SUPREME COURT OF THE UNITED STATES

In the Matter of:

KEVAN BERKOVITZ, A MINOR BY HIS PARENTS AND NATURAL GUARDIANS ARTHUR BERKOVITZ, ET UX., ET AL.,

Petitioners

v.

UNITED STATES

No. 87-498

PAGES: 1 through 51

PLACE: Washington, D.C.

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Washington, D.C.

Tuesday, April 19, 1988

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 1:56 p.m.

APPEARANCES:

ELLEN M. VIAKLEY, ESQ., Pittsburgh, Pennsylvania
on behalf of the Petitioners.

MICHAEL K. KELLOGG, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.
on behalf of Respondent.

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PROCEEDINGS

(1:56 p.m.)

CHIEF JUSTICE REHNQUIST: Ms. Viakley, you may proceed whenever you are ready.

ORAL ARGUMENT BY ELLEN M. VIAKLEY, ESQ.

ON BEHALF OF PETITIONERS

MS. VIAKLEY: Mr. Chief Justice, and may it please the Court:

This case arises under the Federal Tort Claims Act which embodies Congress's broad waiver of governmental immunity and consent to suit for the tortuous conduct of government employees. The conduct complained of here is negligent execution of Section 262(d) of the Public Health Service Act and following regulations which govern the licensing and release of live poliovirus vaccines.

The issue presented involves the applicability of Section 2680(a) of the Tort Claims Act which sets forth an exception to the waiver of immunity to the conduct at issue.

The immunity preserved by 2680(a) is underpinned by separation of powers principles. It is intended to prevent the judiciary, through the medium of an action in tort, from second guessing the reasonableness of executive policy judgments. This Court has consistently held that what is protected by 2680(a) is executive prerogative; decisionmaking grounded in social, economic and political policy.

Congress used two clauses to accomplish its purpose of 2680(a). The first recognizes that conduct which obediently executes policy embodies that policy, is the policy made manifest. A challenge to such conduct is an attack on the policy itself. The first clause, therefore, protects conduct in execution of a statute or regulation provided due care is exercise.

Now under the first clause, it does not matter whether the conduct itself is discretionary or nondiscretionary so long as it represents faithful execution of the regulatory plan.

The second clause in Section 2680(a) protects discretionary conduct, the exercise of discretionary authority. Now whether the conduct here warrants the protection of the second clause, since it has forfeited any claim to immunity under the first clause, requires examination of the statute and the regulations which give this agency its power to act.

The powers and duties of the agency with respect to licensing biologic products, including live virus vaccines, were defined by Congress in Section 262(d) of the Public Health Service Act which directs that licenses may be issued only upon a showing that the product meets regulatory standards. The statute provides no exemptions to the requirements of regulatory compliance, and it does not authorize the agency to act according to its judgment of the best course in deciding

whether compliance is necessary.

The agency's regulations reflect that statutory mandate in providing that licenses may be issued only upon examination of the product and upon demonstrated regulatory compliance.

The regulatory standards particularly applicable to live poliovirus vaccines are specifically charted in 42 CFR 73.110. They cover three characteristics of the vaccines: safety, potency and antigenicity, each of which is reduced to a numerical value.

For example, under 73.115, the data must demonstrate that the concentration of live virus particles in the vaccine is between 200,000 and 500,000 TCID per dose.

Under 73.117, antigenicity, there are specific pre- and post-treatment ratios of type-specific antibodies that must be demonstrated before the vaccine is in compliance with that standard.

QUESTION: May I interrupt just to be sure I have got it clearly in mind?

One of the regulations I know says that the strain must be free of harmful effect, and then I know there is more particularity. But if it just said free of harmful effect, would you agree that was a discretionary judgment?

MS. VIAKLEY: No, I would not, because we have alleged that the strain in fact paralyzed people in the test

studies. That does raise one point, though, because there is some contention in the briefs about exactly what is licensed under this statute: Is it the strain, is it a seed virus, is it a vaccine.

Now the government has contended, and we are willing to accept for present purposes, that the license is issued for the poliovirus vaccine. In this instance, it was the Type III Sabin, live poliovirus vaccine.

Now under the regulation you have mentioned, 73.110, five consecutive monopools produced from that parent strain must be tested and data must be submitted showing that they complied with the neurovirulence criteria. If they do --

QUESTION: Yes, but tested by -- tested by whom?

MS. VIAKLEY: By the manufacturer.

QUESTION: Right.

MS. VIAKLEY: And the data then submitted to the agency and reviewed by the agency.

Now if those five monopools comply, a license is issued. But that license --

QUESTION: But comply with what?

MS. VIAKLEY: Comply with the neurovirulence criteria of 73.114.

QUESTION: But isn't that the criteria that they be free of harmful effect?

MS. VIAKLEY: No. 73.114 sets out the

characteristics of the vaccine to actually produce disease rather than immunity. They cover four specific characteristics.

One, macaca monkeys have to be inoculated with specific amounts of the vaccine, and then sacrificed at the end of an observation period, examined for the number of polio --

QUESTION: Yes, but this is done by the manufacturer, isn't it?

MS. VIAKLEY: The tests are done by the manufacturer.

QUESTION: Right.

MS. VIAKLEY: The manufacturer generates the data which is put on the license applications form and submitted to the agency. The agency's duty is to review that application to make sure the numbers correspond before it issues the license.

QUESTION: Now are you contending that there are regulations specifying numbers -- that the information submitted by the manufacturer had numbers that clearly didn't comply with the required numbers?

MS. VIAKLEY: That's correct, Your Honor.

QUESTION: It's a little hard for me to follow parts of your -- of the way you presented it in the brief.

MS. VIAKLEY: The regulations are a little convoluted.

QUESTION: See, the regulations -- when I look at the

actual regulations, they seem to use words like "free of harmful effect" and so forth, which suggests to me a discretionary judgment.

MS. VIAKLEY: Your Honor, free of harmful effect appears in the first part of 73.110 which talks about the original virus strain.

QUESTION: Right.

MS. VIAKLEY: According to --

QUESTION: Isn't that what we're talking about?

