OFFICIAL TRANSCRIPT

PROCEEDINGS BEFORE

ORIGINAL

THE SUPREME COURT

OF THE

UNITED STATES

CAPTION: MEDTRONIC, INC., Petitioner v. LORA LOHR, ET VIR; and LORA LOHR, ET VIR, Cross-Petitioners v. MEDTRONIC, INC.

CASE NO: 95-754 & 95-886

PLACE: Washington, D.C.

DATE: Tuesday, April 23, 1996

PAGES: 1-54

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IN THE SUPREME COURT OF THE UNITED STATES

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MEDTRONIC, INC., :

Petitioner :

v. : No. 95-754

LORA LOHR, ET VIR; :

and :

LORA LOHR, ET VIR, :

Cross-Petitioners :

v. : No. 95-886

MEDTRONIC, INC. :

- - - - - - - - - - - - - - - - - -X

Washington, D.C.

Tuesday, April 23, 1996

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:08 a.m.

APPEARANCES:

ARTHUR R. MILLER ESQ., Cambridge, Massachusetts; on behalf of Medtronic, Inc.

BRIAN WOLFMAN, ESQ., Washington, D.C.; on behalf of Lora Lohr, et vir.

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APPEARANCES:

EDWIN S. KNEEDLER, ESQ., Deputy Solicitor General, Department of Justice, Washington, D.C.; on behalf of the United States, as amicus curiae, in support of Lora Lohr, et vir.

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PROCEEDINGS

(10:08 a.m.)

CHIEF JUSTICE REHNQUIST: We'll hear argument now in Number 95-754, Medtronic, Inc. v. Lora Lohr and the cross-petition, Lora Lohr v. Medtronic.

Mr. Miller.

ORAL ARGUMENT OF ARTHUR R. MILLER

ON BEHALF OF MEDTRONIC, INC.

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

This case brings before you the question of defining the scope of the express preemption provision in the Medical Device Amendments of 1976.

Medical devices are a heavily regulated industry. That has been true since 1976, when the Congress enacted these Medical Device Amendments and brought them under the jurisdiction of the FDA and made it perfectly clear that it was designing a scheme by which the FDA had basic and complete jurisdiction to deal with medical devices. Indeed, the legislative history said that this preemption provision which is before you this morning acted as a general prohibition on non-Federal regulation.

The provision, which is set out on page 4 of the initial brief, is very, very broad one, almost uniquely

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broad. Reduced to what we think are its simplest terms, it basically says that any Federal requirement under the Medical Device Amendments preempts any State requirement which is different from or in addition to the Federal requirement, and which relates to the safety or effectiveness of the device or to any other matter included as a requirement applicable to the device.

QUESTION: Mr. Miller, is there evidence that you have found that Congress thought it was eliminating all State common law claims and would the action of Congress just last year in proposing, at least, caps on punitive damages but not compensatory damages relating to these devices indicate that at a least Congress thought some claims were preserved?

MR. MILLER: In all honesty, Justice O'Connor, there really is almost nothing in the legislative history.

One can divine from the scope of this provision, its words, its very words, where it uses any requirement, a word that is like all which this court has construed in Norfolk and Western as being very, very broad.

The language of this provision, coupled with the legislative purpose of establishing a unitary, uniform, national regulatory authority under the guidance of statutorily mandated expert advisory committees I think can lead only to the conclusion that the intent of

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Congress, although not expressed as such in the legislative history, is to preclude anything done by a State within the ambit of a Federal requirement --

QUESTION: But the term requirement is by no means self-explanatory. I mean, I don't think it's self-evidence that requirement means State common law provisions.

MR. MILLER: That is true, and we have, on the issue of requirement, the fact that 10 courts of appeals have looked at that word. All except the Ninth Circuit has concluded that the word requirement is broad and, for example, embraces common law claims, a major point made by the plaintiffs in this case. This Court has construed requirement in Cipollone, it has construed it in Morales, it has construed it in Easterwood. It has never been construed as a word of restriction. Also --

QUESTION: Mr. Miller --

MR. MILLER: -- the statute itself, almost as a leitmotif, continues to use the word requirement not simply in the preemption provision, it uses it in the remedies provision, it uses it in the 510(k) provision, it uses it in the manufacturing design provision --

QUESTION: Well --

QUESTION: Mr. Miller, your position, as I understand it, is that the preemption provision not only

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excludes common law actions which seek to impose liability for a mater that is not unlawful under the Federal scheme, but even precludes a State cause of action for a violation of the Federal scheme for an identical requirement.

