# OFFICIAL TRANSCRIPT
# PROCEEDINGS BEFORE

THE SUPREME COURT OF THE UNITED STATES

DKT/CASE NO. 83-1925

TITLE HILLSBOROUGH COUNTY, FLORIDA, ET AL., Appellants V. AUTOMATED MEDICAL LABORATORIES, INC.

PLACE Washington, D. C.

DATE April 16, 1985

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IN THE SUPREME COURT OF THE UNITED STATES

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HILLSBOROUGH COUNTY, FLORIDA, ET AL., Appellants, V. AUTOMATED MEDICAL LABORATORIES, INC. : No. 83-1925

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Washington, D.C.

Tuesday, April 16, 1985

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 1:10 o'clock p.m.



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APPEARANCES:

MS. EMELINE C. ACTON, ESQ., Assistant City Attorney of Hillsborough, Tampa, Florida; on behalf of the appellants.

PAUL J. LARKIN, JR., ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; pro hac vice, on behalf of the United States as amicus curiae in support of appellants.

LARRY A. STUMPF, ESQ., Miami, Florida; on behalf of the appellee.

RICHARD LANDFIELD, ESQ., Washington, D.C.; on behalf of the American Blood Resources Association as amicus curiae in support of appellee.

C O N T E N T S

P R O C E E D I N G S

CHIEF JUSTICE BURGER: We will hear arguments next in Hillsborough County, Florida, against Automated Medical Laboratories.

Ms. Acton, I think you may proceed whenever you are ready.

ORAL ARGUMENT OF MS. EMELINE C. ACTON, ESQ.,

ON BEHALF OF THE APPELLANTS

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

CHIEF JUSTICE BURGER: Would you like to lower the lecturn? If you wish, you may lower it.

MS. ACTON: Thank you.

CHIEF JUSTICE BURGER: We have basketball players occasionally here.

MS. ACTON: Mr. Chief Justice, and may it please the Court, we are asking the Court today to uphold the long acknowledged right of state and local government to legislate in order to protect the health of its people.

The particular health concern involved in this case is the operation of local plasmapheresis centers in Hillsborough County, Florida. We passed ordinances tc address our concerns, and before we enforced those ordinances, we were sued by one of the local plasma

centers.

At trial, the District Court found that our ordinances were constitutional with one exception, but the Court of Appeals reversed and held that we were absolutely preempted in this field from ever regulating because of the comprehensive FDA regulations covering the same subject matter.

We submit that that Eleventh Circuit opinion which held that we were impliedly preempted is incorrect because in this case there is an express statement by the FDA that they never intended to "usurp the powers of state and local authorities to regulate plasmapheresis procedures in their own localities."

The Eleventh Circuit also erred in implying preemption based upon the three findings, that the federal regulations were pervasive, were dominant, and that our regulations were in conflict with the federal regulations.

First of all, there is no conflict. It is not impossible to comply with both systems of regulation simultaneously. The trial court found that our regulations supplement and complement the federal scheme rather than conflicting with it, and in fact they found that we added four additional protections particularly aimed at protecting the health of local paid donors.

QUESTION: Ms. Acton, I guess the Solicitor General's brief identifies at least one local regulation that the Solicitor General says would be preempted, the one that Hillsborough would have that would prevent someone with, for instance, active hepatitis from being a donor, and such people are needed in some circumstances for the plasma.

Do you agree that there might be preemption to that extent?

MS. ACTON: No, I don't, because I don't believe that there is a conflict. In the first place, before we get to the issue of whether there is a conflict, there doesn't appear to be an actual conflict with this particular center on this record before the Court in that they don't engage in that.

QUESTION: Well, your position is just that this center doesn't have standing, I guess.

MS. ACTON: That's correct.

QUESTION: But aside from that problem, would you agree there is a possible conflict there?

MS. ACTON: No, I don't, and the reason I don't is because our regulations expressly incorporate the special exception present in the federal regulations which allows for a center to not follow any of the prescribed regulations by the federal government if they

get express written consent from the Commissioner.

