BERKOVITZ ET AL. *v.* UNITED STATES

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

No. 87–498. Argued April 19, 1988—Decided June 13, 1988

A provision of the Federal Tort Claims Act (FTCA) excepts from statutory liability any claim "based upon [a federal agency's or employee's] exercise or performance or the failure to exercise or perform a discretionary function or duty." Upon contracting a severe case of polio after ingesting a dose of Orimune, an oral polio vaccine manufactured by Lederle Laboratories, petitioner Kevan Berkovitz, a minor, joined by his parents (also petitioners) as guardians, filed an FTCA suit alleging violations of federal law and policy by the National Institutes of Health's Division of Biologic Standards (DBS) in licensing Lederle to produce Orimune, and by the Bureau of Biologics of the Food and Drug Administration (FDA) in approving the release to the public of the particular lot of vaccine containing Berkovitz's dose. The District Court denied the Government's motion to dismiss the suit for lack of subject-matter jurisdiction, but the Court of Appeals reversed. Although rejecting the Government's argument that the discretionary function exception bars all claims arising out of federal agencies' regulatory activities, the court held that the licensing and release of polio vaccines are wholly discretionary actions protected by the exception.

Held:

1. The language, purpose, and legislative history of the discretionary function exception, as well as its interpretation in this Court's decisions, establish that the exception does not preclude liability for any and all acts arising out of federal agencies' regulatory programs, but insulates from liability only those governmental actions and decisions that involve an element of judgment or choice and that are based on public policy considerations. Pp. 535–539.

2. The Court of Appeals erred in holding that the discretionary function exception bars petitioners' claims. Pp. 539–548.

(a) Statutory and regulatory provisions require the DBS, prior to issuing a license for a product such as Orimune, to receive all data which the manufacturer is required to submit, to examine the product, and to make a determination that it complies with safety standards. Thus, a cause of action based on petitioner's allegation that the DBS licensed Orimune without first receiving the required safety data is not barred by the discretionary function exception, since the DBS has no discretion to

issue a license under such circumstances, and doing so would violate a specific statutory and regulatory directive. Petitioners' other claim—that the DBS licensed Orimune even though the vaccine did not comply with certain regulatory safety standards—if interpreted to mean that the DBS issued the license without determining compliance with the standards or after determining a failure to comply, also is not barred by the discretionary function exception, since the claim charges the agency with failing to act in accordance with specific mandatory directives, as to which the DBS has no discretion. However, if this claim is interpreted to mean that the DBS made an incorrect compliance determination, the question of the discretionary function exception's applicability turns on whether the DBS officials making that determination permissibly exercise policy choice, a point that is not clear from the record and therefore must be decided by the District Court if petitioners choose to press this interpretation. Pp. 540–545.

(b) Although the regulatory scheme governing the public release of vaccine lots allows the FDA to determine the appropriate manner in which to regulate, petitioners have alleged that, under the authority granted by the regulations, the FDA has adopted a policy of testing all lots for compliance with safety standards and of preventing the public distribution of any lot that fails to comply, and that, notwithstanding this mandatory policy, the FDA knowingly approved the release of the unsafe lot in question. Accepting these allegations as true, as is necessary in reviewing a dismissal, the holding that the discretionary function exception barred petitioners' claim was improper, since the acts complained of do not involve the permissible exercise of discretion to release a noncomplying lot on the basis of policy considerations. Pp. 545–548.

822 F. 2d 1322, reversed and remanded.

MARSHALL, J., delivered the opinion for a unanimous Court.

Ellen M. Viakley argued the cause for petitioners. With her on the briefs were *Gary S. Gildin* and *Paul R. Friedman.*

Michael K. Kellogg argued the cause for the United States. With him on the brief were *Solicitor General Fried, Assistant Attorney General Bolton, Deputy Solicitor General Ayer, John F. Cordes, William Cole, Thomas Scarlett,* and *Ann H. Wion.**

**Lloyd N. Cutler, James Robertson,* and *Ronald J. Greene* filed a brief for Lederle Laboratories as *amicus curiae.*

JUSTICE MARSHALL delivered the opinion of the Court.

The question in this case is whether the discretionary function exception of the Federal Tort Claims Act (FTCA or Act), 28 U. S. C. § 2680(a), bars a suit based on the Government's licensing of an oral polio vaccine and on its subsequent approval of the release of a specific lot of that vaccine to the public.

