OFFICIAL TRANSCRIPT

PROCEEDINGS BEFORE

THE SUPREME COURT OF THE UNITED STATES

DKT/CASE NO. 83-1878

TITLE MARGARET M. HECKLER, SECRETARY OF HEALTH & HUMAN SERVICES, Petitioner v. LARRY LEON CHANEY, ET AL.

PLACE Washington, D. C.

DATE December 3, 1984

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IN THE SUPREME COURT OF THE UNITED STATES

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MARGARET M. HECKLER, :

SECRETARY OF HEALTH & :

HUMAN SERVICES, : No. 83-1878

Petitioner :

v. :

LARRY LEON CHANEY, ET AL. :

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Washington, D.C.

Monday, December 3, 1984

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:53 o'clock a.m.

APPEARANCES:

KENNETH S. GELLER, ESQ., Washington, D.C.;

on behalf of Petitioner.

STEPHEN M. KRISTOVICH, ESQ., Los Angeles, Cal.;

on behalf of Respondents.

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P R O C E E D I N G S

CHIEF JUSTICE BURGER: Mr. Geller, I think you may proceed whenever you're ready.

ORAL ARGUMENT OF KENNETH S. GELLER, ESQ.

ON BEHALF OF THE PETITIONER

MR. GELLER: Thank you. Mr. Chief Justice, may it please the Court:

This case presents an important issue of administrative law that we had thought was well settled prior to the District of Columbia Circuit's decision in this case. That issue is whether the courts have authority to review and set aside an administrative agency's discretionary determination not to bring law enforcement proceedings against someone who is alleged to have violated a provision of the agency's statute.

QUESTION: Mr. Geller, let me stop you right off the bat, if you don't mind, to just see whether that's the question we would necessarily have to answer. The FDA apparently believed that its statutory mandate just didn't reach the question of state-sanctioned use of lethal injections for executions, and if that is correct would our inquiry just end there?

MR. GELLER: Justice O'Connor, that was one of many reasons that the FDA gave for not bringing an

enforcement action in this case. It also --

QUESTION: Well, if we thought that was right?

MR. GELLER: Well, before the Court could reach the question of whether that was right or not, it would seem that the Court would first have to answer the question whether this decision of the FDA is reviewable. If it's reviewable, then the Court can decide whether the FDA made an error.

QUESTION: Yes. Well, do you think that the question of whether something is within the statutory jurisdiction of FDA at all is something that is reviewable?

MR. GELLER: Not when the question arises in the context of a challenge to the failure or the refusal to bring enforcement proceedings. But here the FDA didn't just say that it didn't have statutory authority. The letter, which is reprinted in the appendix to the petition beginning on page 81A, went on to say as a second and separate basis of denial, it gave a number of reasons why it would not bring this proceeding even if in fact the language of its statute could be stretched to cover this situation.

Now, in the last several years a number of states have passed statutes prescribing lethal injection

with drugs as the method of carrying out the death penalty. Respondents are a group of prison inmates who have been sentenced to capital punishment in two of these states, Texas and Oklahoma.

In 1980 they filed a citizen petition with the FDA contending that the states of Texas and Oklahoma were intending to violate the federal Food, Drug and Cosmetic Act, apparently because the FDA had never approved the drugs in question as safe and effective for the purposes of human execution.

The Respondents asked the FDA to require warning labels on these drugs stating that they couldn't be used as a means of execution, and also asked that the FDA adopt a policy of seizing the drugs, bringing injunctive proceedings, and even criminal prosecutions of the responsible state prison officials.

The FDA declined to take any of these enforcement measures. As I just mentioned in my colloquy with Justice O'Connor, the FDA first concluded that it didn't have jurisdiction to intervene in the states' practice of administering capital punishment, but went on to say that, even if it had jurisdiction, it would decline to exercise it under its inherent discretion not to pursue certain enforcement matters.

Respondents then brought suit to challenge the

FDA's decision. The district court dismissed the complaint on the grounds that the enforcement decisions of an executive agency are simply not amenable to judicial review.

But a divided panel of the District of Columbia Circuit reversed. The D.C. Circuit held that the FDA in fact did have jurisdiction to intervene in this area under the misbranding provisions of the food and drug laws. These provisions prohibit the misbranding of drugs while they are "held for sale," and the Court of Appeals' reasoning seems to have been that these drugs are misbranded because they're warning labels don't state that they can be used for purposes of capital punishment and that they are held for sale when they are forceably administered to these prisoners pursuant to a court order.

The court then went on to hold that the FDA's decision not to exercise its enforcement discretion is subject to judicial review and that the FDA had acted arbitrarily, capriciously, and without legal authority here.

Now, what the District of Columbia Circuit's ruling amounts to is this. First, the court devised a highly imaginative and we think quite dubious construction of the food and drug laws, in an effort to

conclude that the states' lethal injection procedures violated the misbranding provisions of the Act. Then the court compounded the problem by holding that the FDA has a mandatory duty, a mandatory duty to initiate investigative and enforcement proceedings, based on this quite dubious legal theory and against the agency's better judgment, simply because a citizen petition had been filed alleging a statutory violation.

We think this Court should reject this remarkable restructuring of the proper role of an agency. Now, this case, to be sure, arises in a somewhat unusual factual context, but that factual context should not be allowed to obscure the important administrative law issues of general applicability that were decided by the Court of Appeals.

This case only fortuitously involves capital punishment. If Respondents prevail here, then it's reasonable to assume anyone whose citizen petition is denied by the FDA can sue and seek review of whether the FDA should have brought enforcement proceedings.