MR. MILLER: That is our position.

QUESTION: I know it is. Why, then, would you even write this provision? If that's the case, why wouldn't you just say, there shall be no State common -- you know, lawsuits involving these issues, period?

MR. MILLER: We believe that it was necessary to write the provision in this fashion in order to establish the fact that as a precursor to the preemption you had to have a Federal requirement.

Only when you had a Federal requirement, then a State requirement that fell within the subject matter of the Federal requirement would be preempted if it added to or differed from Federal requirements. It seems to me it's a rational -- maybe not the best, but a rational way of writing it to achieve Congress' goal of establishing primary jurisdiction in the FDA.

QUESTION: What if I bring a lawsuit saying that the device, although it was marketed under, what is it, 310(k) as being substantially identical to a preexisting device was, in fact, not, and that the application claiming that substantial equivalence was intentionally

fraudulent, and therefore for violation of that 310(k) provision I want damages.

What additional requirement has that added? What different or additional requirement has the State added when it allows that suit?

MR. MILLER: Two preliminary points, Justice Scalia. Number 1, there is no such claim in this case. Number 2, several courts of appeals have struggled with questions like that and have agreed unanimously that the preemption provision embraces identical State claims or claims of noncompliance with the FDA requirements or even claims of fraud on the FDA, the most notable being a First Circuit --

QUESTION: So there's no possible action in State court against the manufacturers of these devices?

MR. MILLER: There could be actions if they do not fall within the ambit of a Federal requirement.

QUESTION: But so far as the Federal requirement, the State can't impose its own common law and it can't permit suit on the Federal requirement. That's an extraordinary sweep.

MR. MILLER: Well, Mr. Chief Justice, the reason that I think it's a perfectly appropriate conclusion is, number 1, the act itself provides for no Federal private right of action, so the notion --

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QUESTION: Do you think that helps you? I say, even worse. Not only do you not allow a State cause of action, you allow it in a situation where there's no Federal cause of action.

MR. MILLER: That does not leave the situation remediless. The bargain, or --

QUESTION: Mr. Miller, before you proceed with your answer to that, I'd like to know what is within the coverage. I understand that you're arguing about these devices that are substantially equivalent. Does your argument go as well to the grandparented devices? Are they, too, immune from tort liability if there is a Federal requirement?

MR. MILLER: Justice Ginsburg, if a matter being asserted in a State-based action falls within a Federal requirement, it seems to us the text of this statute precludes it.

QUESTION: So your answer is, this covers devices that have not been preapproved -- indeed, the grandparented devices have never been -- gone through the 510(k) procedure, never been through any procedure.

MR. MILLER: Let me clarify something. There is an image that the pre-'76 devices are unregulated. Counsel for the plaintiffs and the Solicitor General have indicated that there's never been a safety and

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effectiveness determination with regard to the 510(k) products.

Two points. If you look at the appendix we have put in the back of our reply brief, you will see that basically every medical device on the marketplace is regulated. It is simply wrong to assume that there are devices out there that are unregulated, that are -- to use the pejorative word, that have been grandfathered, or grandpersoned.

The truth is, even a pre-'76 device, Justice Ginsburg, when it comes onto the market, must comply with the good manufacturing practices. It must comply with the labeling requirements. It is subject to misbranding, adulteration, banning, notification, recall, refund, replacement.

QUESTION: But it hasn't been found safe and effective, and that's in the boilerplate language that goes out with the substantially equivalent approvals that this is not a determination by the FDA that this is safe and --

MR. MILLER: That is correct, but if you look at the language of the preemption provision, it does not say preemption for safe and effective devices, it does not say preemption for premarket approval devices, it says that if there is an applicable Federal requirement -- preemption

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turns on requirement. It does not turn on approval or --

QUESTION: Mr. Miller, can I bring you back to Justice Scalia's question for a moment that you didn't get a chance to answer?