I

On May 10, 1979, Kevan Berkovitz, then a 2-month-old infant, ingested a dose of Orimune, an oral polio vaccine manufactured by Lederle Laboratories. Within one month, he contracted a severe case of polio. The disease left Berkovitz almost completely paralyzed and unable to breathe without the assistance of a respirator. The Communicable Disease Center, an agency of the Federal Government, determined that Berkovitz had contracted polio from the vaccine.

Berkovitz, joined by his parents as guardians, subsequently filed suit against the United States in Federal District Court.[1] The complaint alleged that the United States was liable for his injuries under the FTCA, 28 U. S. C. §§ 1346(b), 2674, because the Division of Biologic Standards (DBS), then a part of the National Institutes of Health, had acted wrongfully in licensing Lederle Laboratories to produce Orimune and because the Bureau of Biologics of the Food and Drug Administration (FDA) had acted wrongfully in approving release to the public of the particular lot of vaccine containing Berkovitz's dose. According to petitioners, these actions violated federal law and policy regarding the inspection and approval of polio vaccines.

The Government moved to dismiss the suit for lack of subject-matter jurisdiction on the ground that the agency actions fell within the discretionary function exception of the FTCA. The District Court denied this motion, concluding

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[1] Petitioners also sued Lederle Laboratories in a separate civil action. That suit was settled before the instant case was filed.

that neither the licensing of Orimune nor the release of a specific lot of that vaccine to the public was a "discretionary function" within the meaning of the FTCA. Civ. Action No. 84–2893 (WD Pa., Apr. 30, 1986). At the Government's request, the District Court certified its decision for immediate appeal to the Third Circuit pursuant to 28 U. S. C. § 1292(b), and the Court of Appeals accepted jurisdiction.

A divided panel of the Court of Appeals reversed. 822 F. 2d 1322 (1987). The court initially rejected the Government's argument that the discretionary function exception bars all claims arising out of the regulatory activities of federal agencies. The court stated that "the discretionary function exception is inapplicable to non-discretionary regulatory actions," *id.*, at 1328, and noted that employees of regulatory agencies have no discretion to violate the command of federal statutes or regulations. Contrary to petitioners' claim, however, the court held that federal law imposed no duties on federal agencies with respect to the licensing of polio virus vaccines or the approval of the distribution of particular vaccine lots to the public. Likening the applicable regulatory scheme to the scheme found to confer discretionary regulatory authority in *United States* v. *Varig Airlines*, 467 U. S. 797 (1984), the court concluded that the licensing and release of polio vaccines were wholly discretionary actions and, as such, could not form the basis for suit against the United States. A dissenting judge argued that the relevant statutes and regulations obligated the DBS to require the submission of test data relating to a vaccine from the manufacturer and to deny a license when the test data showed that the vaccine failed to conform with applicable safety standards. Reading the complaint in this case as alleging a failure on the part of the DBS to act in accordance with these directives, the dissenting judge concluded that the discretionary function exception did not bar petitioners' suit.

We granted certiorari, 484 U. S. 1003 (1988), to resolve a conflict in the Circuits regarding the effect of the discre-

tionary function exception on claims arising from the Government's regulation of polio vaccines. Compare 822 F. 2d 1322, *supra*, with *Baker* v. *United States*, 817 F. 2d 560, 564–566 (CA9 1987) (holding that discretionary function exception did not bar suit alleging a negligent decision to license a polio vaccine); *Loge* v. *United States*, 662 F. 2d 1268, 1272–1273 (CA8 1981) (holding that discretionary function exception did not bar suit alleging negligence in both the licensing of a polio vaccine and the release of a particular vaccine lot). We now reverse the Third Circuit's judgment.

II

The FTCA, 28 U. S. C. § 1346(b), generally authorizes suits against the United States for damages

> "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."[2]

The Act includes a number of exceptions to this broad waiver of sovereign immunity. The exception relevant to this case provides that no liability shall lie 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).

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[2] There is currently no dispute in this case as to whether petitioners have stated a claim that falls within this general waiver of immunity. Although the Government raised this issue in its motion to dismiss petitioners' suit, the District Court found that the complaint stated a claim under the relevant state law, and the Government declined to request certification of this decision for immediate appeal.