I'm informed, by the way, by the FDA that they are besieged by complaints filed by trade and industry representatives claiming that some competitor is engaging in a misbranding violation. In fact, there was a case in the Eighth Circuit just last year in which

some dairy producers sought review of the FDA's refusal to bring enforcement proceedings against people who were selling allegedly misbranded cheese.

QUESTION: Well, the Court of Appeals' decision isn't limited to the FDA.

MR. GELLER: That's another problem, Justice Rehnquist. Of course it's not limited just to the FDA. The FTC, the NLRB, and the SEC, for example, regularly declined to pursue investigative or enforcement activity based on the complaint of someone who claims to have been injured as a result of that activity. And these decisions too would presumably be subject to judicial scrutiny under the Court of Appeals' approach.

This system of judicial oversight of the manner in which executive agencies choose to deploy their enforcement resources would represent a sharp break from the current state of the law. This is a suit under the Administrative Procedure Act. The Administrative Procedure Act generally makes all final agency action subject to judicial review.

But it has two very important exceptions to that general principle. One exception provides that agency action is not reviewable if the matter is committed to agency discretion by law. And we think that the Court of Appeals got off on entirely the wrong

foot in this case when it held that this exception had to be construed very narrowly because all agency action is presumptively reviewable, because any presumption that operates in this area, it's that Congress would never have intended to subject to judicial review the enforcement decisions of an administrative agency without a clear statement to that effect.

And that's because this Court for more than a hundred years has repeatedly held that the decisions of a law enforcement agency whether or not to investigate, institute an investigation or an enforcement proceeding, is committed to the sole discretion of the administrative agency. And the Court reaffirmed this settled principle only a few years ago in the Southern Railway case.

QUESTION: Mr. Geller, do you think your position in this case is consistent with the Government's position in the Florida Power & Light case involving atomic energy, where there you took the position that there was reviewability in the Court of Appeals? The Court of Appeals had said the action was not reviewable.

MR. GELLER: Clearly, many agency actions are reviewable. Refusal to --

QUESTION: No, this was inaction, refusal to

institute a proceeding.

MR. GELLER: Well, the question is what Congress has provided. If Congress has provided a mandatory duty to do something, as it has in many instances --

QUESTION: It did not in that case.

MR. GELLER: There's a mandatory duty to initiate rulemaking, for example, under many statutes: the OSHA statute, the EPA statute. If someone claims that that was violated, then the question is obviously reviewable. But there has to be some law to apply, which is what, of course, the Court said in the Southern Railway case.

Now, the Court of Appeals, Judge Wright, dismissed this hundred year old line of Supreme Court cases as having a so-called anachronistic ring to it. But we don't think that these decisions are anachronistic at all.

The reasons for the settled rule against judicial review of agency enforcement decisions are not very difficult to appreciate. The decision of whether to bring an enforcement proceeding is not simply a mechanical task whereby the agency decides whether they have probable cause to believe the Act has been violated.

The agency also has to make a number of policy, judgment calls. It could decide, for example, to bring a great number of small proceedings because of the in terrorem effect of doing so. On the other hand, it would be equally reasonable to eschew bringing small proceedings, but to bring a number of large enforcement proceedings.

Or it could decide to go against violators of one provision of its statute rather than another, in the view that one portion of the statute is more important. It could also decide only to proceed with enforcement when the law is clear and the agency is likely to win. But it would be equally reasonable for an agency to decide to bring a number of test cases and see if it could expand the outer perimeter of its authority.

All of these are policy and judgment calls. They're not legal decisions. They're not amenable to judicial review.

QUESTION: Mr. Geller, what if in this case, as I understand your position, that the explanation given by the agency had been simply, we have no jurisdiction, that they had said nothing more? What then would your position be?

MR. GELLER: Well, our first -- as I thought I said in the answer to Justice O'Connor's question, the

threshold question is whether the agency's decision not to institute enforcement proceedings is reviewable in court. You would only reach the question --

QUESTION: No, I'm asking you would it be reviewable if that's what they'd said and nothing more?

MR. GELLER: The question would still be, has Congress circumscribed in any way the discretion of the agency to bring enforcement proceedings, and there would have to be some law to apply. And we would think that even in that instance, which I should add is not very likely to occur, because if an agency -- if the only impediment to bringing an enforcement proceeding in the agency's mind is whether they have statutory authority to do it --

QUESTION: Well, you don't support, as I understand your brief, you do not support the view that they don't have jurisdiction?

MR. GELLER: We contend here that the FDA in fact does not have jurisdiction to proceed.

QUESTION: If they exercise their discretion to proceed here, you say that would be in excess of their statutory authority?

MR. GELLER: Well, the FDA has taken the position, and we think that there is certainly textual support for it, that Congress never intended the food

and drug laws to cover this situation, that's correct.

QUESTION: Well, I'm not sure that's an answer.

MR. GELLER: Well, the answer --

QUESTION: If they had done exactly the opposite and gone forward with an investigation as requested, you say they would have violated the statute, or do you not?

MR. GELLER: Well, as an advocate obviously we would think some argument could be made in support of the assertion of jurisdiction. The question here is that Congress quite clearly --

QUESTION: Well, I'm still not quite clear what your position is. They said -- the first paragraph of their letter said they don't have jurisdiction.

MR. GELLER: That's correct.

QUESTION: Do you agree or disagree with that statement?

MR. GELLER: We agree with that, we agree.

QUESTION: You agree with it?

MR. GELLER: We agree that the FDA does not have jurisdiction to regulate the method of carrying out capital punishment by the states. We don't think that was within the intendment of this consumer protection statute. There's certainly not a word in the statute or

in the legislative history or anywhere else that Congress ever thought that the FDA would be getting into this.

QUESTION: Well, do courts have jurisdiction to review that issue and decide it?