Supposing Florida passed a statute and said it shall be unlawful to market any devices that do not comply with the Federal standard, good manufacturing practice, and so forth, and one who distributes such a device shall be liable if it harms anybody, and so there would be no difference between the State requirement and the Federal requirement. Preemption or no preemption?

MR. MILLER: Preemption, because the scheme of the statute is to allow the FDA through its expert advisory committees and all the talent it brings to bear on these devices --

QUESTION: But you can't support that from the text of the statute.

MR. MILLER: I think you can. If --

QUESTION: Because my hypothesis is there's no difference between the State requirement and the Federal requirement.

MR. MILLER: One can argue notice that there's much broader preemption if the State matter deals with safety or effectiveness. That's completely preempted, completely preempted.

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QUESTION: You're using addition to as simply meaning a State requirement. In other words, the fact that it exists, regardless of its terms, means that it is in addition to, isn't that correct?

MR. MILLER: Yes, Justice Souter.

QUESTION: Then that renders the different from totally useless verbiage.

MR. MILLER: No. The different from -- I admit there is an overlap in those two provisions, there's no doubt about it. Different from might be, instead of using insulation that's a 1/4-of-an-inch thick, you use an insulation 1/8th of-an-inch thick. Something that is addition to may be the fact -- take Justice Scalia's hypothetical -- that the State is providing a damage remedy --

QUESTION: Right, yes.

MR. MILLER: -- which is totally unavailable --

QUESTION: And I --

QUESTION: It's not a requirement, though. A damage remedy is not a requirement.

MR. MILLER: That is argued by the Solicitor General. It is a position that we think does not hold water. It is not a position the FDA has taken with any degree of consistent -- consistency. This Court has recognized on many occasions that damage remedies regulate

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and they require.

QUESTION: I'm not arguing the Cipollone point. What I'm saying is, requirement covers any substantive provision imposed by means of the common law, but how is the mere availability of a common law lawsuit a requirement, which is what you're arguing in order to exclude lawsuits entirely.

MR. MILLER: Number 1, two of the provisions of this statute refer to the remedies in this State as requirements. You'll find that at 352t and 331q(1).

If you're looking for textual consistency in this statute, this statute calls the Federal remedies requirements.

QUESTION: Where is that? Is it somewhere in the briefs, the sections you're referring to?

MR. MILLER: We make that point --

QUESTION: Not the point, I want to look at the texts. Are the texts set forth anywhere?

MR. MILLER: No, I'm sorry, they're not, Justice Scalia.

QUESTION: Mr. Miller, the FDA itself appears possibly to have tried to narrow the meaning of requirement by using the words specific requirement in its regulation, indicating that perhaps the Federal requirement the statute refers to must be device-specific

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as opposed to general requirements of the FDA dealing with manufacturing or labeling that apply across the board to all devices.

Now, how do you deal with that apparent attempt to narrow the meaning of requirement?

MR. MILLER: The first level is, there is no modifier on the word, requirement, in the statute. The statute does not say, big requirement, small requirement, specific requirement, or general requirement.

QUESTION: Is it in any way open to interpretation by the agency, do you think?

MR. MILLER: I think it is open to some degree to the agency consistent with the purpose of the statute.

The difficulty I'm having with the hypothetical that Justice Scalia is pushing, the identical, take this simple situation. Let's assume that a company like Medtronic gets a warning letter that says, you have violated the FDA. The warning letter carries no sanction -- no sanction. It's a warning letter. It says, clean up your act, manufacture this better.

The FDA has that authority, and in many instances that's what it will do, because even though there's a defect, the product is basically sound. The public needs that product. Availability and innovation, two basic objectives of the statute.

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Now, along comes the District of Columbia. It's got a financial crisis. Its city council decides to enact a statute. It says, anyone who has been found in violation of the FDA is to pay a fine to the city of $1 million.

