St. Mary's Law Journal

Volume 20 | Number 4 Article 12

1-1-1989

# Causes of Action Stemming from Federal Government's Negligence in Implementing Mandatory Regulations or Statutes are not Barred by Discretionary Function Exception of Federal Tort Claims Act.

Irl I. Nathan

constitutionally suspect. While *Mistretta* foreclosed the major constitutional grounds of attack on the new system, federal appellate courts are likely to be burdened by much piecemeal litigation over the Guidelines' application in individual cases.

*Janis Hillman*

**TORTS**—GOVERNMENTAL IMMUNITY—CAUSES OF ACTION STEMMING FROM FEDERAL GOVERNMENT'S NEGLIGENCE IN IMPLEMENTING MANDATORY REGULATIONS OR STATUTES ARE NOT BARRED BY DISCRETIONARY FUNCTION EXCEPTION OF FEDERAL TORT CLAIMS ACT. *Berkovitz v. United States*, __ U.S. __, 108 S. Ct. 1954, 100 L. Ed. 2d 531 (1988).

In 1979, Kevan Berkovitz, a healthy infant, swallowed a polio vaccine (Orimune) created by Lederle Laboratories (Lederle). Within one month, Berkovitz developed a severely crippling case of polio. The malady left Berkovitz almost totally paralyzed and incapable of breathing without the aid of a respirator. The United States Communicable Disease Center concluded that Berkovitz contracted polio from the vaccine manufactured by Lederle.

Berkovitz's parents, as guardians, filed suit in federal district court against two agencies of the federal government. Berkovitz asserted that the agencies committed two acts which violated the Federal Tort Claims Act (FTCA): (1) the Division of Biologic Standards (DBS) acted negligently in granting Lederle a license to produce Orimune, and (2) the Bureau of Biologics (BOB), a division of the Food and Drug Administration, acted negligently in approving the release of the vaccine taken by Berkovitz. The government filed a motion to dismiss the suit, claiming the agencies' activities were within the FTCA's discretionary function exception (the exception), thus barring any suit and precluding the district court's subject-matter jurisdiction.

The government's motion was denied by the district court, which concluded that both the licensing and release of Orimune were not "discretionary functions" within the interpretation of the FTCA. The Third Circuit Court of Appeals, by a divided panel, reversed the district court's decision. The appellate court rejected the government's contention that the exception bars all claims arising from regulatory functions of federal agencies because, in some instances, representatives of regulatory agencies do not have the

discretion to disobey the orders of federal regulations or statutes. The court held, however, contrary to Berkovitz's claim, that the release and licensing of polio vaccines were entirely discretionary acts and could not constitute the basis for a cause of action against the United States under the FTCA. Berkovitz appealed to the United States Supreme Court which granted certiorari to determine whether the exception applies as a bar to suits arising from the negligent regulation of polio vaccines by the federal government. Held—*Reversed*. Causes of action stemming from the federal government's negligence in implementing mandatory regulations or statutes are not barred by the discretionary function exception of the Federal Tort Claims Act.

In *Berkovitz*, the United States Supreme Court stated that the FTCA generally permits causes of action against the Federal government

> for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

*Berkovitz v. United States*, __ U.S. __, __, 108 S. Ct. 1954, 1958, 100 L. Ed. 2d 531, 540 (1988); *see also* 28 U.S.C. § 1346(b) (1986)(Federal Tort Claims Act). The Court also asserted that the FTCA contains exceptions to this relinquishment of sovereign immunity in section 2680(a) of title 28 to the United States Code which states in part that no liability exists for "any 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) (1986); *see also Berkovitz*, __ U.S. at __, 108 S. Ct. at 1958, 100 L. Ed. 2d at 540. This exception, the Court noted, denotes the delineation between Congress' willingness to exact tort liability from the United States and its intent to shield certain governmental actions from potential suit by private individuals. *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1958, 100 L. Ed. 2d at 540 (quoting *United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 808 (1984)). Defining these borders of Congress' intent becomes difficult because the definition of a discretionary function is not entirely clear. *See* Comment, United States v. Varig*: Can the King Only Do Little Wrongs?*, 22 CAL. W.L. REV. 175, 178 (1985)(discretionary function not defined within FTCA); Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. CHI. L. REV. 1300, 1301 (1987)(discretionary function exception most litigated provision of FTCA).