This exception, as we stated in our most recent opinion on the subject, "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." *United States* v. *Varig Airlines*, 467 U. S., at 808.

The determination of whether the discretionary function exception bars a suit against the Government is guided by several established principles. This Court stated in *Varig* that "it is the nature of the conduct, rather than the status of the actor, that governs whether the discretionary function exception applies in a given case." *Id.*, at 813. In examining the nature of the challenged conduct, a court must first consider whether the action is a matter of choice for the acting employee. This inquiry is mandated by the language of the exception; conduct cannot be discretionary unless it involves an element of judgment or choice. See *Dalehite* v. *United States*, 346 U. S. 15, 34 (1953) (stating that the exception protects "the discretion of the executive or the administrator to act according to one's judgment of the best course"). Thus, the discretionary function exception will not apply when a federal statute, regulation, or policy specifically prescribes a course of action for an employee to follow. In this event, the employee has no rightful option but to adhere to the directive. And if the employee's conduct cannot appropriately be the product of judgment or choice, then there is no discretion in the conduct for the discretionary function exception to protect. Cf. *Westfall* v. *Erwin*, 484 U. S. 292, 296–297 (1988) (recognizing that conduct that is not the product of independent judgment will be unaffected by threat of liability).

Moreover, assuming the challenged conduct involves an element of judgment, a court must determine whether that judgment is of the kind that the discretionary function exception was designed to shield. The basis for the discretionary function exception was Congress' desire to "prevent judicial

'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort." *United States* v. *Varig Airlines*, *supra*, at 814. The exception, properly construed, therefore protects only governmental actions and decisions based on considerations of public policy. See *Dalehite* v. *United States*, *supra*, at 36 ("Where there is room for policy judgment and decision there is discretion"). In sum, the discretionary function exception insulates the Government from liability if the action challenged in the case involves the permissible exercise of policy judgment.

This Court's decision in *Varig Airlines* illustrates these propositions. The two cases resolved in that decision were tort suits by the victims of airplane accidents who alleged that the Federal Aviation Administration (FAA) had acted negligently in certifying certain airplanes for operation. The Court characterized the suits as challenging the FAA's decision to certify the airplanes without first inspecting them and held that this decision was a discretionary act for which the Government was immune from liability. In reaching this result, the Court carefully reviewed the statutory and regulatory scheme governing the inspection and certification of airplanes. Congress had given the Secretary of Transportation broad authority to establish and implement a program for enforcing compliance with airplane safety standards. In the exercise of that authority, the FAA, as the Secretary's designee, had devised a system of "spot-checking" airplanes for compliance. This Court first held that the establishment of that system was a discretionary function within the meaning of the FTCA because it represented a policy determination as to how best to "accommodat[e] the goal of air transportation safety and the reality of finite agency resources." 467 U. S., at 820. The Court then stated that the discretionary function exception also protected "the acts of FAA employees in executing the 'spot-check' program" because under this program the employees "were specifically em-

powered to make policy judgments regarding the degree of confidence that might reasonably be placed in a given manufacturer, the need to maximize compliance with FAA regulations, and the efficient allocation of agency resources." *Ibid.* Thus, the Court held the challenged acts protected from liability because they were within the range of choice accorded by federal policy and law and were the results of policy determinations.[3]

In restating and clarifying the scope of the discretionary function exception, we intend specifically to reject the Government's argument, pressed both in this Court and the Court of Appeals, that the exception precludes liability for any and all acts arising out of the regulatory programs of federal agencies. That argument is rebutted first by the language of the exception, which protects "discretionary" functions, rather than "regulatory" functions. The significance of Congress' choice of language is supported by the legislative history. As this Court previously has indicated, the relevant legislative materials demonstrate that the exception was designed to cover not all acts of regulatory agencies and their employees, but only such acts as are "discretionary" in nature.[4] See *Dalehite* v. *United States*, *supra*, at 33–34.

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[3] The decision in *Indian Towing Co.* v. *United States*, 350 U. S. 61 (1955), also illuminates the appropriate scope of the discretionary function exception. The plaintiff in that case sued the Government for failing to maintain a lighthouse in good working order. The Court stated that the initial decision to undertake and maintain lighthouse service was a discretionary judgment. See *id.*, at 69. The Court held, however, that the failure to maintain the lighthouse in good condition subjected the Government to suit under the FTCA. See *ibid.* The latter course of conduct did not involve any permissible exercise of policy judgment.