Now, surely -- surely this Court in many of its opinions has said the preemption is logical when it interferes with the Federal regime. This Federal regime was designed to let the FDA determine what the qualifications of a product should be, when those qualifications are up to snuff, not up to snuff, 518 of the statute lays out a series of remedies, and to permit any State or municipality to come along and impose in the name of identity an additional sanction seems to me completely destructive.

QUESTION: It begs the question, though. I mean, because that's exactly the question, whether an additional sanction is an additional requirement. That's exactly the point we're arguing, and simply to say it violates the scheme is to beg the question.

QUESTION: And I take it from your answer, Mr. Miller, that you're saying that there is a universe of preemption that is broader than the language itself.

MR. MILLER: Oh, there would be a universe of preemption broader than this. This is a broad preemption,

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but I do not think it is the broadest conceivable.

QUESTION: So we're not --

QUESTION: Well, Justice Scalia --

QUESTION: So we're not confined to the language of the statute in determining the scope of preemption?

MR. MILLER: I think you have to interpret these words in light of what Congress was trying to achieve in 1976.

QUESTION: Was it in 1976, on the effective date of the act, that all State suits were prohibited as to the pacemaker? What was the chronological point at which the State's actions in this case were preempted?

MR. MILLER: Presumably they applied only prospectively, not to devices implanted prior to 1976. For example, that is why much of the Dalkon Shield litigation never came under this statute at all. It preceded the effective date of this statute.

But I think Congress did make it clear that the effect of this provision was to be immediate, with the FDA filling in the gaps of regulation, and that's what that Appendix A is all about.

QUESTION: But before those gaps were filled in, there was still preemption. As of the effective date of this act, a pacemaker suit could not be maintained?

MR. MILLER: Presumably, it would only apply to

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a device that fell within a requirement. For example, if you had a device that had been subjected to the good manufacturing practices provisions, to the labeling provisions --

QUESTION: Well, those weren't even promulgated as of the time of the act. I need to know the chronological date at which you think these claims were preempted.

MR. MILLER: I think the design claim would have been preempted immediately, because design we believe is embedded in substantial equivalents. I know it's not a safety and effectiveness determination, but what is the requirement of substantial equivalents? The requirement is that you must manufacture your device, your design of device, your technological characteristics of your device, must be equivalent to that pre-'76 device. That is a requirement.

QUESTION: But with --

MR. MILLER: 510(k) is characterized as a requirement elsewhere in the statute.

QUESTION: Going to manufacturing for a second, I take it at that same moment that you refer to, there were no manufacturing standards at all with respect to devices. They came later, I assume.

MR. MILLER: They came later, and --

QUESTION: Now, do you say -- you said there would have to be a requirement for preemption, so would there be preemption with respect to a faulty negligent manufacturing claim at that point?

MR. MILLER: Analytically, Justice Souter, if there was no Federal requirement as of the relevant moment in time, there was no preemption.

QUESTION: What about the addition-to argument, because there -- the State cause of action would still be in addition to anything which existed under the Federal act on your analysis.

MR. MILLER: That would be the widest possible preemption.

QUESTION: Well, wasn't that the preemption that you were arguing for earlier?

MR. MILLER: No, we are arguing that there should be, as a limitation on the ambit of preemption, some subject matter congruence. If you have a design requirement, it preempts State design claims. If you have a labeling requirement, it will preclude State labeling.

QUESTION: But most of those requirements were not in force on the effective date of the act. They were subject to the regulatory process.

MR. MILLER: To the development of regulations, that is right, Justice --

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QUESTION: So it's not clear when there was preemption in this case.

MR. MILLER: Oh, in this case, those requirements were in place. Those requirements were in place as --

QUESTION: On the effective date of the act?

MR. MILLER: On the effective date of pre- -- of the substantial equivalent approval for market.

QUESTION: But Mr. Miller --

QUESTION: The States --

MR. MILLER: That came in '83, not '76.

QUESTION: The States can impose shipping requirements, according to what you've just told us now. If there are no Federal requirements governing manner of shipping, the States can impose those.

I really thought that was not your view. I thought your view was that any requirement, even in a different category, is an additional requirement, and therefore no good.

MR. MILLER: This act could be read that way. It could be read to say, any time there is any Federal requirement --

QUESTION: Right.

MR. MILLER: -- any State requirement is precluded.