In that we incorporate that particular provision by reference, I don't think this Court could go ahead and assume that there is a conflict there before it is on the record.

That particular provision that the Solicitor General was interested in and thought there might be a conflict with has to do with our requirement that there be a total health check of a prospective paid donor prior to his even setting foot inside a plasma center.

This is different from the federal regulations which require that center to check the person out when he walks in, and this provision of our local ordinances protects the other persons in the centers from possible exposure to contageous diseases such as hepatitis.

The most important provision, we feel, of our ordinances is that we provide for a single center identification card. With that card, this would prohibit persons from overbleeding themselves in contravention to the goal set forth by the federal regulations, which only provide enforcement mechanisms at a single center.

In other words, under our regulations, persons would not be able to go from center to center where the FDA does not cross check their records and accomplish in

effect what the FDA prohibits.

Third of all, our regulations provide that the prospective paid donors undergo a breath alcohol test prior to undergoing the risk involved in the procedure so that they can appreciate those risks, and so that they can give an accurate medical history to the center personnel, who are required under the federal regulations to ask them those questions.

And finally, we provide a local enforcement system which supplements the federal system of enforcement and which the FDA representatives at trial testified would be helpful for them.

Now, appellee, its amici, and the Eleventh Circuit don't point to any conflict between the regulations. They point to a hypothetical conflict with the federal goal of a national supply of plasma that will be adequate to meet the nation's needs, but there is simply nothing on the record that would support this before this Court.

This was in fact one of the claims that was made at trial, and the claim that the District Court specifically rejected as being too speculative. Furthermore, the FDA in this case has stated that it sees no threat from these ordinances in affecting a blood supply, and they are the agency charged with

balancing the regulations as opposed to the adequacy of the supply.

QUESTION: Ms. Acton, do you know how many other local governments or states have regulations similar to those in Hillsborough?

MS. ACTON: We attempted to ascertain that, and the latest information we could find was, as of 1975 the FDA conducted a very unscientific survey of how many states had this type of regulation, and they reported that approximately 26 did, but I can't represent that they -- well, the course of that survey was that they mailed out questionnaires, and not all the states replied. So, no, I don't have complete information at this time.

At any rate, in this case, because we have a federal statement of an express intent not to preempt, this case can be distinguished from almost every other case that this Court has written, and furthermore, that statement completely dispels any ambiguity that might have been raised by the mere fact of comprehensive regulations existing and by the fact of a dominant national concern for the blood supply.

QUESTION: Ms. Acton, was that statement before the Court of Appeals when it decided this case?

MS. ACTON: No, regrettably it was not

submitted to the Court of Appeals.

QUESTION: Perhaps if it had been, the Court of Appeals might have come out differently on it.

MS. ACTON: It very well could have. The statement by the FDA as well as the lack of conflict between the two schemes provides more than adequate grounds for this Court to reverse the decision of the Eleventh Circuit and to uphold our right to legislate in this area of public health.

I would like to reserve the remainder of my time for rebuttal if I might.

CHIEF JUSTICE BURGER: Very well.

Mr. Larkin.

ORAL ARGUMENT OF PAUL J. LARKIN, JR., ESQ.,
ON BEHALF OF THE UNITED STATES AS AMICUS CURIAE
IN SUPPORT OF THE APPELLANTS

MR. LARKIN: Thank you, Mr. Chief Justice, and may it please the Court, the only issue decided by the Court of Appeals in this case, and the only issue before the Court is whether the FDA's regulations have completely prevented the county from going ahead and adopting the regulatory scheme that it has in this case.

The FDA takes the position now, as it did at the time it promulgated these regulations, that they were not intended completely to foreclose any further

supplementation by state or local governments. The regulations as they were adopted in 1973 didn't state any attempt to preempt. They don't today, even though they have been supplemented since then, and there is no real dispute on that point.

The dispute comes on the question of whether the comprehensive nature of the regulations impliedly preempts any further supplementation, and the agency believes that the statement in its preamble is a conclusive answer to that question.