[4] The House of Representatives Report on the final version of the FTCA discussed the application of the discretionary function exception to the activities of regulatory agencies by stating that it would preclude application of the Act to

"a claim against a regulatory agency, such as the Federal Trade Commission or the Securities and Exchange Commission, based upon an alleged abuse of discretionary authority by an officer or employee, whether or not negligence is alleged to have been involved. . . . The bill is not intended to

This coverage accords with Congress' purpose in enacting the exception: to prevent "[j]udicial intervention in . . . the political, social, and economic judgments" of governmental—including regulatory—agencies. *United States* v. *Varig Airlines*, 467 U. S., at 820. Moreover, this Court twice before has rejected a variant of the Government's position. See *Indian Towing Co.* v. *United States*, 350 U. S. 61, 64–65 (1955) (disapproving argument that FTCA precludes liability for the performance of "uniquely governmental functions"); *Rayonier, Inc.* v. *United States*, 352 U. S. 315, 318–319 (1957) (same).[5] And in *Varig*, we ignored the precise argument the Government makes in this case, focusing instead on the particular nature of the regulatory conduct at issue. To the extent we have not already put the Government's argument to rest, we do so now. The discretionary function exception applies only to conduct that involves the permissible exercise of policy judgment. The question in this case is whether the governmental activities challenged by petitioners are of this discretionary nature.

III

Petitioners' suit raises two broad claims. First, petitioners assert that the DBS violated a federal statute and

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authorize a suit for damages to test the validity of or provide a remedy on account of such discretionary acts even though negligently performed and involving an abuse of discretion. Nor is it desirable or intended that the constitutionality of legislation, or the legality of a rule or regulation should be tested through the medium of a damage suit for tort. However, the common-law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of nonregulatory agencies." H. R. Rep. No. 1287, 79th Cong., 1st Sess., 6 (1945).

This passage illustrates that Congress intended the discretionary function exception to apply to the *discretionary* acts of regulators, rather than to all regulatory acts.

[5] The Government's position in this case at times appears to replicate precisely the position expressly rejected in *Indian Towing* and *Rayonier*. See Brief for United States 20 (arguing that Congress intended to preserve immunity for "core governmental function[s]"); *id.*, at 16.

accompanying regulations in issuing a license to Lederle Laboratories to produce Orimune. Second, petitioners argue that the Bureau of Biologics of the FDA violated federal regulations and policy in approving the release of the particular lot of Orimune that contained Kevan Berkovitz's dose. We examine each of these broad claims by reviewing the applicable regulatory scheme and petitioners' specific allegations of agency wrongdoing.[6] Because the decision we review adjudicated a motion to dismiss, we accept all of the factual allegations in petitioners' complaint as true and ask whether, in these circumstances, dismissal of the complaint was appropriate.

A

Under federal law, a manufacturer must receive a product license prior to marketing a brand of live oral polio vaccine. See 58 Stat. 702, as amended, 42 U. S. C. § 262(a). In order to become eligible for such a license, a manufacturer must first make a sample of the vaccine product. See 42 CFR § 73.3 (Supp. 1964); 21 CFR § 601.2 (1987).[7] This process

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[6] The parties to this case also have disputed in their briefs and arguments before this Court the applicability of the discretionary function exception to a claim alleging that the DBS wrongfully chose not to revoke Lederle Laboratories' license to manufacture Orimune. Neither the Court of Appeals nor the District Court specifically addressed this issue. Moreover, petitioners did not raise the issue in their petition for a writ of certiorari. We accordingly do not consider or decide the question whether the discretionary function exception bars a claim against the Government for failure to revoke a license to manufacture a polio vaccine.

[7] The DBS issued a license to Lederle Laboratories to produce Orimune in 1963. The first citation in the text is to the regulation in effect at that time. Where the regulation has remained substantially in the same form, a parallel citation is given to the current regulations.