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QUESTION: Right. I thought you were reading it that way.

MR. MILLER: No, we are reading it to have some subject matter congruence.

QUESTION: Okay.

MR. MILLER: Because --

QUESTION: They could impose a shipping --

QUESTION: A shipping --

MR. MILLER: That is the intention of subdivision 2.

QUESTION: And Mr. Miller, the agency has said it has to be device-specific. I don't think you've addressed that yet.

MR. MILLER: The agency has said it's device-specific. We think that is an absolutely untenable reading of this provision. It is untenable because there is no such limitation on the word requirement. We have noted that the Solicitor General has conceded that the manufacturing practices --

QUESTION: Why isn't there in subparagraph -- Mr. Miller, why isn't subparagraph 1 -- it says, any requirement applicable under this chapter to the device.

MR. MILLER: It does not say device-specific.

QUESTION: It says, applicable to the device.

MR. MILLER: Yes, applicable to the device.

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QUESTION: That doesn't mean applicable to some other device --

MR. MILLER: It -- yes, but --

QUESTION: Why isn't that language --

MR. MILLER: -- manufacturing is applicable to the device. It doesn't have to be device-specific to be applicable.

QUESTION: No, but you can read it either way. You can say, the device means the specific device, or you can say, it is nondevice-specific but it applies to this one. It can be read either way, and since it can be read either way, why isn't the agency regulation an appropriate choice?

MR. MILLER: Simply because it is impracticable to wait until you have a device-by-device requirement. That will never happen.

QUESTION: Okay, but I take it --

MR. MILLER: It has not happened.

QUESTION: -- you are assuming in your answer that it is consistent with the text, that the agency regulation could, consistently with the text, be as it was promulgated.

MR. MILLER: The difficulty with the position, I believe, is, if you treat that word requirement the same across the spine of the statute, you see that the word

requirement is not used in a device-specific manner. The best illustration of that relates to the section that gives authority to create good manufacturing practices regulation.

It's perfectly clear that the word requirement as used in that connection is not device-specific. The Solicitor General has acceded to the view that the good manufacturing practices regulations are requirements.

QUESTION: All right. Let me assume --

MR. MILLER: They are not device-specific.

QUESTION: Let me assume that that is correct. It is still, I take it, consistent with the text of the preemption provision, is it not? And if it is consistent with that text, then the most your argument shows, it seems to me, is that there is ambiguity in the use of the word requirement, and that would seem to me to open the door to exactly the regulation that the agency has promulgated.

MR. MILLER: We do not believe it is consistent with that statute when viewed in the light of the objectives of Congress in enacting this provision.

QUESTION: Why can't you read the statute as simply giving to the agency the power to say, within every broad reason, which requirements do what in respect to preemption? That would make the statute work, and we know

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at least here one thing is true. The agency has said -- I think it's ambiguous. What they said is, it doesn't preempt anything unless there's a specific requirement.

I don't know if that has to be -- I mean, something specific, which I don't see here anything specific, so I mean, why wouldn't that make sense in the statute? We are going to preempt things. Which things? Well, the agency has the power to tell us which. That would seem a sensible thing to do, wouldn't it, and isn't that consistent with the language, normal practice? We give lots of powers to agencies.

MR. MILLER: I believe it was in footnote 4 of your Chevron decision that it was pointed out that this Court is the ultimate arbiter of statutory construction, and that an administrative interpretation that did not do justice to the legislative purpose was not entitled to deference.

QUESTION: Well, wouldn't it be a sensible legislative purpose -- I mean, you've given, I've written down six different -- within the ambit of, subject of, subject matter congruence, which are perfectly sensible, but you've created them.

Rather than taking what you created, why not take what the agency's created?

MR. MILLER: Except that the agency has

consistently taken the position, for whatever reason, that the scope of preemption under this provision should be basically nonexistent, a device-specific requirement, eviscerates preemption that clearly was not the intention of Congress in enacting a preemption provision which is very, very, very broad.

QUESTION: Mr. Miller, do you know of any case in which we've given Chevron deference to an agency determination regarding preemption? I thought we gave deference to those determinations that the agency has to make in the course of the agency's implementation of a statute.

