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Discretionary Function Exception to Federal Tort Claims Act Does Not Bar Claim that Federal Agencies Improperly Licensed and Released Polio Vaccine

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RECENT CASES

DISCRETIONARY FUNCTION EXCEPTION TO FEDERAL TORT CLAIMS ACT DOES NOT BAR CLAIM THAT FEDERAL AGENCIES IMPROPERLY LICENSED AND RELEASED POLIO VACCINE

In *Berkovitz By Berkovitz v. United States*, ___ U.S. ___, 108 S. Ct. 1954 (1988), the United States Supreme Court held that the discretionary function exception to the Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2680(a) (1982 & Supp. IV 1986), did not bar a claim alleging that the Division of Biologic Standards ("DBS"), then a part of the National Institutes of Health, licensed the production of an oral polio vaccine without first receiving required test data. The Court also held that the discretionary function exception to the FTCA did not bar a claim that employees of the Food and Drug Administration's Bureau of Biologics ("Bureau") knowingly approved the release of a specific lot of vaccine which failed to conform to safety standards.

Background

In May, 1979, Kevan Berkovitz, then a 2-month-old infant, ingested a dose of Orimune, an oral polio vaccine manufactured by Lederle Laboratories ("Lederle"). Berkovitz subsequently contracted a severe case of polio which left him almost completely paralyzed and unable to breathe without a respirator. Berkovitz, joined by his parents as guardians, filed suit in federal district court alleging that the vaccine had caused his injuries and that the United States was liable under the FTCA. The complaint stated that the DBS wrongfully licensed Lederle to produce Orimune and that the Bureau wrongfully approved release of the specific lot of Orimune containing Berkovitz's dose.

District Court

In the district court, the Government moved to dismiss the suit for lack of subject matter jurisdiction. The FTCA contains a provision which immunizes employees of federal agencies from suits based upon their exercise or failure to exercise a discretionary function or duty. In its motion to dismiss, the Government argued that its actions were barred from suit because they fell within this discretionary function exception. The district court denied this motion, finding that neither the licensing nor the release of a specific lot of the vaccine fell within the discretionary function exception. Upon the Government's request, the district court granted the Government's motion for an immediate appeal to the United States Court of Appeals for the Third Circuit.

Court of Appeals

A divided panel of the United States Court of Appeals for the Third Circuit reversed the district court's decision. The court rejected the Government's argument that all regulatory activities of federal agencies are discretionary, but held that licensing and releasing polio vaccines were discretionary actions. Thus, the court held that the district court lacked subject matter jurisdiction over Berkovitz's claims because these claims were barred by the discretionary function exception. The dissent contended that the licensing and releasing of polio vaccines were activities controlled by regulatory and statutory directives which left no room for any exercise of discretion on the part of government officials.

United States Supreme Court: The Discretionary Function Exception

Because Berkovitz's claims came before the Court on a motion to dismiss, the Court considered only whether Berkovitz's claims could survive a motion to dismiss, not whether his claims had been proven. Writing for a unanimous Court, Justice Marshall began his analysis by considering the scope of the discretionary function exception as it relates to governmental activities. Specifically, the Court addressed whether the discretionary function exception would protect governmental actions involving the licensing of an oral polio vaccine and the release to the public of a specific lot of the vaccine.

The Court stated that Congress' purpose in enacting the discretionary function exception was to prevent outside interference with the judgments of governmental agencies. The discretionary function exception "marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." 108 S.Ct. at 1958 (quoting *United States v. Varig Airlines*, 467 U.S. 797, 808 (1984)). In considering the applicability of the discretionary function exception, the Court observed that the exception precludes liability only in cases involving the permissible exercise of policy judgment. In cases where a statute, regulation, or policy specifically prescribe a course of action, no exercise

of judgment is needed, so the discretionary function exception cannot be invoked in order to avoid liability. The Court thus rejected the Government's argument that any and all regulatory acts of federal agencies are exempt from liability.

Unclear Whether DBS' Licensing of Vaccine Improper

In accordance with the Public Health and Welfare Act, 42 U.S.C. § 262(a) (1982 & Supp. IV 1986), a manufacturer must be licensed by the DBS in order to market an oral polio vaccine. To become eligible for a license, a manufacturer must first submit to the DBS samples of the vaccine made during the various stages of the manufacturing process, as well as a sample of the finished product. The DBS is required by various statutory and regulatory provisions to inspect the submitted samples to ensure that they comply with safety standards. In 1963, the DBS licensed Lederle to produce Orimune.

Berkovitz made two allegations regarding the DBS's licensing of Lederle. First, Berkovitz alleged that the DBS issued the license before receiving the required samples of the vaccine. The Court found that the DBS exercises no discretion in issuing product licenses because this activity is directed by statute and regulation. Therefore, Berkovitz's claim based on an allegation of improper licensing was not barred by the discretionary function exception of the FTCA.

Second, Berkovitz alleged that the license was issued even though the vaccine did not meet the required safety standards. Because the parties failed to address this allegation in detail, the Court determined that it could be construed in any one of three ways. If Berkovitz's allegation meant *either* that the DBS licensed the vaccine without determining whether the vaccine complied with regulatory standards *or* that the DBS licensed the vaccine after establishing that the vaccine failed to meet the standards, the discretionary function exception would not bar the claim. No discretion is involved in either of these circumstances because the agency may not deviate from mandated procedure.

If Berkovitz's allegation meant that the DBS licensed the vaccine as the result of an incorrect finding that the vaccine met the required safety standards, the Court held that it was then unclear whether the discretionary function exception barred the claim. The decision turned on whether government officials can exercise policy judgment in determining compliance with the safety standards. Because the Court did not have enough information to make this determination, the matter was remanded to the district court for decision.

Bureau's Release of Specific Lot of Polio Vaccine May Be Discretionary

Berkovitz alleged that the Bureau had adopted a policy of testing each and every vaccine lot for compliance with safety standards. If a lot failed to comply with these standards, the Bureau would prohibit its distribution to the public. Berkovitz alleged that this policy was non-discretionary, and that even though the policy left no room for officials to implement independent policy judgment, employees of the Bureau knowingly released a lot which failed to comply with safety standards. Regulations of the federal Food and Drug Administration ("FDA") generally allow the Bureau to establish the appropriate method for releasing lots of any licensed product. The regulations provide that the Bureau is authorized to examine any vaccine lot and to prohibit its distribution if it fails to comply with safety, purity, or potency standards. 21 CFR § 610.2(a) (1988). A manufacturer may not distribute a particular lot until it is released by the Bureau.

The Court distinguished this regulatory scheme from that governing the issuance of licenses. Because the FDA regulations governing release of vaccine lots do not require the Bureau to take action in all cases, the Court found them to be discretionary. Accordingly, the discretionary function exception would bar suits alleging that the Bureau had inappropriately formulated methods of regulating the release of vaccine lots. With regard to the liability of individual governmental officials, the Court held that if the regulatory scheme left room for the exercise of independent policy judgment concerning the release of vaccine lots, then the discretionary function exception would protect these individuals from liability. The discretionary function exception would not bar a claim that an act was negligent or wrongful if the official's act did not involve the exercise of policy judgment.

The Court held that Berkovitz's claim regarding the Bureau's release of the vaccine lot in question survived the Government's motion to dismiss because this claim was directed at a governmental action that allegedly left no room for individual officials to exercise independent judgment. In remanding the case for further proceedings, the Court stated that until a determination is made as to whether the release of vaccine lots involves the exercise of policy judgment, Berkovitz should be allowed to maintain his claim regarding the release of a specific lot of the vaccine.

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