MS. VIAKLEY: According to the government, we're talking about the vaccine monopools themselves.

QUESTION: Well, you're the Petitioner, and I thought you were complaining about the original Sabin strain.

MS. VIAKLEY: We are, Your Honor. As I was trying to explain to Justice Stevens --

QUESTION: And on that is it necessary that the agency determine that it's without harmful effect?

MS. VIAKLEY: What is necessary is for the agency to review the five original monopools that were produced from that parent strain and assess them for compliance with the neurovirulence criteria.

QUESTION: Well, that's later on.

MS. VIAKLEY: No, that's set out in 73,110, the section that applies even in the original virus strain.

Now when a license is issued for that vaccine that's

represented by those monopools, what that amounts to is an approval for the continued use of the parent strain.

QUESTION: Well, can't the agency say that something is without harmful effect even though it causes let's say one case of polio in a hundred thousand?

MS. VIAKLEY: The critical allegation here, Your Honor, is that the qualifying monopools exceeded quantitative standards in the regulations, in 73.114. That's the critical allegation with regard to the original licensing decision.

QUESTION: Ms. Viakley, where in your petition for certiorari do we find -- I know that Section 262 is set forth on Page 41(a) of your petition. Section 601.20 is set forth there. But you have referred to several other regulations. Where do we find them either in your brief or in your petition?

MS. VIAKLEY: In the brief, Your Honor, they are reprinted in the appendix.

QUESTION: In the appendix to the brief?

MS. VIAKLEY: Yes. They are referred to throughout the text of the brief.

QUESTION: Thank you.

QUESTION: I take it your position is that if they didn't qualify under those specific standards, there was a nondiscretionary duty just not to license.

MS. VIAKLEY: That's correct, Your Honor.

QUESTION: As Judge Higginbotham said.

MS. VIAKLEY: That's correct, and that arises both from the statute and the regulations.

Again, if you take a look at 73.114, which is the critical standard here, it's the critical one that was violated when the original license was issued.

QUESTION: You said there isn't any room anywhere for somebody who knows that the batch or lot doesn't comply with those specific standards, there is no room to nevertheless go ahead with it.

MS. VIAKLEY: None. There is no authority provided either by the statute or the regulations to license despite noncompliance.

QUESTION: Well, what's your theory about how it did happen then? Do you think there was just pure sheer negligence, or that --

MS. VIAKLEY: There may have been pure sheer negligence, or in the Griffin case what happened, and the proof that was recounted in the district court's opinion, was that agency employees decided that the neurovirulence criteria weren't really as strict as the regulations made them seem, and an agency employee decided to ascribe the difference to something called biological variation.

QUESTION: Well, doesn't the agency say there is some kind of discretion here?

MS. VIAKLEY: No, not in these regulations. They

pointed to nothing in the regulations that confers policy judgment to license.

QUESTION: What's their theory for affirmance?

MS. VIAKLEY: Their theory for affirmance is basically asking this Court to provide what Congress did not -- a broad per se exception for regulatory conduct. There is no argument made in the brief that would entitle this Court to conclude that the specific conduct at issue here is discretionary.

QUESTION: They don't claim that there was any room for discretion either.

MS. VIAKLEY: They have identified no argument that this conduct is discretionary, no exercise of policy judgment.

QUESTION: So whether this was a deliberate ignoring of the -- whether this was a deliberate act, or a negligent act, they say it makes no difference.

MS. VIAKLEY: Makes no difference, because there is no authority to exercise policy judgment in making this decision.

QUESTION: Now the first thing that happens is that the strain is licensed; is that correct? Is that chronologically the first thing that happens?

MS. VIAKLEY: I think we should use the word "product" because whether it's the strain or the vaccine itself is a question that's not clear from the regulations. There is

a licensed issued for the live poliovirus product. That license is issued based on the qualifications of the five original monopools. That's the first thing that happens.

QUESTION: And there must be a determination under 73.114 that the characteristics had been met?

MS. VIAKLEY: That the characteristics of all five consecutive monopools comply with the criteria set out in 73.114.

QUESTION: I thought the monopools didn't come until after the strain had been first manufactured.

MS. VIAKLEY: No, in 73.110, the second that refers to the strain, you see that the process goes all the way down to the monopool level.

QUESTION: No, I'm talking about just licensing, manufacture of the strain, does 73.114 apply before that license can be granted?

MS. VIAKLEY: Yes, it does, and that's clear in 73.110. The regulation itself refers specifically to the criteria of 73.114, and says that five consecutive original qualifying monopools must meet those criteria.

QUESTION: Was there a separate license granted for the seed virus?

MS. VIAKLEY: Well, Your Honor, our understanding, based on documents reviewed from some of the state court litigation, was that there was government approval of the seed

virus which we interpreted to mean issuance of a license. The government has contended in its brief that a formal license is not issued, but admits that government approval is required.

Now the record does not demonstrate the nature of that approval.

QUESTION: What agency action with respect to the seed virus are you complaining about?

MS. VIAKLEY: We are complaining about the initial approval of the seed virus, because we have alleged that the particular seed virus that produced the vaccine that paralyzed this child also demonstrated excessive neurovirulence.

QUESTION: Now according to the Third Circuit, I believe, your claim relating to the approval of the seed virus, and your claim relating to release of the lot of vaccine were the same issue.

MS. VIAKLEY: Well, Your Honor, the Third Circuit didn't distinguish among any of the claims. It made no distinction between the licensing lot release, made no distinctions at all among --

QUESTION: But the regulations make that distinction, don't they?

MS. VIAKLEY: Yes, they do, Your Honor.

QUESTION: Is the seed virus approved in some way other than by approval of the lot of vaccine?

MS. VIAKLEY: Your Honor, that is not clear from the

record presented. We have alleged that it is tantamount to licensing decision.

As we indicated in the reply brief, given the contentions raised by the government, I think that is an issue on which it might be appropriate to remand for factual consideration and factual development of, number one, what the nature of the government approval was; and, number two, whether or not the recertification requirement of the regs was a mandatory directive.