There was a concern directly addressed to the agency at the time it adopted these regulations that the plasmapheresis regulations that the agency was going to adopt would preempt the states, and the FDA clearly said it had no intention of doing so.

Now, the appellees and the amici in support don't claim that that is ambiguous, and they do not claim that it was not an authoritative statement. Basically, their claim is that the FDA has changed its mind over the decade that has occurred since then, and they rely on a variety of different items in support of that claim, but none of them can justify the result they seek.

The item they rely on most heavily is the National Blood Policy that the FDA promulgated -- excuse

me, the Department of Health, Education, and Welfare promulgated the following year, in 1974. That policy was that, a policy. It was not a regulation. It didn't preempt the fields. It didn't state that preemption was necessary to carry out any of the goals that the policy stated.

The policy didn't discuss preemption at all. And it implied quite clearly and stated at several points quite expressly that there would be both a cooperative effort between the federal government and the states and between both of the governmental areas and private industry.

In fact, it was envisioned that the private sector would carry out the implementation of this goal. The appellees and the amici have also relied on several statements that the agency has made when it has promulgated additional regulations in this area, two particular types of regulations in particular.

One deals with regulations designed to cover the manufacture of blood plasma into plasma products. Nothing in the preamble to those regulations or the regulations themselves indicates that the agency ever intended to retract its earlier statement or that preemption was necessary in ordr to carry out this further area.

The agency also decided to extend the regulations that it had originally adopted in 1973 in certain respects in order to ensure the safety of donors was preserved when plasma was obtained not only for use in humans in injectable products, as the term is used, but also for use for laboratory and scientific use.

But neither those regulations nor the preambles can reasonably be read to conclude that the agency at any rate wittingly or unwittingly changed its mind in this matter.

The last item they rely on are the guidelines the FDA has adopted and the standard operating procedures that all the centers must follow. The guidelines bind the FDA. They don't bind private parties. The agency issues issues those for the edification of people in the field.

The standard operating procedures at best would support a claim that the agency has extensively regulated the area, and they are in no way inconsistent with the agency's statement that it intended to allow the states to go forward.

Appellees and amici have also greatly relied on the claim that there will be a frustration of federal policies in this area. There are three primary federal policies: ensuring that the quality of blood plasma and

plasma products remain safe, that donors' health remains intact, and that there is an adequate national supply of product available.

The county's regulations in no way would adversely affect the first two federal goals. The only dispute is whether they would decrease the supply. As Ms. Acton has pointed out, the District Court found to the contrary based on the evidence in the record before it. Appellees and amici have basically attempted to relitigate that factual issue in this Court, even though they have not expressly asked the Court to find that the District Court's finding was clearly erroneous.

Given the agency's statement of its intent, which it has never retracted, which was issued at the time it issued the regulations, and therefore essentially has the same force as the regulation itself, and the fact that there is going to be no frustration of federal policies, the agency doesn't see any need to preempt the regulations and ordinances that the county has adopted in this case.

Unless the Court has any questions, I have nothing further.

QUESTION: May I just ask one question? It is perhaps similar to one already asked, but to what extent is the local regulation in this area a matter of state

law as opposed to county law? This is a county ordinance or county regulation. Is that typical, do you happen to know?

MR. LARKIN: In the survey the agency conducted it was very varied. Some statutes allow counties to adopt ordinances, but it was unclear as to how many had. Some states adopt them by statute on a nationwide basis, and some counties have done it on their own. So it is really quite varied. I don't think there is any direct answer I can give to that.

QUESTION: I thought the government's brief identified one section of the local regulation that it did think was preempted or in conflict with the federal laws and regulations.

Yes, Your Honor, there is one area of potential conflict. The problem arises in the fact that you can't issue a donor identification card in the county if you have a history of hepatitis, so the fact that a center in the county may have an exemption and may be able to apply its procedure to a person who comes in with an identification card doesn't help if the person can't get the identification card at the outset.