The Court emphasized that whether the exception applies to a given act is determined by the application of a "two-pronged" test. *See Berkovitz v. United States*, __ U.S. __, __, 108 S. Ct. 1954, 1958-59, 100 L. Ed. 2d 531,

540-41 (1988)(exception applies only where choice involved in act and exercise of judgment based upon permissible policy). To determine whether the "two-prong" test applies, one must initially ascertain if the government employee had a choice in his ultimate decision to act. *Id.*; *see also Dalehite v. United States*, 346 U.S. 15, 34 (1953)(exception protects discretion of employee to act according to best judgment). The Court concluded that if a federal regulation, policy, or statute specifically imposes a course of conduct, the exception would not bar a suit based upon an employee's failure to obey that course of conduct. *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1958-59, 100 L. Ed. 2d at 540-41. If the disputed conduct comprises an element of judgment, however, the Court noted that one must then decide "whether that judgment is of the kind that the discretionary function exception was designed to shield." *Id.* at __, 108 S. Ct. at 1959, 100 L. Ed. 2d at 541 (exception insulates government from liability if action challenged involves acceptable exercise of policy judgment); *see also United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 814 (1984)(Court noted congressional basis for exception was desire to prevent second-guessing of administrative and legislative decisions established upon economic, political, or social policy). Under this second "prong" the court reasoned that the exception shields the government from liability so long as the action challenged consists of "the permissible exercise of policy judgment." *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1959, 100 L. Ed. 2d at 541.

Using this "two-pronged" test, the Court initially rejected the government's argument that the exception prohibits liability for all acts stemming from regulatory programs of federal agencies. *See id.* at __, 108 S. Ct. at 1960-61, 100 L. Ed. 2d at 542 (exception applies solely to conduct involving permissible exercise of judgment); *cf. Rayonier, Inc. v. United States*, 352 U.S. 315, 318-19 (1957)(FTCA does not prevent liability for performance of proprietary or uniquely governmental acts); *accord Indian Towing Co. v. United States*, 350 U.S. 61, 64-65 (1955)(disapproving contention that FTCA prevents liability for execution of uniquely governmental functions). The Court then segmented Berkovitz's initial two claims into five distinct allegations: 1) DBS licensed Orimune without initially receiving data from the manufacturer; 2) DBS licensed the vaccine without initially ascertaining whether the vaccine conformed to regulatory standards; 3) DBS issued a license to Lederle laboratories for the vaccine despite a finding that the vaccine failed to comply with regulatory standards; 4) DBS's determination that the vaccine is in compliance was in error; and 5) BOB violated federal policy and regulations governing the release of polio vaccines. *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1962-64, 100 L. Ed. 2d at 545-47.

The Court, addressing Berkovitz's first allegation, noted that the exception would not prohibit a cause of action against the Division of Biologic Standards for negligent licensing because the decision to issue a product li-

cense to Lederle before receiving the requisite data from the manufacturer was not a matter of choice. *See Berkovitz v. United States*, __ U.S. __, __, 108 S. Ct. 1959, 1962, 100 L. Ed. 2d 541, 544 (1988)(Court noted that if DBS distributed license to Lederle without first acquiring needed test data, violation of specific regulatory and statutory directives occurred); *see also id.* at __, 108 S. Ct. at 1962-63, 100 L. Ed. 2d at 545-56 (both claims are governed by mandatory regulations or statutes); 42 U.S.C. § 262(d) (1982)(license shall be issued only upon production of test data by manufacturer); 21 C.F.R. § 601.2(a) (1987)(application for license deemed filed solely upon receipt of test data). Addressing Berkovitz's second and third allegations, the Court similarly noted that the exception would not prohibit an action against DBS because under the scheme monitoring the regulation of polio vaccines, DBS was required to analyze the product and make a conclusion that the product conforms with all regulatory standards. *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1962, 100 L. Ed. 2d at 545; *see also* 21 C.F.R. § 601.4 (1987)(license issued upon determination that product meets applicable standards). Regarding Berkovitz's fourth allegation, the Court stated that if DBS determined Orimune to be in conformity with regulatory standards, but such a determination was in error, the question would be whether the method and manner of ascertaining conformity with the relevant safety standards include an agency judgment of the type safeguarded by the exception. *Berkovitz*, __ U.S. __, 108 S. Ct. at 1963, 100 L. Ed. 2d at 546. The Court, however, declined to rule upon this allegation, stating that there was no evidence presented by the parties regarding the procedures used by DBS to decipher and implement the regulations and criteria for compliance. *Id.* Finally, the Court declined to apply the exception to Berkovitz's fifth allegation and instead remanded this issue for a factual determination because Berkovitz had not proved whether the BOB's policy allowed an official to release a non-complying vaccine lot based upon policy considerations. *See id.* at __, 108 S. Ct. at 1964, 100 L. Ed. 2d at 547 (exception only applies if official's acts involve permissible exercise of judgment based upon policy considerations).