And we have indicated those facts we think would be appropriate for development on that issue in the reply brief.

QUESTION: May I go back for a moment to 73.114(b), your position on that?

Are you alleging that the tests were not valid in the sense that the samples weren't sufficient as they describe, or that valid tests were conducted but they produced results which failed the standard in the regulation?

MS. VIAKLEY: We're saying that the numbers on the license application reviewed by the DBS employee demonstrated excessive neurovirulence; that the numbers on the form were higher than the numbers in the NIH reference. And under those circumstances, a red light went on and the agency had no authority to proceed; the employee had no authority to proceed.

QUESTION: So you are not saying the tests were invalid.

MS. VIAKLEY: No.

QUESTION: But, rather, that valid tests were conducted which produced numbers that violated a standard that is somewhere in this regulation -- I've had difficulty finding, frankly. But the standard that they violated is where?

MS. VIAKLEY: In 73.114(b).

QUESTION: And where in 114(b) is it?

MS. VIAKLEY: Tests after filtration.

QUESTION: There are a number of subheads. Can you pick out any particular subhead there?

MS. VIAKLEY: Subhead (b)(i)(iii), determination of neurovirulence.

QUESTION: And what are the numbers that are shown in that section that were violated?

MS. VIAKLEY: The numbers of animals showing lesions characteristic of poliovirus; the severity of the lesions; severity of size. That's again a figure that's in numerical terms. It's expressed in centimeters. The degree if dissemination of the lesion, and that is the distance from the point of inoculation to where the lesion has appeared, again expressed in centimeters; and the number of paralyzed monkeys.

QUESTION: So that in other words when it talks about a comparative evaluation toward the end, that's a evaluation to be made by the manufacturer making the test, isn't it?

MS. VIAKLEY: The manufacturer generates this data,

puts it on a license form, and the DBS employee has to review the numbers to see that they match or do not exceed the NIH reference numbers, and that's the conduct we're complaining of here.

QUESTION: Well, how can you tell from (iii), the subhead, what reference numbers we're talking about unless it's the 80 percent, because that subsection doesn't seem to have any numbers in it?

MS. VIAKLEY: That subsection, Your Honor, under subheads again (a), (b), (c), (d) and (e).

QUESTION: Well, I thought you were referring a moment ago on Pages SA-7 through 9, to 73.114(b)(i) and under that (iii).

MS. VIAKLEY: Right.

QUESTION: Determination of neurovirulence. And then you are talking about things not matching the numbers, but I don't see any numbers in Section (iii) except for the 80 percent.

MS. VIAKLEY: Well, that section refers to the NIH reference strain. It incorporates --

QUESTION: And where is that in your brief?

MS. VIAKLEY: It's not in the regulations. The numbers for the NIH reference aren't in the regulations. Those are figures that are maintained by the agency.

QUESTION: And you haven't put them in your brief or

in your petition?

MS. VIAKLEY: No, Your Honor, we've just alleged that the demonstrated characteristics of this vaccine exceeded the NIH reference.

We are here on a motion to dismiss. All we have are the allegations of the complaint. There has been no discovery in the case.

QUESTION: Is there any issue that we have to decide whether or not this strain or whatever you call it complied with the numbers?

MS. VIAKLEY: No, you have to accept the allegations of the complaint as true.

QUESTION: Yes, exactly.

MS. VIAKLEY: And we have alleged that the strain exceeded the numbers, violated the regulations.

QUESTION: And you also allege that the people who reviewed the tests knew that they didn't --

MS. VIAKLEY: We've alleged that it was demonstrated on the face of the application. Whether that gave the employee actual knowledge or constructive knowledge is irrelevant.

QUESTION: I would have found it helpful, in view that we are supposed to be deciding whether this is or is not a possibly discretionary function, to have the thing taken one more step down the line.

MS. VIAKLEY: And what step would that be, Your

Honor?

QUESTION: To see what the effect of these numbers that you allege would have been filtered into sub (iii).

MS. VIAKLEY: The numbers are just -- they are in very small -- for example, four lesions, a lesions that's two centimeters in diameter, those are the numbers we're talking bout.

QUESTION: Is this all alleged in your complaint?

MS. VIAKLEY: It's not in the complaint, because the NIH reference numbers are not of record since we've had no discovery in this case. We've had discovery in state court cases that led to the basis for this case being filed.

What we have alleged is that this vaccine violated and exceeded the numbers of the NIH reference that specifically incorporated into the regulatory standard under subsection (iii).

QUESTION: Can the vaccine be produced before this strain is licensed?

MS. VIAKLEY: Well, again we're going back to the question of exactly what is licensed.

According to the regulation, the product --

QUESTION: Does a manufacturer have to have any license before he produced the vaccine in his own laboratory?

MS. VIAKLEY: No. He has to have an establishment license.

QUESTION: Has to have a?

MS. VIAKLEY: An establishment license, but that's something different.

QUESTION: But that's not an issue here.

MS. VIAKLEY: No, this is a product license. That's all that's at issue here. He has to take the original strain all the way through one complete process of replication and produce a consumer level vaccine, test that vaccine for neurovirulence, demonstrate its compliance before he can qualify for a licence for that product. That's the process.

QUESTION: These NIH reference numbers that we don't have, and I understand you say we don't need them, that at this stage we accept the allegation that they were clear numbers that were clearly different from what happened here, they are made up by NIH -- made up -- I mean developed.

MS. VIAKLEY: That's correct.

QUESTION: And that does take judgment, right?

MS. VIAKLEY: No, it take scientific evaluation. It takes counting the number of lesions.

QUESTION: No, no, no. The reference numbers.

MS. VIAKLEY: The reference numbers are the same as those we're talking about here.

QUESTION: No, no, but I assume the reference numbers are numbers that NIH develops using its judgment as to how high the numbers have to be before the product is dangerous, no?

MS. VIAKLEY: No, the NIH tests a reference strain, and the demonstrated characteristics of that reference strain represent the NIH numbers. They are not numbers arbitrarily picked out of a hat, but will accept three lesions as being acceptable.