Preemption has nothing to do with the agency's implementation of a statute. We have not given Chevron deference to an agency's determination that there is or is not judicial review of a particular provision under a statute. Why should --

MR. MILLER: That is obviously an argument I find great sympathy with.

QUESTION: I thought you might.

QUESTION: You wouldn't give deference to the agency's interpretation of the word "requirement" in the statute, which happens here to fall within a preemption section?

MR. MILLER: Not -- not --

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QUESTION: Is there something different about that word, depending on what --

MR. MILLER: Not when the agency's interpretation would completely eviscerate the provision, and I think that is why the Solicitor General's -- has backed away from --

QUESTION: All they've said here is that the kinds of requirements that bring into play the preemption are specific requirements. I mean, that -- if you just pass a general thing -- hey, manufacturers, do your best. Suppose they wrote that. I mean, do you think then, therefore, no State, no tort actions -- all they said was, do your best. You're saying, that's not the kind of requirement. 14-inch-thick plastic is. All right.

MR. MILLER: That is not what either the labeling or the good manufacturing practice is, or this matrix we have put together suggests in terms of the plethora of requirements that have, in fact, been imposed on every device manufacturer pre-, post-, 510(k), PMA --

QUESTION: Mr. Miller, this act uses the word requirements dozens of times. Is it your argument that every time that word is used in this statute it means the same thing?

MR. MILLER: It is our argument that when the use of the requirements work, as in 510(k), as in

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remedies, as in good manufacturing practices, make sense in terms of this preemption provision, it should be given a consistent reading: What is the best evidence of what Congress was trying to do? Then this provision, and the use of the operative word, requirement, in the critical portions of the statute.

QUESTION: Isn't it odd, don't you think, that with an agency that is charged with regulating food, drugs, medical devices, that Congress would create this regime that ousts State tort remedies for medical devices but not for drugs, not for food, not for cosmetics? Why would Congress do that?

MR. MILLER: That, of course, is a decision for Congress to make, and it did make it. It is quite conceivable that the sociology of the device industry and the critical character of the device industry as perceived in the seventies, the need for innovation, the need for availability, motivated that Congress to do this.

Keep in mind, device technology in 1957, Mrs. Lohr would be dead. In 1977, her pacing would simply be metronome pacing. In --

QUESTION: I think you've answered the question, Mr. Miller.

MR. MILLER: Thank you, Mr. Chief Justice.

QUESTION: Your time has expired.

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Mr. Wolfman, we'll hear from you.

ORAL ARGUMENT OF BRIAN WOLFMAN

ON BEHALF OF LORA LOHR, ET VIR.

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

Listening to the argument, and reading Medtronic's briefs, the most remarkable feature of Medtronic's arguments is what the company does not say.

If the company is correct, every case claiming personal injuries caused by a medical device, whether based on defective manufacture, grossly negligent manufacturing practices, or a knowing failure to disclose defects in the product, all were swept away on the day that the law was enacted in 1976.

To appreciate why the company is wrong, I want to step back for a minute and explain the section 510(k) process, the substantial equivalent process, which is the key element of Medtronic's preemption defense, and then move on to some of the other FDA rules which the company claims totally immunize it from tort liability.

The 4011 pacemaker lead implanted in Lora Lohr was marketed solely on the basis of Medtronic's 1982 claim of substantial equivalence to a device marketed prior to the enactment of the MDA, a device which the FDA never reviewed at all for safety and effectiveness.

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The 510(k) process does not establish an device design requirements that could possibly preempt Ms. Lohr's design-defect claim. Indeed, the FDA itself has repeatedly ruled to require that States are free to require full premarket approval for Class III, like pacemaker leads, Class III 510(k) devices --

QUESTION: Full premarket approval from the FDA?

MR. WOLFMAN: The States would be free, in that circumstance, because the device was only subject to the 510(k) process, that until such time the DA had required the PMA, that the States would be free to require their own PMA's for that device, and there is a reason for that.

QUESTION: You say the FDA has ruled that. You think the FDA has authority to rule as to when the States are preempted or not?