The United States Supreme Court in *Berkovitz* has "put to rest" any argument that the discretionary function exception precludes liability for all acts stemming from the regulatory procedures of federal agencies. *Compare Berkovitz v. United States*, __ U.S. __, __, 108 S. Ct. 1959, 1959-60, 100 L. Ed. 2d 541, 542 (1988)(exception not applicable to all regulatory functions) *with United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 813 (1984)(legislative history repetitiously refers to exploits of regulatory agencies as illustrations of those covered by exception). *See generally* Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. CHI. L. REV. 1300, 1317 (1987)(dicta in *Varig* discussed exception as if every regulatory operation might be shielded from liability). Instead of concentrating upon the status of the actor, the

Court focuses upon the nature of the act itself, thereby barring the exception's applicability to all conduct by a federal regulatory agency. *See Berkovitz*, __ U.S. at __, 108 S. Ct. at 1960, 100 L. Ed. 2d at 542 (Court focused upon particular nature of regulatory conduct at issue); *see also* Comment, *The Discretionary Function Exception and Mandatory Regulations*, 54 U. CHI. L. REV. 1300, 1317 (1987)(most striking gap in *Varig* opinion is Court's failure to indicate whether exception applicable to negligent regulatory activities other than aircraft inspection). This interpretation also conforms with Congress' intent behind the exception: to prevent judicial intervention in political, economic, and social judgments of regulatory agencies. *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1960, 100 L. Ed. 2d at 542. Thus, there is no blanket exclusion from liability for federal regulatory activities. *Id.*

In addition, the Court distinguished a policy decision made by a federal agency, and a mandatory regulation that stems from that policy, thereby providing a cause of action for litigants where none had previously existed. *Compare United States v. S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797, 819-20 (1984)(exception bars claims contesting FAA's decision to initiate a spot checking program) *with Berkovitz v. United States*, __ U.S. __, __, 108 S. Ct. 1959, 1963, 100 L. Ed. 2d 542, 546 (1988)(exception does not apply to suit charging agency with failure to perform in accordance with specific mandatory directive). If the agency's policy leaves no margin for an administrator to exert judgment in executing a given act, the exception does not prohibit a challenge that the act was wrongful or negligent. *Id.* at __, 108 S. Ct. at 1964, 100 L. Ed. 2d at 547. The Court also clarified its interpretation of the exception by providing a workable test to be applied to federal regulatory acts. *See id.* at __, 108 S. Ct. at 1958-59, 54 L. Ed. 2d at 540-41 (exception does not apply if act was mandatory or did not involve exercise of judgment based upon public policy). Initially, if the regulatory act is mandatory, that is, no exercise of judgment is involved, a claim would not be barred by the exception. *Id.* at __, 108 S. Ct. at 1958-59, 54 L. Ed. 2d at 540-41. If, however, the regulatory act is discretionary, that is, involves some use of judgment, a determination of whether the act consists of the permissible exercise of policy judgment would be necessary. *Id.* at __, 108 S. Ct. at 1959, 100 L. Ed. 2d at 541.

Finally, the Court resolved a conflict between two lower court decisions involving the government's administration of polio vaccines. *See Baker v. United States*, 817 F.2d 560, 564-66 (9th Cir. 1987)(holding exception did not prohibit suit alleging negligent decision to *license* polio vaccine); *Loge v. United States*, 662 F.2d 1268, 1272-73 (8th Cir. 1981)(holding exception did not prohibit suit alleging negligence in *licensing and release* of particular polio vaccine lot). By holding that no bar existed to both the licensing and release of polio vaccines, the Court followed both *Baker* and *Loge* because

DBS violated a specific mandatory directive and statute. *Berkovitz*, __ U.S. at __, 108 S. Ct. at 1962, 100 L. Ed. 2d at 544-45 (statute and regulation require as precondition to licensing that DBS receive test data from manufacturer relating to product's compliance); *accord Baker*, 817 F.2d at 564-66 (negligent failure to follow specific mandatory regulation in licensing vaccine not barred by FTCA); *Loge*, 662 F.2d at 1272-73 (negligent failure to test polio vaccine before licensing not discretionary and not barred by exception). The Court also held, as did the court in *Loge*, that the release of a polio vaccine by the government was subject to liability if the procedure involved a specific mandatory directive which was negligently performed. *See id.* at __, 108 S. Ct. at 1964, 100 L. Ed. 2d at 547 (exception not applicable if act does not pertain to permissible exercise of policy); *accord Loge*, 662 F.2d at 1272-73. Therefore, federal agencies can be subject to liability under the FTCA for both the negligent licensing and release of polio vaccines if such conduct involves the mandatory directive of a federal regulation or statute. *See Berkovitz*, __ U.S. at __, 108 S. Ct. at 1962, 1963-64, 100 L. Ed. 2d at 544-45, 546-48 (mandatory regulation or statute leaves no discretion to issue license or release vaccine without receiving test data and therefore no bar to suit exists).

After *Berkovitz*, it is clear that federal regulatory agencies do not have a blanket immunity to the FTCA. Equally clear is the Court's establishment of a viable test for determining whether the discretionary function exception applies to a given regulatory act. Finally, in relation to the licensing and release of polio vaccines by the federal government, such acts are not discretionary when they are mandated by a statute or regulation.

*Irl I. Nathan*