The NIH numbers are the demonstrated characteristics of a particular reference poliovirus strain.

QUESTION: Why do they pick that particular reference strain?

MS. VIAKLEY: Your Honor, that's not in the record. There may have been some exercise --

QUESTION: They might have picked another strain.

MS. VIAKLEY: There may have been an exercise of judgment initially, and there was in promulgating these regulations.

QUESTION: Well, I assume -- I mean these NIH reference numbers come from somewhere. It's up to NIH which reference numbers to pick. They select a strain, or they develop the numbers. It takes scientific judgment, I gather.

MS. VIAKLEY: Which strain to pick, correct.

QUESTION: Okay, now, you think that there would be one judgment in this case if NIH left it to a particular scientist or teams of scientists to both pick the strain and therefore develop the NIH number, and then apply that to the data from the manufacturer, because that would involve

discretionary judgment, right?

But if they divide it into two steps, and they have one team pick the NIH reference numbers and then have another team say, take these numbers and put it up against what comes in from the manufacturer. That makes the difference as to whether there is liability on the part of the United States.

MS. VIAKLEY: Your Honor, that's the argument essentially made by the government when it says because the agency had discretion initially at the head of the stream of activity to promulgate regulations, that all conduct is protected.

QUESTION: Well, I'm not taking it all the way up to the top. I'm taking it to the very close step of the NIH reference number which they are comparing to what comes in from the manufacturer.

MS. VIAKLEY: You're taking it back up the stream though.

QUESTION: Yes.

MS. VIAKLEY: And it is true, of course, that every activity undertaken by government is borne is discretion. If the inquiry ended there, if that was the court's holding, the Tort Claims Act would be eviscerated. There would be no more waiver of immunity. There would be no more liability.

The question here is not where does discretion begin. The question is where in that stream of activity does

discretion end; where does the exercise of policy judgment stop; is the particular conduct at issue conduct which involves the exercise of judgment or embodies policy judgment by faithful execution of it.

If not, if it simply represents negligent execution of nondiscretionary directives, that's exactly the conduct that Congress intended to subject the government to liability for, and that's what we have here. And the government is unable to point to any policy decision that's jeopardized by this action.

QUESTION: Counsel, could we take a look at the last page of your brief, SA-10, Regulation 610.2(a)?

This permits the director to require that certain samples or results be sent to the bureau; is that correct?

MS. VIAKLEY: That's correct.

QUESTION: Is that mandatory or discretionary?

MS. VIAKLEY: Well, again, Your Honor, in our reply brief we indicate it's not clear on this record. The regulation on its face is not mandatory. What we have indicated in the reply brief is that facts of record in other cases which we have submitted to this Court indicate that as applied to live poliovirus vaccines, that directive is mandatory.

But more significantly on that issue, I think, is what happened after the decision to test was made. And, again, even if that decision was discretionary, discretion ended there

because the decision subsequent to that to release the vaccine which was known to be excessive neurovirulent did not involve exercise of policy.

QUESTION: Now, is that (b), which is under (a)?

MS. VIAKLEY: No, Your Honor. We indicated in our brief that there was a typesetting error there, and that the section head, which is 630.17, was omitted.

QUESTION: So (b) is a different numerical heading, is it not?

MS. VIAKLEY: That's correct.

QUESTION: And that applies to the manufacturer, not to the government.

MS. VIAKLEY: Our submission is that applies to anybody who is in the position of releasing the vaccine.

QUESTION: (b) says that no lot shall be released, but it applies only to the manufacturer, does it not?

MS. VIAKLEY: Again, our position is that that -- the only sensible reading of the regulations is that that standard applies to anybody who is in the position of issuing a release for the vaccine.

QUESTION: And what is the correct numerical reference for (b)?

MS. VIAKLEY: 630.17 in 21 CFR.

QUESTION: 630.17.

MS. VIAKLEY: That's correct, Your Honor.

QUESTION: Thank you.

MS. VIAKLEY: If the Court has no further questions, I would like to reserve the remainder of my time.

CHIEF JUSTICE REHNQUIST: Thank you, Ms. Viakley.

Mr. Kellogg, we will hear now from you.

ORAL ARGUMENT BY MICHAEL K. KELLOGG, ESQ.

ON BEHALF OF RESPONDENT

MR. KELLOGG: Mr. Chief Justice, and may it please the Court:

I think it may be helpful, given the questions during counsel's argument, to go through exactly what the regulations require in this instance, and focus on the specific allegations made by Petitioners.

The first thing that's done is that a product license is issued for a vaccine product. Now that vaccine product will use a particular strain of poliovirus. And according to the regulations, the strain of poliovirus must have been tested on 100,000 susceptible people and shown to be without harmful effects.

Now one of Petitioners' allegations appears to be that the strain of poliovirus at issue here was tested and found to have been with harmful effects. Our position would be, as Justice Stevens pointed out, that the phrase "without harmful effect" embraces considerable policy judgment.

In fact, as we pointed out in our brief, that the

issue in this case was considered by a panel of scientific experts over a two-year period before finally --

QUESTION: Yes, but the problem, and I think Justice Scalia put his finger on it and I want to be sure you address it. Supposing we all agree that that's a discretionary standard "without harmful effect".

But supposingly they then further particularize certain standards that are reducible to numerical values that would be a regulation saying if it crosses the line, it shall be deemed to have harmful effects and shall not be licensed.

And assume that in a very liberal reading of the complaint they have said that the test results, when delivered to the agency, showed that they violated the particularized standard, but somebody failed to read the thing, or said, I don't care, it's only a slight deviation or something of that kind.

Would that be also covered by the discretionary --

MR. KELLOGG: Yes. Our position is that it would be.

QUESTION: Even though it's reduced to particular standards?

MR. KELLOGG: Yes, even though the particular employee might have acted wrongly or negligently.

QUESTION: Or even if he just knew --

MR. KELLOGG: Even if he --

QUESTION: -- specifically that this did not comply?

MR. KELLOGG: Even if he knew.

QUESTION: Even though there was no discretion in that particular employee?