Manufacturers are required to obtain an establishment license in addition to the product license. See 42 CFR §§ 73.2–73.4 (Supp. 1964); 21 CFR 601.1–601.2, 601.10 (1987). Petitioners have not challenged the issuance of an establishment license to Lederle Laboratories.

begins with the selection of an original virus strain. The manufacturer grows a seed virus from this strain; the seed virus is then used to produce monopools, portions of which are combined to form the consumer-level product. Federal regulations set forth safety criteria for the original strain, see 42 CFR § 73.110(b)(2) (Supp. 1964); 21 CFR § 630.10(b)(2) (1987), the seed virus, see 42 CFR §§ 73.110(b)(3), (4) (Supp. 1964); 21 CFR §§ 630.10(b)(3), (4) (1987), and the vaccine monopools, see 42 CFR § 73.114 (Supp. 1964); 21 CFR § 630.16 (1987). Under the regulations, the manufacturer must conduct a variety of tests to measure the safety of the product at each stage of the manufacturing process. See 42 CFR §§ 73.110, 73.114 (Supp. 1964); 21 CFR §§ 630.10, 630.16 (1987). Upon completion of the manufacturing process and the required testing, the manufacturer is required to submit an application for a product license to the DBS. See 42 CFR § 73.3 (Supp. 1964); 21 CFR § 601.2 (1987).[8] In addition to this application, the manufacturer must submit data from the tests performed and a sample of the finished product. *Ibid.*

In deciding whether to issue a license, the DBS is required to comply with certain statutory and regulatory provisions. The Public Health Service Act provides:

> "Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products [including polio vaccines] may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they

[8] In 1972, the DBS was transferred from the National Institutes of Health to the FDA and renamed the Bureau of Biologics. See 37 Fed. Reg. 12865 (1972). In 1984, the Bureau of Biologics was renamed the Office of Biologics Research and Review. See 49 Fed. Reg. 23834 (1984). The regulations have been amended accordingly.

> meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations . . . ." § 351(d), 58 Stat. 702–703, as amended, 42 U. S. C. § 262(d).

A regulation similarly provides that "[a] product license shall be issued only upon examination of the product and upon a determination that the product complies with the standards prescribed in the regulations . . . ." 42 CFR § 73.5(a) (Supp. 1964); see 21 CFR § 601.4 (1987). In addition, a regulation states that "[a]n application for license shall not be considered as filed" until the DBS receives the information and data regarding the product that the manufacturer is required to submit. 42 CFR § 73.3 (Supp. 1964); 21 CFR § 601.2 (1987). These statutory and regulatory provisions require the DBS, prior to issuing a product license, to receive all data the manufacturer is required to submit, to examine the product, and to make a determination that the product complies with safety standards.

Petitioners' first allegation with regard to the licensing of Orimune is that the DBS issued a product license without first receiving data that the manufacturer must submit showing how the product, at the various stages of the manufacturing process, matched up against regulatory safety standards. See App. 12–13; Brief for Petitioners 5–6. The discretionary function exception does not bar a cause of action based on this allegation. The statute and regulations described above require, as a precondition to licensing, that the DBS receive certain test data from the manufacturer relating to the product's compliance with regulatory standards. See § 351(d), 58 Stat. 702–703, as amended, 42 U. S. C. § 262(d) (providing that a license shall issue "only upon a showing" by the manufacturer); 42 CFR § 73.3 (Supp. 1964); 21 CFR § 601.2 (1987) (providing that application for license shall be deemed as filed only upon receipt of relevant test data). The DBS has no discretion to issue a license without first receiving the required test data; to do so would violate a specific statutory

and regulatory directive. Accordingly, to the extent that petitioners' licensing claim is based on a decision of the DBS to issue a license without having received the required test data, the discretionary function exception imposes no bar.

Petitioners' other allegation regarding the licensing of Orimune is difficult to describe with precision. Petitioners contend that the DBS licensed Orimune even though the vaccine did not comply with certain regulatory safety standards. See App. 12; Brief for Petitioners 4–6.[9] This charge may be understood in any of three ways. First, petitioners may mean that the DBS licensed Orimune without first making a determination as to whether the vaccine complied with regulatory standards. Second, petitioners may intend to argue that the DBS specifically found that Orimune failed to comply with certain regulatory standards and nonetheless issued a license for the vaccine's manufacture. Third, petitioners may concede that the DBS made a determination of compliance, but allege that this determination was incorrect. Neither