MR. GELLER: The issue of whether the FDA has jurisdiction?

QUESTION: Yes.

MR. GELLER: If the FDA brought an enforcement proceeding and the states sought to have it dismissed on the ground that this would not be within the FDA's jurisdiction, then of course the courts would have something to review.

QUESTION: You don't think the issue is before us and we could decide that in this case?

MR. GELLER: I think there is a threshold issue before the Court of whether or not the agency's decision not to institute enforcement proceedings is a decision that is subject to judicial review. If the answer to that question is yes, if the Court disagrees with our threshold submission, that it is subject to judicial review, then the question arises, has the agency abused its discretion in not bringing a proceeding?

One of the reasons that the agency gave for

not bringing the proceeding is that it concluded it did not have jurisdiction. In that context, the Court would then have to decide that question, because of course if the agency did not have jurisdiction it couldn't abuse its discretion by not bringing the proceeding.

QUESTION: But your answer to the combined import of Justice O'Connor's and Justice Stevens' questions, as I understand those questions, is that if the FDA had said only in this case, we have no jurisdiction to institute a prosecution or to institute an action, this Court should decide, because that type of decision, whether or not to institute an action, is not reviewable by the courts, that we don't reach the question of FDA jurisdiction because we don't review that kind of decision?

MR. GELLER: That is precisely correct. It's no different than if a prosecutor had decided, I'm not going to bring a prosecution because I don't think that state of facts satisfies the bank robbery statute.

QUESTION: Mr. Geller, I don't understand how you can take that position, which is directly opposed to the position you took in the Florida Power & Light case. You said the jurisdiction was in the Court of Appeals to review that precise decision.

MR. GELLER: Well, I'm not familiar with the

position that we took in that case.

QUESTION: That was an agency inaction case in which the Government --

MR. GELLER: But it is not -- Justice Stevens, it is not simply agency inaction. It is a question of whether Congress has required the agency to act. If Congress has required the agency to act in a particular area, then agency inaction is subject to judicial review because there is law to apply.

When Congress has not in any way circumscribed the agency's discretion, when there is no law to apply to decide whether or not the agency has to act, then an agency's decision not to act is in fact not judicially reviewable.

And that's what the Court said in the Southern Railway case. That was a case in which shippers challenged the ICC's refusal to investigate whether or not certain railroad tariffs were lawful. The Commission refused to bring enforcement proceedings, and the shippers sought judicial review. And this Court in a unanimous decision held that the decision of the ICC not to bring enforcement proceedings is not judicially reviewable.

And what the Court said there is equally applicable here. Let me just read two sentences. This

is at 442 U.S. at page 455. The Court said: "With respect to the Commission's enforcement power, the statute is written in the language of permission and discretion. The statute is silent on what factors should guide the Commission's decision. There is simply 'no law to apply' in determining if the decision is correct."

Well, we contend that the same situation is fully applicable here. There is nothing in the food and drug laws that in any way circumscribes the Food and Drug Administration's inherent discretion whether or not to bring an enforcement proceeding. No provision of the food and drug law says that the agency has to prosecute if a violation of the law is found. No provision of the food and drug law even sets out criteria that the agency has to follow in determining whether or not to exercise its discretion in bringing an enforcement proceeding.

There is simply no law to apply, and it's not clear how a court would even go about deciding whether an agency properly decided to bring enforcement proceeding A rather than enforcement proceeding B.

It's worth pointing out and the Court should keep in mind the massive responsibilities of the Food and Drug Administration. It is essentially responsible for the safety of virtually all the food and drugs

distributed in interstate commerce in this country.

Now, obviously the resources of the FDA are finite and not every violation can be investigated.

QUESTION: Mr. Geller, I'm sorry to interrupt you so often. I do want to be sure I understand your no law to apply argument. You're not arguing that if they did think they had jurisdiction and if they decided to exercise their discretion and then they went ahead to bring a proceeding, that there would not be law to apply in the enforcement field, but rather that there's no law to apply to the decision of whether or not to institute a proceeding?

MR. GELLER: Precisely.

QUESTION: It's the latter that you're contending?

MR. GELLER: Precisely, it's the latter, and that is the area that --

QUESTION: So that whenever there's a statute which does not describe the circumstances under which enforcement proceedings should be started, your no law to apply rule would apply?

MR. GELLER: That's exactly our position. And what the Court of Appeals did and I'm afraid what the Respondents have done is to confuse the two situations: one where the statute provides circumstances in which a

violation of the law occurs, where first there's law to apply and if the Government brings a prosecution or an enforcement proceeding the court can decide whether or not the statute has been violated -- that is, the run of the mill enforcement proceeding -- and this situation, where the statute provides -- Congress has not provided any standards by which to decide whether the FDA should or shouldn't bring any particular enforcement proceeding. So it's not clear how a court could even go about deciding.

QUESTION: Is there any statute in which Congress has provided law on that decision?

MR. GELLER: Well, the only statute that I am aware of is Title IV of the Labor Management Reporting and Disclosure Act, which is of course what was involved in Dunlop versus Bachowski. What makes Bachowski so distinguishable is that in that case Congress had provided -- and it was quite unusual, but I think understandable in that context -- that if the Secretary of Labor had probable cause to believe a violation of the law had occurred, the Secretary had to bring an enforcement proceeding.

The statute was written in that peculiar way, I think in part because it wasnt a true exercise in prosecutorial discretion. The Secretary, as this Court

said in Bachowski, was really acting as the union members' lawyer. And in that situation, in that narrow situation, the Court said that there is at least judicial review to require the Secretary to provide a statement of reasons why he hasn't brought an enforcement proceeding.

But here there is nothing comparable in the FDA statute, Title IV, and there is nothing that requires the FDA to bring any particular enforcement proceeding.