MR. KELLOGG: Even though that employee had a specific mandate as to what his duty was to be, because the wording of the discretionary function exception focuses on functions of the agencies, not just on duties of particular employees.

The inquiry were under a qualified immunity case in which the individual employee were being sued, it might well be appropriate to look at his specific mandate to determine whether he violated that mandate with a view to whether he personally should be liable in tort.

QUESTION: Taking it a step further. You would say then that even if the regulations required the tests to be conducted by government personnel, and even if they conducted them negligently and saw that the results were wrong and went ahead and said, oh, the heck with it, we're not worried about this, we'll go ahead and license it anyway, there would be no liability.

MR. KELLOGG: That could pose a different problem. There could be liability if the government set itself up to displace the manufacturer as the primary --

QUESTION: No, they just say, we want you to do it, and we'll them ourselves also. We'll have a double standard.

We'll do it --

MR. KELLOGG: If it's doubled, then the primary responsibility is on the manufacturer, and the government is exercising its discretion to spot check or to thoroughly reject or even to retest all the results. But the government's responsibility is fundamentally different in regulating as opposed to --

QUESTION: Do you think Varig would have come out the same way if there had been an inspection, and the employee knew that there was something wrong?

MR. KELLOGG: Yes, because --

QUESTION: Well, that certainly isn't what the case said.

MR. KELLOGG: Well, the issue was not raised because there was not an inspection.

QUESTION: Well, but the government argued the position you are arguing today. And do you think the court accepted that argument in Varig?

MR. KELLOGG: I think the court --

QUESTION: And didn't the government take the same position you are taking today essentially?

MR. KELLOGG: Yes, the government did, and I think the court came very close to accepting that position in Varig Airlines.

QUESTION: Well, the langauge just doesn't quite say

what you are arguing for today, does it, of our opinion?

MR. KELLOGG: Our position today is that the regulatory functions of government, whether it be writing the regulations or enforcing compliance with those regulations, are protected from suit. They are protected from suit whether the agency elects to perform its function by spot checking compliance, by rechecking test results, or by methodologically redoing and duplicating every test.

QUESTION: Where does it break down? What about the employee of the regulatory agency who is negligently driving his automobile to do the inspection?

MR. KELLOGG: Well, then he is not performing a regulatory activity.

QUESTION: Well, he is. He's going out to perform the inspection and od the job the regulatory agency has asked him to do.

MR. KELLOGG: That's true, but it is clear from the legislative history that Congress intended to draw a distinction between the common law torts of the employee's regulatory agencies and the peculiar regulatory activities of inspecting, licensing and certifying.

And ordinary car accident on the way to perform an inspection would not be distinguishable from an ordinary tort by an employee of some other agency. It would not impact upon the peculiar regulatory functions at the agency.

QUESTION: Congress embodied all of that in the phrase "discretionary function", and also embodied the distinction that you urged upon us between -- you say it would make a difference whether the government here was displacing the manufacturer in the testing or not. And all of that Congress chose to express that by the term "discretionary function".

MR. KELLOGG: I think that's right, Justice Scalia. The court in Varig said quite clearly that the original purpose, the original proposals for the discretionary function exception were to name certain specific agencies by name, like the Federal Trade Commission, or the SEC, and exempt them completely.

Congress decided not to do that because as the court in Varig said, the langauge of the discretionary function exception would "exempt from the acts claims against federal agencies growing out of their regulatory activities."

QUESTION: Why would it make any difference whether you were displacing the manufacturer's testing or not, whether you are doing the testing yourself or displacing the manufacturer's testing?

How could that possibly made a difference as to the degree to which it's a discretionary function of the federal agency?

MR. KELLOGG: It makes a difference in several

respects. One of the primary purposes of the act was to compensate people who would otherwise go uncompensated.

In the case where you have a primary actor in the regulatory context, the injured party can look first, as Petitioners did in this case, to the primary actor.

QUESTION: It makes a lot of sense to me, but I asked why does it have anything to do with whether it's a discretionary function or not. You're telling me why it would be a good idea to write a statute that way. I'm not asking whether it would be a good idea. I'm asking why that in one case it's a discretionary function, and in the other one it isn't.

MR. KELLOGG: It's a discretionary function in the sense that -- well, take the specific statute and regulations at issue here. They require the agency to license drugs and make a determination of whether the drugs are safe. They do not specify in any sense what the standards are to be applied by the agency or --

QUESTION: Well, Mr. Kellogg, that's not quite fair, because your opponents refers us to Section 73.114, tests for safety and the neurovirulence standards, and says they are very specific and require numerical calculations that can easily be determined mechanically, and that the complaint alleges a failure to meet the standards, the mechanical standards.

MR. KELLOGG: The regulations in question apply to

the manufacturer, Justice O'Connor. The manufacturer is required to perform those tests. The manufacturer is required to demonstrate compliance.

QUESTION: And to submit the results of the test to the federal government for its license, right?

MR. KELLOGG: That's correct, but the --

QUESTION: And the allegation is that the numbers didn't add up.

MR. KELLOGG: But the regulations do not require the federal government to do anything in respect to that data. They do not require the government -- they do not specify whether the government is supposed to check, recheck the data in detail, or redo the tests, or otherwise check up on the --

QUESTION: You mean any time they file a piece of paper the government need not look at it at all. It just may issue whatever that is. What is it you call it, a license? No, what do you do if you want to --

MR. KELLOGG: Well, there are three separate allegations.

QUESTION: You are going to free it for distribution. What are you going to do?

MR. KELLOGG: With respect to the lot release, yes. The regulations do not specify anything whatsoever --

QUESTION: Now suppose this lot is presented to the agency and the agency looks at the piece of paper, and knows

exactly -- the person looking at it knows exactly what that lot is about, and knows that it doesn't comply.

MR. KELLOGG: Then if he --

QUESTION: And do you think at that point there is some discretion involved?

MR. KELLOGG: For that particular employee --

QUESTION: Yes or no.

MR. KELLOGG: No, not for that particular employee; for the agency function in question there is.

QUESTION: No, but the agency function is not to issue that release if those numbers don't add up. What discretion does the agency have in issuing that release?