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[9] Petitioners point to two specific regulatory standards that the product allegedly failed to satisfy. First, petitioners claim that an original virus strain from which the vaccine was made did not comply with the requirement that the strain be "free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis." 42 CFR § 73.110(b)(2)(i) (Supp. 1964); see 21 CFR § 630.10(b)(2)(i) (1987). Second, petitioners assert that the strain, a seed virus, a vaccine monopool, and the ultimate vaccine product failed to comply with the regulatory scheme's neurovirulence requirement. See 42 CFR §§ 73.110(b)(2)(ii), 73.110(b)(4), 73.114(b)(1) (Supp. 1964); 21 CFR §§ 630.110(b)(2)(ii), 630.110(b)(4), 630.16(b)(1) (1987). Neurovirulence is the capacity of an infectious agent to produce pathologic effects on the central nervous system. In this context, it refers to the vaccine's ability to cause paralytic poliomyelitis. The neurovirulence of a vaccine product is tested by injecting the product into monkeys. The product meets the neurovirulence criterion only if a specified number of the animals survive and a "comparative analysis" demonstrates that the neurovirulence of the vaccine product "does not exceed" the neurovirulence of a reference product previously selected by the agency. 42 CFR § 73.114(b)(1)(iii) (Supp. 1964); 21 CFR § 630.16(b)(1)(iii) (1987).

petitioners' complaint nor their briefs and argument before this Court make entirely clear their theory of the case.

If petitioners aver that the DBS licensed Orimune either without determining whether the vaccine complied with regulatory standards or after determining that the vaccine failed to comply, the discretionary function exception does not bar the claim. Under the scheme governing the DBS's regulation of polio vaccines, the DBS may not issue a license except upon an examination of the product and a determination that the product complies with all regulatory standards. See 42 CFR § 73.5(a) (Supp. 1964); 21 CFR § 601.4 (1987). The agency has no discretion to deviate from this mandated procedure.[10] Petitioners' claim, if interpreted as alleging that the DBS licensed Orimune in the absence of a determination that the vaccine complied with regulatory standards, therefore does not challenge a discretionary function. Rather, the claim charges a failure on the part of the agency to perform its clear duty under federal law. When a suit charges an agency with failing to act in accord with a specific mandatory directive, the discretionary function exception does not apply.

If petitioners' claim is that the DBS made a determination that Orimune complied with regulatory standards, but that the determination was incorrect, the question of the applicability of the discretionary function exception requires a some-

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[10] Even the Government conceded at oral argument that the DBS has no discretion to issue a product license without an examination of the product and a determination that the product complies with regulatory standards. The transcript reads:

"QUESTION: [Supposing the DBS] did not make any examination of the application at all, or any determination other than some papers have been filed and I will now issue the license.

"Would that comply with the regulation?

"[COUNSEL]: No, it would not comply with the regulation.

"QUESTION: It would violate a mandatory duty . . . , wouldn't it?

"[COUNSEL]: In the extreme instance you are talking about . . . , it would definitely violate that regulation." Tr. of Oral Arg. 34–35.

what different analysis. In that event, the question turns on whether the manner and method of determining compliance with the safety standards at issue involve agency judgment of the kind protected by the discretionary function exception.[11] Petitioners contend that the determination involves the application of objective scientific standards, see Brief for Petitioners 16–17, whereas the Government asserts that the determination incorporates considerable "policy judgment," Brief for United States 36. In making these assertions, the parties have framed the issue appropriately; application of the discretionary function exception to the claim that the determination of compliance was incorrect hinges on whether the agency officials making that determination permissibly exercise policy choice. The parties, however, have not addressed this question in detail, and they have given us no indication of the way in which the DBS interprets and applies the regulations setting forth the criteria for compliance. Given that these regulations are particularly abstruse, we hesitate to decide the question on the scanty record before us. We therefore leave it to the District Court to decide, if petitioners choose to press this claim, whether agency officials appropriately exercise policy judgment in determining that a vaccine product complies with the relevant safety standards.

