege that the FDA's behavior amounted to intentional or possibly criminal misconduct," Pet. App. 34, and reasoned that such conduct would in any event not generally "fall within the scope of the FTCA's immunity waiver," *id.* at 35-36. The court thus held that the "proposed discovery was aimed at supporting claims that * * * fall outside the FTCA." *Id.* at 40.

The petition does not challenge either the court of appeals' factual conclusion that petitioners' complaint does not assert claims of intentional wrongdoing by the FDA or the court's legal conclusion that the proposed discovery was not relevant to any viable claims under the FTCA. Instead, petitioners argue that a remand for discovery "would create no precedent" and "would be limited to the facts unique to this case." Pet. 18. The fact-bound and allegedly unique nature of the discovery issue in this case, however, only confirms that review by this Court is not warranted. See *Tiffany Fine Arts, Inc.* v. *United States*, 469 U.S. 310, 317 n.5 (1985) (noting that the Supreme Court will rarely disturb concurrent factual findings by an appellate court and a trial court); *Branti* v. *Finkel*, 445 U.S. 507, 512 n.6 (1980) (same).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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