So, the county has incorporated the federal regulations, and they may also incorporate the exemption process, but it is not entirely clear to us that that

would necessarily be sufficient.

QUESTION: Do you agree that the appellees here don't have standing then to raise that?

MR. LARKIN: Yes, Your Honor. They have never identified in their complaint, in their briefs, anywhere, as far as we know, that they have an exemption or that they have any right that is being infringed under the federal regulations in this respect.

Thank you.

CHIEF JUSTICE BURGER: Mr. Stumpf.

ORAL ARGUMENT OF LARRY A. STUMPF, ESQ.,

ON BEHALF OF THE APPELLEE

MR. STUMPF: Mr. Chief Justice, and may it please the Court, not surprisingly, we take quite a contrary view with regard to the correctness of the Eleventh Circuit opinion, and most specifically the legal standard that the Eleventh Circuit applied.

It is our position that the Eleventh Circuit applied the correct legal standard, and that this Court should affirm the decision below on that opinion. We submit that affirmance of this case on the Eleventh Circuit opinion would be consistent with sound and recent precedent of this Court, would be consistent with sound policy, and would be consistent with simple logic.

This case in our view does not present a novel issue of law as suggested by my adversaries, and does not mandate a significant change in well settled principles of preemption analysis. The rule of law suggested by my adversaries, primarily the Solicitor General, reduces to this.

They advocate the position that in the absence of express Congressional intent to preempt an area, that it is necessary to a finding of preemption that the regulating agency has specifically expressed the intent to preempt the field.

It is our position that a trilogy of very recent decisions decided by this Court demonstrate that that, the rule being advocated by the Solicitor General is not now the present rule of law with respect to preemption analysis, and that it should not be the rule of law with regard to preemption analysis.

The three cases I am referring to, of course, are De La Questa, the Capital Cities case, and the Michigan Canners case, about which we all spent a great deal of time discussing in our brief.

The present legal standards in measuring or determining a preemption claim are in my view well settled. The first standard is to look to the Congressional intent to determine if there has been a

Congressional expression of intent to preempt the area.

We concede that in this case no such finding could properly be made, so we are down to the second level, which is analysis of implied preemption. The law is equally well settled, we submit, that if in the -- even in the absence of express Congressional intent to preempt, a finding of preemption is properly made and has been repeatedly made in the absence of agency expression of intent to preempt, when the Court determines that the feel of regulation has been occupied by the regulatory system in total, the statute and the regulations thereunder, where the federal regulatory system in total is so comprehensive and pervasive that the conclusion is inescapable, that there is no room left in the field, as the terminology is used, for local regulation. We feel we have that situation here.

QUESTION: Mr. Stumpf, in this case I don't suppose we have to reach the holding that you say the Solicitor General urges that there is no preemption unless the agency expressly says there should be preemption in the absense of a Congressional finding, because here the agency said it didn't want to preempt.

MR. STUMPF: The agency --

QUESTION: Do any of the cases you rely on involve the situation where the regulatory, federal

regulatory agency said it didn't want to preempt?

MR. STUMPF: No, Your Honor, the cases we rely on are cases where the agency was silent, and we feel in all sincerity that that is the situation that we have here. Let me try to explain very briefly why.

The agency comment that is now relied upon was made in 1973. It was a comment made by the Commissioner in commenting on comments that were received by the agency in response to a specific set of proposed rules.

Just one year before that comment was made, the FDA was given the authority to regulate in this area. Prior to that it had been, I believe, the Public Health Service.

So what the agency said in 1973 was that these regulations are not intended to preempt, are not intended to usurp. Those regulations, as the Solicitor General acknowledges, were limited to a specific field of injectable products.

Since that time, the evolution of the regulation in this area has expanded dramatically, and I will concede that we have not been able to find an express statement by the FDA that the new, the continually evolving, expanded, more comprehensive regulations, we can't find an agency expression of intent to preempt.

We do find things that are very close.