So as I was saying a moment ago, not every violation can be investigated or enforced. The resources of the agency are finite. If it has to bring, pursuant to the D.C. Circuit's order, if it has to bring 15 enforcement proceedings around the country against states that use drugs for capital punishment on the grounds that it's a misbranding violation, those resources are going to be taken away from some other enforcement activity that the agency wants to pursue.

So the question in this case really boils down to who is to decide how the agency's enforcement resources are going to be allocated? Is it going to be the D.C. Circuit or is it going to be the Commissioner of Food and Drugs?

Now, for all these reasons we think that the

Court of Appeals erred in holding that the FDA's decision not to undertake enforcement activity was not subject to judicial review, simply because there's no judicially manageable standards to decide whether a particular enforcement proceeding should have been brought.

But if we're wrong about that and if the FDA's decision was in fact judicially reviewable, then, as I said a moment ago, the question remains whether the FDA abused its discretion in not bringing the particular enforcement proceeding. I want to spend just a few moments of my remaining time on this secondary aspect of the case which, I repeat, the Court need not reach if it agrees with us that the decision itself is not judicially reviewable.

It is truly hard to fathom how the Court of Appeals could have concluded that the agency acted arbitrarily and capriciously in refusal to involve itself in an area as far removed from its statutory mandate as the investigation of state capital punishment procedures. Needless to say, there is not a shred of evidence anywhere in the language or legislative history of the food and drug laws that Congress intended the FDA statute to reach this sort of activity.

Now, the Respondents' brief contains repeated

references to what they say is the "thwarting of Congressional intent" here. That's the phrase they repeatedly use, the FDA is thwarting Congressional intent.

We challenge Respondents to cite one provision in the food and drug laws that suggests Congress intended to cover state capital punishment procedures. We challenge them to list one statement in the legislative history in which anyone thought that the statute would cover this unique situation, or one statute in any of the agency's regulations, or even one sentence in any court decision construing the food and drug laws, suggesting that anyone until this lawsuit ever thought that the food and drug laws were intended to cover the court-ordered imposition of capital punishment.

And I think it takes a fair amount of violence with the statutory language to even fit the states' activity within the statutory terms. The Court of Appeals seemed to think that Texas and Oklahoma were engaging in a misbranding violation, but I think it's fair to say that that conclusion is not intuitively obvious.

But even if a colorable argument could be made that the drugs used for lethal injections are misbranded

because their labels don't list capital punishment as an approved use, and even if we were to somehow conclude that the drugs were held for sale when they were coercively administered to a prisoner, even if we indulge in those two assumptions, then at the very least we think Judge Scalia's dissent shows that a very powerful and respectable argument could be made against that.

It's hard to see how an agency could possibly be said to have abused its discretion in not bringing enforcement proceedings that are sure to be contested and sure to lead to protracted and quite likely unsuccessful litigation. In fact, it's not even clear how the D.C. Circuit imagined the whole system would work, because what the D.C. Circuit did is devise, we think, a somewhat strained construction of the food and drug laws that the FDA itself doesn't agree with, and ordered the FDA to bring enforcement proceedings which would surely be contested and lead to litigation. And I assume that the District of Columbia Circuit envisioned that the FDA would be presenting in litigation a construction of its statute that it doesn't agree with at all.

QUESTION: Mr. Geller, would the use by law enforcement officers of Mace in control of riots or in

their police work be something that's subject to FDA regulation?

MR. GELLER: I would think that the D.C. Circuit's construction of the misbranding provisions would extend that far, or the use of chloroform by a mugger.

I should add that the agency's fears of disruptive and ultimately futile litigation against the states here are not far-fetched. In fact, in recent weeks or recent months they have been proven quite well founded.

The Court will recall a couple of months ago the case of Mr. O'Brien, who had been sentenced to death by lethal injection in Texas. He brought a suit here last March in the District of Columbia based on the Chaney decision, seeking to have the FDA enjoined to seize the drugs that the State of Texas was planning to use for his execution. And the district court here in the District of Columbia, based on the decision below, granted a preliminary injunction requiring the FDA to seize these drugs.

Within hours, within hours of the grant of that preliminary injunction, the State of Texas had sued the FDA down in Houston, claiming that this was not within the FDA's statutory mandate, and the Fifth

Circuit in fact held that the FDA was not acting within its powers in seizing these drugs.

Surely the FDA acted responsibly and reasonably in conserving its limited enforcement resources for matters much more closely related to its principal mission of protecting consumers in the marketplace from unsafe and ineffective drugs.

If the Court has no questions, I'd like to reserve the balance of my time.

CHIEF JUSTICE BURGER: Mr. Kristovich.

ORAL ARGUMENT OF STEPHEN M. KRISTOVICH, ESQ.,

ON BEHALF OF RESPONDENTS

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

The Food and Drug Administration aggressively asserts its jurisdiction over the use of drugs on state prisoners in clinical and drug investigations. FDA aggressively asserts its jurisdiction with regard to drugs produced to kill animals, to ensure that those drugs will produce a quick and painless death.

In footnote 34 at page 45 of its brief, the Government concedes that if the manufacturers of lethal injection drugs promoted these drugs for this purpose FDA would assert its jurisdiction, would regulate these drugs, and would investigate and make sure that they

produced a quick and painless death.

Those three examples are no different from the facts of this case. When all is said and done, the only reason the Government has refused to assert its jurisdiction over lethal injection drugs is because it is a state-mandated activity. There is nothing in the statute, there is nothing in the legislative history underlying the statute, that gives any indication that Congress intended state-mandated activities to be exempt from FDA's jurisdiction.