MR. KELLOGG: Well, the agency does not have to perform any test or check any data whatsoever.

QUESTION: I don't care. I didn't ask that. But there it is, the numbers are filed with the agency. All it has to do is look at it and they will know that it does not comply. And the order is don't issue the release if those numbers don't add up. Now I don't understand why you say there is any discretion whatsoever in that situation.

MR. KELLOGG: The problem is with the word "order". I mean in that sense, Justice White, employees never have discretion to be negligent.

QUESTION: Well if you win, I suppose you might as well repeal the Tort Claims Act.

MR. KELLOGG: I don't think that follows at all. What we are dealing --

QUESTION: No one is ever negligent.

MR. KELLOGG: What we are dealing with is a very specific and limited situation in which the primary burden of compliance is on the manufacturer.

QUESTION: But the exemption here is not for negligence; it's for discretion.

MR. KELLOGG: Well, what the court made clear in Dalehite is that abusive discretion covers both negligence and wrongful acts. So the mere fact that we have negligence or a wrongful act in permitting the lot to be released does not take this case out of the discretion.

QUESTION: No, no, and you have to have negligence to establish liability under the Tort Claims Act. Then there is an exception for discretion. And if the act charged is negligent, that does not mean they are liable if you can show that it was also discretionary.

MR. KELLOGG: That's correct.

QUESTION: But you have got to show that it was not only negligent, but that it was discretionary.

MR. KELLOGG: But the language of the exception is the discretionary function of the agency. The regulations in question here do not bind the agency in any respect. We would say that an individual employee could be negligent or perform

wrongfully, and yet the agency is still protected because its essential function of policing compliance does not change that.

QUESTION: But that may be a defense on the merits that the agency -- nobody in the agency had a duty to do anything which may be a defense on the merits of the Federal Tort Claims Act charge. But it doesn't seem to me it's a ground for invoking the discretionary exemption.

MR. KELLOGG: It is in the sense that the government has discretion whether to invoke its regulatory powers in this context or not.

QUESTION: What is that right, Mr. Kellogg? The statute says on product license, Section 73.5, "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 in this part."

Is that a statute or the regulation? I'm sorry.

MR. KELLOGG: That is a regulation.

QUESTION: I'm sorry. But certainly imposes a duty on the agency, doesn't it?

MR. KELLOGG: Well, not a very specific one. It does not say --

QUESTION: But let me just -- supposing they filed an application -- it says, "...only upon examination of the product and upon a determination" that it complied. They file it and they say, oh, don't bother reading it. Go ahead an

issue the license.

They 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?

MR. KELLOGG: No, it would not comply with the regulation.

QUESTION: It would violate a mandatory duty to make an examination, wouldn't it?

MR. KELLOGG: In the extreme instance you are talking about where he does not look at the paper at all, it would definitely violate that regulation.

QUESTION: Well, why is not looking at the paper any different from looking at it and seeing that it doesn't comply?

MR. KELLOGG: Because the regulation does not specify what the nature of the examination or the determination of compliance has to be. It does not specify what to --

QUESTION: But if the subsidiary regulations, and I know there is a lot of detail here and they haven't had discovery, but taking the most liberal reading of the complaint that they are out there somewhere in the closet some very, very detailed regulations that in effect say, unless it's 9.6.000 or more, don't issue the license, then wouldn't you have a mandatory duty then?

MR. KELLOGG: Only on the point of the particular

employee. I don't think that the regulations --

QUESTION: Well, that's enough, isn't it?

MR. KELLOGG: If the agency itself does not comply with the regulations, the APA is available to enforce compliance, but the FTC was not to --

QUESTION: You are not arguing that respondeat superior doesn't apply, are you?

MR. KELLOGG: Pardon?

QUESTION: You are not claiming that respondeat superior doesn't apply; these are not government agents.

MR. KELLOGG: No.

QUESTION: Okay.

MR. KELLOGG: I do want to qualify the position we're taking in two respects in arguing that the regulatory activities of agencies are protected. We are not saying, as Justice O'Connor pointed out, that everything is protected. The ordinary torts of an employee in a car accident on the way would not be protected. We are limiting it to the inspection, licensing and certification activities as discussed by this Court in Varig Airlines.

In Varig the Court noted that, "The FAA certification process," quoting here at 467 USC 797, "is founded upon a relatively simple notion. The duty to ensure that an aircraft conforms to FAA safety regulations lies with the manufacturer and operator while the FAA retains the responsibility for

policing compliance."

QUESTION: But there was no examination of the product in that case.

MR. KELLOGG: That's correct, there was no action inspection.

QUESTION: And the agency had decided just to have a spot check system.

MR. KELLOGG: That's correct.

QUESTION: Well, now, that's completely different from this case.

MR. KELLOGG: Petitioners concede at Page 25, Note 47 of their brief that if the inspection had actually been conducted in Varig Airlines, but conducted negligently, that it would have been protected from suit, and that seems clearly right.

QUESTION: Well, I'm not sure I'm bound by a concession.

QUESTION: But that was in a regime in which inspections were not always required.

Here, for the initial issuance of the licenses as I understand it, the agency must make this determination and at some later point they can call in particular lots. But initially the inspection must be made by the agency; is that not correct?

MR. KELLOGG: The agency must make a determination

that it complies with the standard, that is correct.

QUESTION: Mr. Kellogg, can I ask about a possible narrower basis to get where you want to go?

Does all of this case turn upon the obligation that a product license shall be issued only upon an examination of the product, and upon a determination that the product complies with the standards? That's the guts of it, right? It all flows from that?

MR. KELLOGG: That's the guts of one of their allegations.

QUESTION: Well, all right.

MR. KELLOGG: Yes.

QUESTION: Now that determination, we have some of the standards reproduced here. Are there any other standards that do involve a bit of discretion?

I mean these standards that I see here don't. I mean, if it's just, you know, the number of lesions, length of lesions, things like that, that's no discretion.

Are there any other standards that have to be determined, compliance with which has to be determined by the agency that do involve some discretion?