QUESTION: But here you have the Solicitor General in a brief in this Court speaking for the FDA, which is the relevant agency, saying as of now there is no intent to preempt.

MR. STUMPF: And I submit, Mr. Justice Rehnquist, that to adopt that rule advocated by the Solicitor General or even, with all due respect, the Solicitor General's position in this case cannot withstand analysis.

Let me try to explain that. The foundation, of course, for preemption is the supremacy clause. The supremacy clause, of course, says federal law is the supreme law of the land. Where Congress has determined that it is in the -- the national interest requires federal regulation of an area, and whether that regulation is done either by a comprehensive, detailed statute, or whether the regulation is done, as it is in this case, with what I call a more skeleton statute, which the agency fills the field with the detailed and technical regulations, that you look to see whether the system in total fills the field.

Under the rule of law that is advocated in this case, the determining element would be the comments of the agency made at the time the regulations are

enacted that would determine whether preemption exists or not. I submit that is unsound as a matter of policy, and frankly as a matter of constitutional law.

QUESTION: There is no suggestion by the Solicitor General, I take it, that if there is a square conflict between the regulations and the state law, the state law would have to give way.

MR. STUMPF: I agree with that --

QUESTION: Nor does he challenge the fact that if the state law would really frustrate some purpose, that the state law would have to give way.

MR. STUMPF: I read the Solicitor General's --

QUESTION: You are just disagreeing on whether or not there is a total occupation of the field.

MR. STUMPF: Yes, Your Honor. However --

QUESTION: Do you say that that is what Congress intended, independent of what the FDA is telling us now? Is that your view?

MR. STUMPF: It is my view that under the supremacy clause, federal law is the supreme law of the land. That federal law includes both the statute and the regulations authorized by Congress thereunder, so that you look to the entire federal scheme of regulations.

So, what I am saying, Mr. Chief Justice, is

that -- and the case law, of course, is replete with examples of this, that even in the absence of express Congressional intent to preempt, and in the absence of express agency intent to preempt, a finding of preemption properly made when the field of regulation has been filled --

QUESTION: How do you square that with the often repeated statement here that we pay great deference to the views of the agency created by Congress to administer these complex programs?

MR. STUMPF: I square that in this way, Mr. Chief Justice. I think those cases stand for the proposition that in dealing with the technical aspects of the regulation, what do the regulations mean, how far should we go in regulating, that a deference is properly made to the agency having the expertise to deal in, shall I say, the nuts and bolts of the area.

I don't -- I think it is clear that the question of whether an area has been preempted is a question for the judiciary and not for the executive, and that is why I come back to saying that under the rule of law advanced by the Solicitor General -- maybe an example. You can have a situation where Congress enacts what I call the skeleton statute.

The agency fills the field, and they are

silent with respect to their intent. You can have, in two separate areas, you could have exactly the same system of statutory authorization to the agency and the filling of the field by the agency.

Under the rule advanced by the Solicitor General, the determining element would be comments made by the agency at some point in the evolution of the enactment of the regulations. That would be determinative, what the agency says.

To reduce it to perhaps more practical language, I am suggesting that we must look to what the agency has done and not to what the agency says. So that is where I make the distinction, and that is how I square it.

QUESTION: But the agency is talking about now, and you are talking about what the agency was talking about before.

MR. STUMPF: Yes, Your Honor. I am suggesting --

QUESTION: So doesn't it seem proper that we listen to what they are saying now, since we are deciding now, and we are speaking for the future?

MR. STUMPF: Again --

QUESTION: Are you saying they are estopped or something?

MR. STUMPF: No, not at all. What I am suggesting --

QUESTION: If it is not estoppel, what is it?

MR. STUMPF: What I am suggesting, Mr. Justice Marshall, is that the question of whether a federal system of regulation is preempted in the field is to be determined by the courts, and not to be determined by the agency itself.

And I think that that statement finds support in the supremacy clause, which of course is the benchmark for this entire discussion of preemption. The supremacy clause gives to the legislature --

QUESTION: What do you have to counteract what he says is the present policy of the agency?