In this Court's decision in United States v. Rutherford, the Court held that the FDA had jurisdiction over Laetrile, even though 17 states had passed statutes allowing the prescription and use of Laetrile by terminally ill cancer patients. FDA itself, with regard to the use of drugs on state prisoners in clinical drug investigations, rejected arguments by the states that FDA somehow was intruding into state penal systems.

In short, FDA's argument that it has no jurisdiction here is nothing more than an abnegation of its statutory authority. The issue here is not whether FDA should take some particular regulatory action with regard to lethal injection. Rather, the issue is a narrow one, and that issue is to what extent will there be judicial review of an executive branch abnegation of

a Congressional mandate of enforcement responsibility.

The Administrative Procedure Act provides that all final agency action is subject to judicial review unless it is precluded by statute or unless the action is committed by law to agency discretion. This Court in Abbott Laboratories v. Gardner held that there's a strong presumption that favcrs judicial review of all agency actions.

Mr. Geller tcday argues that the agency has a right to protect its limited resources with regard tc enforcement, that it must jealously preserve these rescurces, that it has budgetary constraints that limit its actions.

That is all very true, but that is not the reason why the FDA denied the Respondent's administrative petition here. That argument was not made in the district ccurt, that argument was not made in the Court of Appeals. It is simply a post hoc rationalization of counsel that is made for the first time in this Court by the Solicitor General's Office.

In any event, there is a clear distinction between an everyday individualistic retail-type enforcement decision in which an agency will have to make a determinatien whether it should allocate its rescurces for that enforcement action or not and what

has happened here.

What we have here is a wholesale categorical class-like determination by the FDA, based upon statutory interpretation and based upon what it calls notions of federalism, that it just simply does not have jurisdiction and will not exercise jurisdiction. This Court in Office Employees v. National Labor Relations Board held that the Secretary of Labor could not renounce jurisdiction over an entire category of employees, that being unions when they were acting as employees. This Court clearly has jurisdiction to review an agency determination that it does not have jurisdiction under the statute to take an enforcement action.

The Government also argues that the agency enforcement decision here is like that of a criminal prosecutor. Criminal prosecutions are brought for the protection of society at large, rather than any particular individual, and no individual has standing to request that a particular prosecution be brought.

But this Court has stated --

QUESTION: Are you suggesting that there's no social question involved here?

MR. KRISTOVICH: Not at all, Your Honor. Of course there are clear broad social questions involved

here.

QUESTION: I took it from your prior statement you were ruling that out.

MR. KRISTOVICH: No, Your Honor. I was merely stating that criminal prosecutions are brought for the protection of society at large. The Act here, of course, was enacted for the benefit of the public at large. But it was also enacted for the benefit of individuals, those individuals who use drugs.

Administrative proceedings, unlike criminal prosecutions, have a direct impact on individuals, the individuals for whom Congress enacted the statute either to benefit or to protect. The Government studiously ignores this Court's decision in Dunlop v. Bachowski, in which the Court held that the strong presumption in favor of judicial review applies with equal force to agency enforcement decisions.

In that case, the Bachowski case, the Court held that the Secretary of Labor had failed to carry his heavy burden of showing that Congress did not intend to preclude judicial review of his decision not to enforce the Labor Management Reporting and Disclosure Act.

Even the cases relied upon by the Government for their claim of an absolute immunity from judicial review, such as the Southern Railway case, do not

support that proposition. In that case, the Court said that it will not lightly interpret a statute to confer upon an agency unlimited discretion.

The Government argues that if a court were to review its enforcement decision here it would do violence to the doctrine of separation of powers.

QUESTION: Mr. Kristovich, can I interrupt, please. You say they ignored the Bachowski case, but Mr. Geller said that's the one case in which the Court identified law to apply to the decision to bring or not to bring an enforcement proceeding.

MR. KRISTOVICH: Well, he tried to distinguish it away, Your Honor. But he ignores the clear language in the case that is applicable also to this case, and that is the strong presumption in favor of judicial review of agency actions, which also applies to enforcement --

QUESTION: But do you think the presumption is equally strong in favor of review of a decision not to bring a proceeding as there is review of some action that affects rights?

MR. KRISTOVICH: Well, Your Honor --

QUESTION: I mean, his basic distinction, his basic point is there's a big distinction between refusing to act and deciding to act.

MR. KRISTOVICH: Well, as this Court stated in Marshall v. Jerrico, the decision to enforce or not to enforce often places a significant burden on the statutory beneficiary, as is shown by this case. The agency's decision not to enforce the statute places an enormous burden on the Respondents.

QUESTION: Where are the rules that tell us whether they have acted correctly in refusing to enforce the statute? He says there's no law to apply to that decision. What is the law that governs that?

MR. KRISTOVICH: Your Honor, the law to apply is in the express language of the statute itself, the 1972 FDA policy statement, and FDA and court interpretations of the statute. We would say there is law to apply because the statute sets forth criteria for determining noncompliance with the statute.

QUESTION: But then every nonenforcement decision has law to apply to it? Whenever you can find a violation, you're really, I think, saying that there's law to apply if, after making the decision to enforce, there's some law deciding how to decide the case.

MR. KRISTOVICH: Well, Your Honor, in the Dunlop v. Bachowski case this Court held there was law to apply because you could look at the Secretary of Labor's decision and determine whether he was correct in

saying there was no probable cause that there was a violation and no probable cause that that violation had affected the outcome of the union election.

In Citizens to Preserve Overton Park, the Court said there was law to apply because it could look at the Secretary of Transportation's decision and make a determination whether it was rational in saying that all feasible and prudent planning had been done and that there were no steps that could be taken to minimize the impact of the highway in that case.