MR. KELLOGG: Well, certainly the standard I was noting to Justice Stevens earlier about the strain of poliovirus used in the vaccine has to be determined to be free from harmful effect, and we would say that that involves

considerable discretion.

QUESTION: Well, but that's not a determination about the product. I want a determination that the product complies with the standards. All those --

MR. KELLOGG: Well, one of the regulatory requirements is that the product must use a strain that has been found to meet these requirements.

QUESTION: I see.

QUESTION: May I ask you a factual question?

Do you need a separate product license for a seed virus?

MR. KELLOGG: No.

QUESTION: You don't.

MR. KELLOGG: No. The seed virus, in fact the seed virus in question here, which Petitioners are referring to, was first begun to be used by Lederle three years after the product was originally licensed.

QUESTION: I might agree with you, Mr. Kellogg, this far, that if an agency has a determination to make that involves some elements that require a lot of judgment, but also five elements that are either they are or they aren't, and they are quite clear, I would still call that probably a discretionary judgment.

But you really haven't given me very many examples of any discretion in this at all.

MR. KELLOGG: Well, with respect to the seed virus, for example, all the requirements apply to the manufacturer. The regulations are quite explicit that the manufacturer must perform certain tests and determine that they comply. They don't impose any duties at all on the government.

The same applies to the lot release questions. There are certain tests --

QUESTION: Well, did the agency approve the seed virus, Mr. Kellogg?

MR. KELLOGG: The agency did approve Lederle's use of the seed virus. The regulations do not --

QUESTION: And was that different from the lot release?

MR. KELLOGG: Yes. Specific lots of vaccines are made from a particular seed virus. And before any lot of vaccine can be released, additional tests have to be performed by the manufacturer on each lot. And Petitioners are claiming that some of those tests were not done.

The regulations put the burden of compliance in that respect on the manufacturer, not on the government.

Now the Court of Appeals in this case adopted a position that is really very close to what we were arguing. They ostensibly rejected the broader proposition that all regulatory activities are protected from suit, but they nonetheless stressed that in undertaking the discretionary

function exception you do not isolate one regulation and look for whether that particular regulation has in it mandatory langauge or not. You look to the regulations as a whole to determine whether the ultimate burden of compliance is on the manufacturer or on the government.

The court said that in this case after looking through the regulations, and I am quoting here from Page 20-A of the Petitioners' appendix, "The FDA made a policy choice to leave compliance in the first instance with the manufacturer."

That seems to be the crucial point in this case. That is the manufacturer who has the primary duty of responsibility for compliance.

QUESTION: And in no event shall a lot be released unless so and so.

MR. KELLOGG: The regulations do not say that in fact.

QUESTION: No, it's awfully close.

MR. KELLOGG: The regulations apply specifically to the manufacturer. They do not purport to limit in any sense the discretion of the Surgeon General to release --

QUESTION: I thought you conceded that if they file this piece of paper, this lot like they were supposed to, and there was no examination whatsoever, there would be liability.

MR. KELLOGG: The lot release regulations, Justice White, they are printed in the last page of Petitioners' brief,

610.2(a).

QUESTION: SA-10?

MR. KELLOGG: SA-10, that's correct.

It says specifically that upon notification by the director of the Bureau of Biologic, a manufacturer shall not distribute a lot of product until the lot is released by the director.

QUESTION: Right.

MR. KELLOGG: But it does not limit in any sense the discretion of the director as to whether or not he is going to issue such a notification, as to whether or not he is going to require that that approval in any specific instance.

QUESTION: Well, how does this thing work in practice? The manufacturer gets these lots ready for release. And can he just decide I've passed the test, so I am going to release them, or does he have to come to the FDA or whatever it is and say, okay, I'm about to release these?

MR. KELLOGG: As a practical matter in the area of the oral poliovirus vaccine, the FDA requires them to bring every lot to them, and the FDA is quite thorough in rechecking test results, and even performing some of the tests itself to double check the manufacture.

QUESTION: And then it determines whether the manufacturer has adequately performed the tests, or whether the stuff complies with the regulations, or what?

MR. KELLOGG: That's correct, that's correct.

Our central contention would be that there is not a sliding scale in this area so that when one agency elects to spot check compliance, another agency elects to check compliance thoroughly, and a third elects actually to redo test results itself. Yet the greater the oversight, the more potential exposure to liability on the part of the government.

There are a couple of reasons why that would be a very unfortunate result. It would on the one hand reduce the manufacturer's own incentive to be safe if part of the burden for compliance can be pushed off to the government.

For example, Lederle Laboratories filed an amicus brief in this case saying this is a joint responsibility as to whether a product complies. That's precisely the attitude we do not want manufacturers to be able to take. It is their primary responsibility to comply in each instance with the regulatory requirements. And the extent of oversight exercised by the government should not take away any of their primary responsibility.

Furthermore, there should not be a disincentive created to the government as to the extent of oversight its going to conduct, because the government clearly has a discretionary choice here as to the extent of monitoring compliance with the regulations.

And if the greater the monitoring undertaken by the

government, the more the potential tort liability. That's a disincentive for the government to engage in extensive oversight. So, in effect, you have a double underlining of the entire purpose of a regulatory program which is to require the manufacturer to comply with the regulatory requirements.

QUESTION: That is not true though -- what you say is really, it seems to me, relevant to the lot release by the manufacturer, but not to the issuance of the initial license, because there must be a test before the license can be issued, and there must be an examination by the government.

MR. KELLOGG: Well, there must be tests performed by the manufacturer. The regulations are quite specific as to all the tests that the manufacturer --

QUESTION: And those tests must be reviewed by the government.

MR. KELLOGG: They must be submitted to the government, and there has to be some sort of examination of compliance.

With respect to the licensing claim, the specific provision that the agency claims we violated has to do with whether the strain involved was tested on 100,000 people and shown to be without harmful effect.

We would contend that that determination by the agency involves considerable policy judgment.

QUESTION: Well, I thought the Petitioner says that

the original license has to meet -- the strain has to meet the test for safety in 73.114.

MR. KELLOGG: Not the strain itself, Justice O'Connor, but particular lots of vaccines have to be produced and meet the requirements.