MR. STUMPF: What I have to counteract those, again as opposed to what their position is, what they say their position is, is, I have the comprehensiveness of the regulations, the pervasiveness of the regulations, and the three-tiered policy that those reguliations furthered, as stated by Mr. Larkin, the period of the product, the safety of the donor, and perhaps most importantly, to assure that there is an adequate supply of plasma, which of course is the raw material for vitally important pharmaceutical products.

QUESTION: That was decided already in this

case, wasn't it, the third one?

MR. STUMPF: That was one of the tests used by the Eleventh Circuit.

QUESTION: Do you --

MR. STUMPF: I am sorry.

QUESTION: Do you agree with that?

MR. STUMPF: I am not sure I understand your question, sir. I am sorry.

QUESTION: Do you agree with that? You are supporting it. You must be agreeing with it.

MR. STUMPF: I agree that the enforcement of these ordinances would frustrate that important policy. Absolutely. And I think the trial record substantiates that, and I think the Eleventh Circuit enunciated that as cogently and persuasively as I ever could.

In applying those standards, the correct legal test to see if in the absence of express Congressional preemption the regulations are so comprehensive they regulate virtually -- not virtually. They regulate every aspect of this procedure. That requires a judicial determination, not an agency determination, as to whether this area has been preempted.

With all due and sincere respect to the Solicitor General's position, a careful reading of their brief is somewhat troublesome, because what they seem to

be saying is that a little bit of frustration or a little bit of conflict with federal policies is okay. They say they don't now take the position that there is preemption.

There may come a time in the future when the diminished supply of plasma resulting from the enforcement of local ordinances becomes important enough, as it were, so that it would raise to the dignity of preemption.

I don't think that's an acceptable standard. I think we have to look now at the comprehensiveness of the regulations, and we have to make the determination that local legislation is wholly preempted. Now, I want to talk very briefly --

QUESTION: When you say local, do you mean both state and county?

MR. STUMPF: Yes, under the City of New Orleans case, local legislation has the same dignity or position as statewide enactments.

Even without regard to the implied preemption analysis, the third tier of the legal standard for determining when local or state laws are preempted is when the local legislation stands as as significant obstacle to the attainment of the federal purposes.

And we feel that under this case, under the

facts of this case, that also requires a finding that the local legislation here at issue must fall, and I take that position because of the national policy of assuring that there is an adequate supply of plasma.

The trial record in my view was quite clear as found by the Elevent Circuit that enforcement of these ordinances would significantly reduce the ability of plasma centers in Tampa to continue in operation, quite frankly.

And again, we feel that we should not wait for any snowballing effect, that when we have a frustration of the national policy of maintaining the supply now, now is the time to affirm the Eleventh Circuit finding, that enforcement of these local ordinances would frustrate the national policy.

In conclusion, again I would state that this is not the case that mandates or requires a significant reshuffling of the law of preemption. The standards are there. Application of those standards to this case, as was done by the Eleventh Circuit, mandates the conclusion, in my view, that the Eleventh Circuit's opinion should be affirmed.

QUESTION: May I ask one perhaps --

MR. STUMPF: Yes, sir.

QUESTION: -- too simple question? Would you

agree that the agency could have promulgated much less comprehensive regulations consistently with the statute without preempting?

MR. STUMPF: Yes, I do, I agree with that. However, having regulated every aspect --

QUESTION: -- regulations rather than anything in the statute itself on which you rely, is what I am really asking.

MR. STUMPF: Yes.

I would conclude, of course, by saying that we think the Eleventh Circuit opinion should be affirmed, or in the alternative, this case should be remanded to the Eleventh Circuit to address those issues that were not addressed by the Eleventh Circuit due to their holding of preemption. Thank you very much.

CHIEF JUSTICE BURGER: Very well.

Mr. Landfield.