We disagree with Mr. Geller's assertion that the law to apply goes to whether there are standards to judge the FDA's exercise of enforcement discretion. But even if you take that as being the test -- and we don't think Bachowski makes it the test or Citizens to Preserve Overton Park makes it the test. But even if you take that as the standard, there is law to apply here.

Section 336 of the Act -- and I will read it because it is very brief -- states: "Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice

or warning."

We think Section 336 indicates the clear Congressional intent that, with regard to major violations of the statute, the FDA has no enforcement discretion to ignore its enforcement powers. If Congress had intended Section 336 to apply to major violations, it would not have restricted it to minor violations.

QUESTION: Mr. Kristovich, are you also relying on Judge Wright's reliance on the preamble to the '72 FDA legislation?

MR. KRISTOVICH: Yes. Yes, we are, Your Honor. The 1972 preamble --

QUESTION: That was never adopted, though, was it?

MR. KRISTOVICH: It was a preamble to a proposed rulemaking that was never adopted. But the Government in the courts below conceded that this preamble is still in effect. In fact, under FDA regulations it is an advisory opinion, and under 21 CFR Section 10.85(e) the FDA is obligated to comply with it unless it is amended or revoked. It has not been amended or revoked.

And that preamble states: "Where the unapproved use of an approved new drug becomes

widespread or endangers the public health, the Food and Drug Administration is obligated" -- and that's the term they use -- "obligated to investigate it thoroughly and to take whatever action is warranted to protect the public health."

What Respondents ask is that FDA live up to this preamble, that they do what they're obligated to do, that they investigate the use of these drugs, and that they take whatever action is warranted to protect these prisoners from what the uncontroverted evidence in the record shows may be a painful, agonizing, excruciating death.

QUESTION: Well, under your view I suppose the use of an electric chair as well would be a device subject to FDA regulation?

MR. KRISTOVICH: No, it would not, Your Honor. An electric chair is not a device under the statute, because it is not promoted or intended by its makers to be used in the diagnosis, the cure, the mitigation, or the prevention of disease. It has no --

QUESTION: But it would affect the structure or function of the body.

MR. KRISTOVICH: It certainly would.

QUESTION: And I assumed you were relying on that.

MR. KRISTOVICH: No, we are not, Your Honor. We are relying on the definition for drug, the definition I just gave you.

QUESTION: Does an electric chair go to the Consumer Product Safety Commission?

(Laughter.)

MR. KRISTOVICH: I do not know the answer to that, Justice Rehnquist. I assume it does not.

Justice O'Connor, we are not arguing -- and Judge Wright's opinion I do not think can be read to mean -- that FDA has jurisdiction over Mace. It has jurisdiction over chloroform. Mace is not intended by its manufacturers to have a medical, healthful, therapeutic benefit. The drugs here that are used for lethal injection do have these benefits and are intended to have those benefits.

It is the Government's argument for absolute immunity from judicial review that is anathema to the separation of powers doctrine. Without judicial review of agency action, there is no guarantee that agencies will observe the Congressional mandates that the statutes provide for them, and there is a chance that the goals of Congress can be negated or frustrated by agency inaction.

In short, the strong presumption that favors

judicial review of agency action applies to this case, and there is law to apply, given in Section 336 of the Act, given in the preamble, the 1972 preamble, and in other provisions of the Act.

Section 352 of the Act provides that a drug shall be misbranded unless its labeling bears adequate directions for use and adequate warnings against dangerous uses. FDA concedes that there has been no new drug application approved by it for any of these drugs. Consequently, the labeling of these drugs do not bear adequate directions for use as lethal injections, and they are misbranded under the statute.

Section 331(b) of the Act, which you will not find any reference to in the Government's briefs, provides that a misbranding in interstate commerce is prohibited. The Government concedes and the court below found that these drugs are manufactured for distribution and use in interstate commerce. Therefore, we have a misbranding of a drug and we have the misbranding in interstate commerce, and the jurisdictional nexus for FDA jurisdiction is met.

In addition, Section 331(k) of the Act provides that it would be prohibited to misbrand a drug while it is held for sale after shipment in interstate commerce. The "held for sale" provision is a term of

art. It does not mean technically that the drug has to be sold. It merely means distributed to the consumer or the user.

This Court in United States v. Sullivan said: "The words of paragraph (k), 'while such article is held for sale after shipment in interstate commerce,' apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce before it finally reached the ultimate consumer." Several courts have held that the section (k) provision merely means that the channels of interstate commerce have been used and it applies all the way from the point of manufacture up to the ultimate consumer.

In addition to the express language of the statute and in addition to the 1972 preamble, FDA interpretations and court interpretations also provide law to apply in this case. The cases have uniformly condemned the unapproved use of approved drugs outside the practice of medicine, and that is precisely what we have here, an unapproved use of a drug outside the practice of medicine.

In addition, as I've already noted, FDA vigorously asserts its jurisdiction over drugs used to produce death in animals, it vigorously asserts its

jurisdiction over state prisoners who are used in clinical drug investigations.

There is absolutely nothing in the statute or in the Congressional history that indicates Congress did not intend that this enforcement decision here is not reviewable, and the Government has not cited anything either in the statute or in the legislative history to support its claim of nonreviewability here.

In fact, in Abbott Laboratories v. Gardner this Courtm cited the Department of Justice memorandum that was read on the House floor in 1938 at the time the Act was passed, in which the Justice Department at that time argued that the special review provisions set forth in Section 371 of the Act were not really needed, because even without these provisions there would be judicial review if an aggrieved party wanted to complain about an action taken by the agency. It's ironic that the Government here is now taking the opposite position.

In short, the Government has failed to meet its heavy burden that Congress intended to preclude judicial review of its nonenforcement decision here.