B

The regulatory scheme governing release of vaccine lots is distinct from that governing the issuance of licenses. The former set of regulations places an obligation on manufacturers to examine all vaccine lots prior to distribution to ensure that they comply with regulatory standards. See 21 CFR

[11] As noted, see n. 9, *supra*, the regulatory standards that petitioners claim were not satisfied in this case are the neurovirulence criterion and the requirement that virus strains be free from harmful effect. The question presented is thus whether the determination that a vaccine product complies with each of these regulatory standards involves judgment of the kind that the discretionary function exception protects.

§ 610.1 (1978).[12] These regulations, however, do not impose a corresponding duty on the Bureau of Biologics. Although the regulations empower the Bureau to examine any vaccine lot and prevent the distribution of a noncomplying lot, see 21 CFR § 610.2(a) (1978), they do not require the Bureau to take such action in all cases. The regulations generally allow the Bureau to determine the appropriate manner in which to regulate the release of vaccine lots, rather than mandating certain kinds of agency action. The regulatory scheme governing the release of vaccine lots is substantially similar in this respect to the scheme discussed in *United States* v. *Varig Airlines*, 467 U. S. 797 (1984).

Given this regulatory context, the discretionary function exception bars any claims that challenge the Bureau's formulation of policy as to the appropriate way in which to regulate the release of vaccine lots. Cf. *id.*, at 819–820 (holding that discretionary function exception barred claim challenging FAA's decision to establish a spot-checking program). In addition, if the policies and programs formulated by the Bureau allow room for implementing officials to make independent policy judgments, the discretionary function exception protects the acts taken by those officials in the exercise of this discretion. Cf. *id.*, at 820 (holding that discretionary function exception barred claim that employees charged with executing the FAA's spot-checking program made negligent policy judgments respecting the proper inspection of airplanes). The discretionary function exception, however, does not apply if the acts complained of do not involve the permissible exercise of policy discretion. Thus, if the Bureau's policy leaves no room for an official to exercise policy judgment in performing a given act, or if the act simply does

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[12] The citation is to the regulation in effect at the time Lederle Laboratories released the lot of Orimune containing Kevan Berkovitz's dose. None of the regulations governing the release of vaccine lots has changed significantly since that time. The current regulations dealing with this subject have the same title and section numbers as the regulations cited in the text.

not involve the exercise of such judgment, the discretionary function exception does not bar a claim that the act was negligent or wrongful. Cf. *Indian Towing Co.* v. *United States*, 350 U. S., at 69 (holding that a negligent failure to maintain a lighthouse in good working order subjected the Government to suit under the FTCA even though the initial decision to undertake and maintain lighthouse service was a discretionary policy judgment).

Viewed in light of these principles, petitioners' claim regarding the release of the vaccine lot from which Kevan Berkovitz received his dose survives the Government's motion to dismiss. Petitioners allege that, under the authority granted by the regulations, the Bureau of Biologics has adopted a policy of testing all vaccine lots for compliance with safety standards and preventing the distribution to the public of any lots that fail to comply. Petitioners further allege that notwithstanding this policy, which allegedly leaves no room for implementing officials to exercise independent policy judgment, employees of the Bureau knowingly approved the release of a lot that did not comply with safety standards. See App. 13; Brief for Petitioners 20–21; Reply Brief for Petitioners 15–17. Thus, petitioners' complaint is directed at a governmental action that allegedly involved no policy discretion. Petitioners, of course, have not proved their factual allegations, but they are not required to do so on a motion to dismiss. If those allegations are correct—that is, if the Bureau's policy did not allow the official who took the challenged action to release a noncomplying lot on the basis of policy considerations—the discretionary function exception does not bar the claim.[13] Because petitioners may yet show,

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[13] The Government's own argument before this Court provides some support for petitioners' allegation regarding the Bureau's policy. The Government indicated that the Bureau reviews each lot of vaccine and decides whether it complies with safety standards. See Tr. of Oral Arg. 42. The Government further suggested that if an employee knew that a lot did not comply with these standards, he would have no discretion to approve the release of the lot. See *id.*, at 31–32.

on the basis of materials obtained in discovery or otherwise, that the conduct challenged here did not involve the permissible exercise of policy discretion, the invocation of the discretionary function exception to dismiss petitioners' lot release claim was improper.

IV

For the foregoing reasons, the Court of Appeals erred in holding that the discretionary function exception required the dismissal of petitioners' claims respecting the licensing of Orimune and the release of a particular vaccine lot. The judgment of the Court of Appeals is accordingly reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.