ORAL ARGUMENT OF RICHARD LANDFIELD, ESQ.,
ON BEHALF OF THE AMERICAN BLOOD RESOURCES ASSOCIATION
AS AMICUS CURIAE IN SUPPORT OF APPELLEE

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

CHIEF JUSTICE BURGER: You may lower the lecturn if you would like.

MR. LANDFIELD: Thank you. I think it is

fine, sir.

I would like to add a little more to Justice O'Connor's questions about the states with similar regulations. The number is in the mid-twenties, and most, I believe, are -- it is probably split between local and state regulations.

The significant point about them is that most of those go right up to the line of the federal regulations and don't go beyond it. This is one of the first instances where the regulations actually go beyond the federal regulations, and that is what causes the concern in this case.

In addition to that, there are at least two pending examples of additional statewide legislation that is coming along that the industry feels will be a problem.

Texas is proposing a registration ordinance which doesn't go as far in some ways as Hillsborough County but in other ways it goes beyond it, and California is also considering legislation which deals with how the blood industry deals with its donors.

The Solicitor General made the comment that we are relying on the National Blood Policy, but that is only a policy. It is a little hard to understand the reasoning behind that. It is a policy, but it is a

policy where the agency of which FDA is a part considered over a period of time what the policy of the United States ought to be with respect to blood and blood products, and it concluded several important things, and the Solicitor General, the United States, and Hillsborough County ignore many of the passages in the National Blood Policy that we feel govern this case.

The seventh paragraph of the policy statement states that "It is the policy of the United States government," which in itself is a very broad way of entering the subject, "to employ the full regulatory authorities now vested in the federal government for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis."

So, right from the very start we have a National Blood Policy that does take in plasmapheresis. It talks about the highest attainable standards. And it talks about assuring uniform adherence to that. The National Blood Policy also states that it is the policy of the United States to assure ample donation of blood and plasma.

It encourages research on the entire spectrum of blood therapy activities, and it talks about

including in benefits in national health insurance and private health insurance benefits for blood and blood products, including cost of plasma acquisition.

So, this is not a mere policy. It is a very comprehensive policy issued by the parent agency of FDA, and we submit that it should be binding on FDA, and FDA can't lightly look away from it and ignore it.

The government has argued that the 1973 preamble statement is ample support and is dispositive for this Court to reverse the Eleventh Circuit.

QUESTION: May I interrupt with just one question? If the national policy is the strictest possible standard, the highest possible standard, and if, as I understand the record to indicate, in some respects the ordinance is even more strict than the federal regulation, how can that violate the national policy?

MR. LANDFIELD: Well, Your Honor, the federal government has different goals than does Hillsborough County. The federal government has the twin goals of protecting donor safety and assuring quality product, and at the same time assuring that in the entire nation as a whole there is going to be sufficient whole blood, blood products, and plasma for the therapeutic needs of the country.

Those two duties have a built-in tension. You can't satisfy one without affecting the other.

QUESTION: Well, but you surely aren't going to say, we will do everything that will maximize the supply of blood.

MR. LANDFIELD: No, sir.

QUESTION: That is what the tension is.

MR. LANDFIELD: No, sir, and that is exactly why we say, when the FDA exercises its duties to assure an ample supply of blood and at the same time give the maximum feasible protection to donors, that it is taking into consideration exactly the balancing and coming up with a very --

QUESTION: You have introduced the word "feasible." You have introduced the word "feasible," which I didn't hear you read before. "Maximum feasible protection."

MR. LANDFIELD: That is my word. It is not the FDA's word. They have to build that into their process. But in the process, they have to come to a conclusion that these are the regulations, because if we allow hundreds of jurisdictions to have different standards, even going beyond the national standards with respect to donor safety, we inevitably are going to have an impact on the other side of that equation which is

the ample supply or the supply of plasma available.

Now, the 1973 preamble statement could also be interpreted consistently with my observation about the various state and local legislation that is currently in effect, which is that when the commissioners said, we are not usurping local governments, we are going to recognize that the local governments do have a legitimate interest in going right up to the line that the federal government has drawn, so we won't usurp that, he didn't way we are not preempting. He said we won't usurp the rights of local jurisdictions, so they can go right up to that line.