QUESTION: Before the initial license can be granted.

MR. KELLOGG: Before the initial license can be obtained, that's correct.

QUESTION: And they say that those tests are very specific in terms of the numerical comparisons.

MR. KELLOGG: Well, they are not really so specific. There is a number of comparative factors.

QUESTION: But we take the complaint as it's drafted, don't we?

MR. KELLOGG: We do as far as the factual allegations, but not as far as what the regulations state and require. That we determine by reading the particular regulations in issue here.

QUESTION: Well, SEction 262 says that the license has to meet standards prescribed in regulations showing they meet such standards, and they say that 114 is the regulation.

MR. KELLOGG: That's correct, Justice O'Connor, but the statute does not specify in any sense what the nature of the tests are going to be, how specific they have to be, or how specific the overview or review has to be by the agency.

The statute at issue in Varig Airlines was fairly specific too. That set out in the opinion of the Court of Appeals, and it says with respect -- at Page 19-A of the appendix to the petition. It says that a production certification can only be issued. The Secretary of Transportation shall make such inspection, and may require such tests as may be necessary to ensure manufacture of each unit in conformity with the type of certificate for which the airplane has been issued.

And the court made it clear that that gave the agency considerable discretion to decide -- to institute a spot checking program in which it would place the burden on the manufacturer to perform the initial test and do a lot of the checking.

QUESTION: The two statutes may look alike, but when you get down to the regulations, the FDA performed a lot differently than the FAA in Varig.

MR. KELLOGG: The FDA engages in substantially more oversight than the FAA did in Varig Airlines, that is correct.

Our position would be that that in itself does not make the discretionary function exception not apply. That certainly increases the opportunities for negligence, or for wrongful acts. But the discretionary function exception applies whether or not the discretion has been abused in that way.

QUESTION: Is it clear that you can't get where you are concerned with getting, and that is to somehow immunize the government's activity and simply regulating private sector activities, by a defense on the merits?

I mean that is to say the allegation here essentially is you have been negligent in not governing. You are suing the government for not governing. That's quite different from suing the government from hitting you with a car. Whether it's the government or not, you have a right not to be hit by a car.

MR. KELLOGG: That's correct.

QUESTION: But what's being complained of here is essentially you haven't governed the way you were suppose to. Is that merits defense still open in the case?

MR. KELLOGG: I'm not quite sure under what provision you would be saying that we raised that defense.

QUESTION: I don't know either.

MR. KELLOGG: We would say that those considerations are embodied in the discretionary function exception.

CHIEF JUSTICE REHNQUIST: Thank you, Mr. Kellogg.

Ms. Viakley, you have five minutes remaining.

ORAL ARGUMENT BY ELLEN M. VIAKLEY, ESQ.

ON BEHALF OF PETITIONERS - REBUTTAL

MS. VIAKLEY: Thank you, Your Honor.

Just briefly I would like to address the suggestion that's been made that if you can find discretion anywhere in

this regulatory scheme, that you need not look at the specific allegations of misconduct. That argument, that approach to immunity is contradicted by the language of the statute itself, by its legislative history, and by every case that this Court has considered construing the statute.

The second clause of 2680(a) talks about the exercise of discretionary function. The legislative history which was reviewed and set out by the court in Dalehite at Note 21, I believe it's Page 29, talks about protection for discretionary acts, and for the exercise of discretionary authority.

So you cannot look beyond our specific allegations of negligence here. It doesn't matter if in some other part of the regulations the agency may have had discretion in making some other kind of judgment. I think you are bound to look at our allegations of negligence. And to extend the inquiry beyond that again would be to create the equivalent of a per se exception, because at some point in every scheme you are going to be able to find some discretion. That's not the test.

The test is whether or not discretion has ended by the time you get down to the level of conduct that the Petitioners are complaining of.

In this case, there is no principled basis for distinguishing between a truck driver who runs a red light which, after all, is no more than a nondiscretionary directive not to proceed. This agency --

QUESTION: Except that it does say discretionary function as the government points out, and not discretionary act, and there is some functions that you would consider discretionary functions even though there are elements within them where you really don't have much of a choice. You have to do it one way or another.

But as a whole there is so much of an element of discretion involved that you could call it a discretionary function. Isn't that a conceivable interpretation?

MS. VIAKLEY: The only way it can get there is to provide a per se exception for regulatory conduct, and Congress expressly did not choose to do that.

I submit that the same separation of powers principles that underlie 2680(a) and prevent the Court from second guessing the reasonableness of executive decisions prevent this Court from second guessing the wisdom of legislative decisions. Congress did not provide that exception. The Court cannot go beyond the exception provided by Congress.

QUESTION: Do you think it rejected it?

MS. VIAKLEY: I think it did, Your Honor.

QUESTION: On the face of the statute?

MS. VIAKLEY: I think it did. In 2674, Congress purposefully adopted a state law standard of tort liability, and the state tort principle that underlies this action and

many FDCA actions is the good samaritan doctrine. Now that doctrine the reporter's notes to restatement 323 cite a case from Pennsylvania in 1804. That doctrine was already in the state's common law at the time Congress adopted a state common law standard to govern liability here.

QUESTION: Well, I know, but that still leaves the discretionary function problem.

QUESTION: They didn't deal with regulation of Salk vaccine in 1804, I take it.

MS. VIAKLEY: No, they did not deal with regulation of vaccines, Your Honor.

Unless the Court has any further questions, thank you.

CHIEF JUSTICE REHNQUIST: Thank you, Ms. Viakley.

The case is submitted.

(Whereupon, at 2:55 o'clock p.m., the case in the above-entitled matter was submitted.)

REPORTERS' CERTIFICATE

DOCKET NUMBER: 87-498

CASE TITLE: Kevan Berkovitz, A Minor by his Parents and Natural Guardians Arthur Berkovitz, et ux., et al. v United St

HEARING DATE: April 19, 1988

LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Supreme Court and that this is a true and accurate transcript of the case.

Date: 4-25-88

Margaret Daly

Official Reporter

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