QUESTION: Do you think an ordinary -- am I taking your time?

MR. KRISTOVICH: No, that's fine, Your Honor,

please. I'm sorry.

QUESTION: Is it part of your position that an ordinary prosecutorial decision to bring a criminal case is subject to judicial review?

MR. KRISTOVICH: That is not our position, Your Honor.

QUESTION: Well, what's the difference between that kind of a case and this one?

MR. KRISTOVICH: Your Honor, a criminal prosecution is brought for the benefit of society at large, not for the benefit of any particular individual. No particular individual, consequently, has standing to request that a particular prosecution be brought.

Administrative proceedings, on the other hand, have a direct impact on those individuals for whom the statute was enacted, either to protect or to confer a benefit upon. Those people therefore have standing to request a particular --

QUESTION: Well, any member -- let's suppose that there is a complaint with the Food and Drug Administration that a certain food is on the shelves that is unsafe, and the Food and Drug Administration says: No, we're not going to start any action against that; you're just wrong. Is that subject to review?

MR. KRISTOVICH: Your Honor, if an individual could meet the standing requirements --

QUESTION: Well, that's what I'm asking you. That's just, any member of the public has got the same standing as everybody else, I suppose?

MR. KRISTOVICH: Well, Your Honor, certainly in this case only the prisoners have standing to complain about the use of lethal injection drugs.

QUESTION: What about my example?

MR. KRISTOVICH: Your Honor, I believe if an individual in that case could show that there was a likelihood that he would be injured by that drug, that therefore he could file a citizen's petition, as Respondents did here, with the agency and request that they take action.

QUESTION: And what standard would determine whether the agency had failed to act properly if they refused to take action?

MR. KRISTOVICH: Well, Your Honor, that case, unlike our case, would be an individual retail type enforcement decision, at which point Mr. Geller's arguments about marshalling the agency's resources would come into play.

QUESTION: In other words, the arbitrary and capricious standard would apply?

MR. KRISTOVICH: Yes, Your Honor, that's right.

QUESTION: Why wouldn't the arbitrary and capricious standard apply to this case?

MR. KRISTOVICH: Well, Your Honor, I believe it does. But we are also arguing --

QUESTION: Well, could not this decision be held to be non-arbitrary even if they gave the wrong reason when they refused to go forward? Say we think it makes sense not to interfere with state-mandated procedures like that. Say we thought that, even though they didn't articulate it very well in their response. Would that require -- what should we do then?

MR. KRISTOVICH: Well, Your Honor, if I understand your question, the Court then would be saying that the FDA's decision here was not arbitrary and capricious.

QUESTION: Correct, yes. And then you would lose?

MR. KRISTOVICH: That's right, Your Honor. We are arguing two things, though: one, that it's arbitrary and capricious; but aside from that, it's a complete abnegation of its statutory duty, a renunciation of jurisdiction, which in essence is an attempt by the agency to take upon themselves the

Congressional right of repeal, which is beyond their delegated powers, not unlike the Office Employees v. Labor Board case, and that, if the Court so finds, that it will affirm the Court of Appeals' decision and direct the agency to assert its jurisdiction --

QUESTION: The agency did consider this.

MR. KRISTOVICH: Your Honor, the agency --

QUESTION: The agency considered it and did what any legal body would do, said: We find no jurisdiction. I say that in a lot of Court opinions.

MR. KRISTOVICH: That's right, Your Honor, that was the basis for their decision.

QUESTION: So they did say it. They did consider it.

MR. KRISTOVICH: Only to the extent that they said they had no jurisdiction.

QUESTION: Well, I'm objecting to you saying they didn't consider it.

MR. KRISTOVICH: Yes, Your Honor. Well, they did consider it to the extent they said they had no jurisdiction. But they did not consider it to the extent of looking at the affidavits that were submitted at the agency level --

QUESTION: They didn't consider it the way you wanted them to determine.

MR. KRISTOVICH: That's right, Your Honor, that's right.

QUESTION: And you're unhappy.

MR. KRISTOVICH: That's exactly right, Your Honor.

QUESTION: And I don't know what section of the Constitution protects that.

MR. KRISTOVICH: Well, Your Honor, the Administrative Procedure Act, which provides that agency actions shall not be arbitrary and capricious, protects us here. And we would argue that their decision, in addition to being a renunciation of the Congressional mandate, was arbitrary and capricious, and it was so because of their prior enforcement of the Act with regard to drugs used to produce death in animals, with regard to the assertion of their jurisdiction over state prisoners used in clinical drug investigation.

In support of their administrative petition, Respondents submitted affidavits from leading anesthesiologists that stated that there is no expert consensus founded upon substantial evidence, as required by the Food, Drug and Cosmetic Act, that these drugs will produce a quick and painless death. FDA disregarded those affidavits and described them as being not pertinent.

In the letter from the FDA Commissioner rejecting Respondents' petition, FDA stated, nevertheless, that they considered there to be no danger to the public health here. Well, the uncontroverted evidence in the record is that there is a substantial likelihood that the use of these drugs on approximately 450 prisoners will produce an excruciating, slow, painful and tortuous death.

Because this case was decided below on a motion for summary judgment, Respondents' allegations in their complaint of a substantial likelihood of a slow, painful death must be assumed to be true.

QUESTION: Could you have brought this case in the state court against a state?

MR. KRISTOVICH: Excuse me, Your Honor?

QUESTION: Could you have brought the case in a state court against a state, saying you can't use this horrible drug?

MR. KRISTOVICH: Well, Your Honor, in the O'Brien case which Mr. Geller alluded to Mr. O'Brien brought a 1983 action. But this particular case against the Food and Drug Administration would have to have been brought in federal --

QUESTION: I didn't say that, I said against a state, to enjoin the state from using this horrible

drug.