The problem comes when they go beyond and you find, as in this case, the kinds of conflicts that we have. The Hillsborough ordinances do stand as an obstacle to the attainment of the federal goals. Not only are they burdensome, with their registration and their reregistration requirements and with the daily reporting requirements.

I can't imagine anything that is as burdensome as having to submit daily reports on hundreds of bleeding sessions conducted in a plasma center. They are also expensive, with daily bleed fees, the extra expenses of administration and registration.

And here again we have rules that contravene

the National Blood Policy, which talks about efficiency in blood collection and blood distribution, and these extra rules and regulations are undoubtedly going to cause at least some people to refrain from donating, or at least some plasma centers to reconsider their business relationships.

But the fundamental conflict, Your Honors, is that Hillsborough County has in effect redefined what constitutes a suitable donor. Under the federal regulations, any otherwise healthy person who meets the specified standards can give plasma.

These regulations were adopted after they were proposed, and comments, and the normal regulatory procedures. Any healthy person can give plasma.

In Hillsborough County, that is not so. Only a healthy person who also has before even going into the plasma center, as Ms. Acton has said, has to go somewhere else and be certified as being healthy.

QUESTION: And sober? And sober?

MR. LANDFIELD: And sober, but under the federal regulations, Your Honor, the donor must also be sober. That is quite clear.

QUESTION: Counsel, the government policy doesn't agree with you, does it?

MR. LANDFIELD: No, sir. The government

doesn't agree with us. That is the position they have taken in this case. Yes, sir. That is right.

QUESTION: I don't see why you are looking at me. I am satisfied.

MR. LANDFIELD: All right. Thank you.

The fundamental -- this fundamental concept -- conflict constitutes a dramatic redefinition in our view of what constitutes a suitable donor and constitutes a real obstacle to the attainment of the federal goals.

FDA's concession that it could preempt but it is not going to at the present time because they don't see the threat, we submit, is not a responsible position. It is not responsible because, as Mr. Stumpf pointed out, it poses the possibility that some people will go without plasma product. Some hemopheliacs or Rh mothers may have to suffer until FDA reacts to a shortage that could be precipitated by a patchwork of regulations.

But it also misconstrues the nature of the supremacy clause cases. As this Court observed in the Pacific Gas case, we don't have to wait until all the adverse consequences are in. We can look at the regulatory scheme here and the regulatory scheme there and make a judgment about whether there was a preemption.

Finally, we submit that after the National Blood Policy was enunciated, for FDA to take a contrary position to the uniformity which is mandated, they should have developed an administrative record with respect to the question of preemption.

The Eleventh Circuit correctly observed that the National Blood Policy is the controlling element in this case, and that the National Blood Policy required uniform regulation, required that ordinances which go beyond the federal regulation, as these do, must fall under the preemption doctrine.

Thank you, Your Honor.

CHIEF JUSTICE BURGER: Ms. Acton, do you have anything further?

ORAL ARGUMENT OF MS. EMELINE C. ACTON, ESQ.,
ON BEHALF OF THE APPELLANTS

MS. ACTON: I would just add, Mr. Chief Justice, that if there is a problem with the statement made by the FDA early on, that the implied preemption that the Court of Appeals found is likewise not applicable in this case, the mere comprehensiveness of the regulations in this field, which is quite a technical field, such as that in the case of Dablino, which dealt with welfare law, is just a part of its nature, and not something that one could infer intent to

preempt from.

If there are no further questions, thank you.

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

(Whereupon, at 1:53 o'clock p.m., the case in the above-entitled matter was concluded.)

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:

#83-1925 - HILLSBOROUGH COUNTY, FLORIDA, ET AL., Appellants V.

AUTOMATED MEDICAL LABORATORIES, INC.

and that these attached pages constitutes the original transcript of the proceedings for the records of the court.

BY Paul A. Richardson

(REPORTER)