MR. KRISTOVICH: Your Honor, I suppose under a 1983-type argument such a case could be brought.

QUESTION: But you'd much rather bring it up here.

MR. KRISTOVICH: Pardon me, Your Honor?

QUESTION: You'd much rather take this sideways.

MR. KRISTOVICH: Well, Your Honor, we thought it'd be better to go to the agency itself, the agency that has jurisdiction over drugs, the agency with the expertise to investigate these drugs, to determine whether they will do what they are being touted as doing.

QUESTION: Mr. Kristovich, there was an argument made in some Texas appellate case, wasn't there, that death by lethal injection amounted to a cruel and unusual punishment in the criminal case itself?

MR. KRISTOVICH: Yes, Your Honor, that's right. That's right. But we are not making an Eighth Amendment argument here. It's clearly --

QUESTION: Statute.

MR. KRISTOVICH: -- purely a statutory argument.

QUESTION: May I ask one other question about the state of the record on the effects of using the drugs. As I understand it, your allegations in your complaint are a little more powerful, you might say, than those in the letter asking for agency action. Do we judge the likelihood of misuse of the drugs on the basis of what was submitted to the agency or by what you've alleged in your complaint after they decided not to enforce?

MR. KRISTOVICH: Well, Your Honor, I think the allegations are the same in both, both in the complaint --

QUESTION: Well, the letter to the agency more or less says there's an absence of consensus and there's a possibility that they might be misused in particular cases, rather than that there's a probability. I think there's a difference.

MR. KRISTOVICH: Your Honor, the letter to the agency had attached to it the affidavits from the anesthesiologists that said there is a substantial likelihood that these drugs will produce an excruciating death. And it is the application we made to the agency with the exhibits attached that this Court needs to review.

In conclusion, the uncontraverted evidence in

the record is that there is no substantial evidence that these drugs will produce the quick and painless death that they are being promoted and touted as doing. FDA has failed to carry its heavy burden that Congress intended to preclude judicial review of its nonenforcement decision here.

Respondents request that this Court affirm the Court of Appeals' decision, that it direct the agency to do what it should have done in the first place, and that is merely to look at these drugs, to conduct an investigation, to make a determination whether in fact these drugs will produce a quick and painless death.

QUESTION: You're submitting on your brief the question of the agency's jurisdiction?

MR. KRISTOVICH: I'm sorry, Your Honor. We're merely asking that this be sent back to the agency so that they can examine the evidence.

QUESTION: Well, I thought it claimed it didn't have any jurisdiction.

MR. KRISTOVICH: It did, Your Honor, and we would request that this Court affirm Judge Wright's opinion which held that they did have jurisdiction. So we would ask this Court to find it does have --

QUESTION: Well, you haven't orally argued that, have you?

MR. KRISTOVICH: Well, Your Honor, I thought I had. I thought I had.

QUESTION: I didn't understand that.

MR. KRISTOVICH: Well, if I haven't, we are certainly making that request, that this Court find that it does have jurisdiction and that it exercise this jurisdiction, and that it do the investigation that it should have done in the first place.

Thank you, Your Honor.

CHIEF JUSTICE BURGER: Do you have anything further, Mr. Geller?

REBUTTAL ARGUMENT OF KENNETH S. GELLER, ESQ.,

ON BEHALF OF PETITIONER

MR. GELLER: Just a few short matters, Mr. Chief Justice.

First, on this business about clinical investigations and dogs which Mr. Kristovich managed to mention three times in 25 minutes. The distinction which the FDA has consistently made, but which Respondents don't accept, is that those cases, the cases they rely on involving FDA regulation of drugs used for clinical investigations and for euthanasia for dogs, involve the marketing, the marketing of those drugs for those particular purposes, even though a new drug application had not been approved. That is precisely

what the agency views as its central purpose.

This case, on the other hand, does not involve the marketing of any drug for an improper purpose. There's no suggestion that the manufacturer of these drugs does not have a proper new drug application on file. This is a misbranding case.

At the end of the road, someone has taken an approved drug and allegedly used it for an unapproved purpose. That is a different section of the FDA's responsibilities, and its authority to act is much more uncertain. The Everest case, for example, which was a decision of the Fifth Circuit, the same circuit that would hear any case involving the State of Texas, had given a fairly narrow construction to that provision of the Act. So those cases are not in point involving the dogs and the clinical investigations.

And second and finally, I just want to mention the preamble that Justice Brennan alluded to and which is quoted at pages 24a and 25a of the appendix to the petition. The preamble, as Justice Brennan noted, was the preamble to an unadopted regulation. It has no -- the only force it has under the FDA's regulations is as an advisory opinion, and all that means under the FDA's regulations is that the FDA has committed itself not to take action against someone who may have relied on the

preamble.

The regulations make quite clear that the preamble was not committing the agency to bring an enforcement proceeding against somebody else, and that's made quite clear by the FDA's regulations, which we quote at page 25 of our brief, which retains the agency's inherent authority to decide completely and for itself which enforcement proceedings it would bring.

Thank you.

CHIEF JUSTICE BURGER: Thank you, gentlemen. The case is submitted.

(Whereupon, at 11:51 a.m., argument in the above-entitled case was submitted.)

* * *

CERTIFICATION

Alderson Reporting Company, Inc., hereby certifies that the attached pages represents an accurate transcription of electronic sound recording of the oral argument before the Supreme Court of The United States in the Matter of:

#83-1878 - MARGRET M. HECKLER, SECRETARY OF HEALTH & HUMAN SERVICES, Petitioner v. LARRY LEON CHANEY, ET AL.

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BY Paul A. Richardson

(REPORTER)