MR. WOLFMAN: Well, Justice Scalia, that goes --

QUESTION: I mean, they are by the statute or they aren't, unless the statute says they'll be preempted when the FDA says so.

MR. WOLFMAN: Well --

QUESTION: I find it extraordinary to give deference to the agency on an issue like this.

MR. WOLFMAN: Well, the Court has done it on two occasions that we find.

QUESTION: We have?

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MR. WOLFMAN: Yes. In the Hillsborough County case, which is cited at different points in our brief, Hillsborough County gave Chevron-style deference to one, just one sentence in regulatory commentary concerning the issue in that case which was whether States could regulate in the area of plasmapheresis even though the FDA had already done so, and the Court deferred.

Here, there is even more reason for deference, Your Honor, because under 360k(B), the exemption from preemption provision, it really is necessary for the FDA to say both what the scope of preemption is and whether there -- an exemption ought to be granted.

QUESTION: What's the other case? You said there were two.

MR. WOLFMAN: There's the Lee --

QUESTION: One is Hillsborough County.

MR. WOLFMAN: Excuse me. The Lee Deadwood case, and I can get you that cite. That would be at 469 U.S. 256 at page 261 and 262, and as I say, there as well they gave deference to the agency's interpretation of the preemption provision, and for the reasons I stated, Justice Scalia, there's more reason to do it here because more instrumentation is necessary.

Getting back to the 510(k) process, as I say, the States have ruled that that could be done, and there

is a reason for that, Mr. Chief Justice.

QUESTION: You mean the FDA has ruled, not the States have ruled.

MR. WOLFMAN: Yes, that's right, the FDA has ruled, and there is a reason for that, Mr. Chief Justice, which is this, that for Class III devices the relevant requirement as to safety and effectiveness is clearly the premarket approval. The statute defines Class III devices as devices that ought to go through premarket approval. The fact is, that has not happened yet for pacemaker leads because the implementation of the statute has been delayed.

Now, there is --

QUESTION: Mr. Wolfman, once there has been -- once, one fine day when the FDA does have a premarket approval setup of its own, and a device does get that premarket approval, would there will be State tort remedies?

MR. WOLFMAN: Well, I think there would be State tort remedies. It's clearly a closer question, but there are still going to tort remedies for two reasons. One, as we address in our brief extensively, we do not believe this Congress in 1976 was referring to State damages actions when it was using term requirement, for the many reasons stated in our brief.

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Secondly, even with respect to a PMA, there is no device design requirement. It is true that the agency allows the device to be marketed under the standards for premarket approval, but it never says to the manufacturer that your device has to be designed in a specific manner, and that's really the point here. A jury's finding --

QUESTION: I'm not sure of that. Doesn't it have to be designed substantially, to be substantially equivalent to what was on the market before, and --

MR. WOLFMAN: Well, now we're moving back to the 510(k) process.

QUESTION: Yes.

QUESTION: Yes.

MR. WOLFMAN: That is --

QUESTION: Oh, I'm sorry, you're --

QUESTION: I was talking about when the FDA reaches the -- it gets free market approval.

MR. WOLFMAN: To answer your question, Justice Ginsburg, we think it a closer question. Once we get by the question whether damages actions are covered by the statute, we think it a closer question as to whether the FDA's permission to market the device under the PMA processes would preempt, but still there, there was no device design requirement specifically.

But here, and I think this is responsive to

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Justice Scalia's question, here all there was is a finding of equivalence, and the clear purpose of that in the statute was to ensure that the grandparented devices, the pre-1976 devices, the manufacturers of those devices did not obtain a competitive advantage over the subsequent --

QUESTION: Mr. Wolfman, you're going so rapidly, you're losing me a little bit, and I think you may be losing some of my colleagues.

MR. WOLFMAN: I'd be glad to slow down. Thank you, Your Honor.

The purpose of it was not to gain a competitive advantage over the manufacturers of devices who came later, and that was the sole purpose of it.

To be sure, it is true, as your question indicates, that there has been delays in the implementation of these processes, but that doesn't suggest that there was a design requirement on 510(k) devices.

There is one other regulation that the -- Medtronic relies upon to say that there's some device requirement here with respect to this substantial equivalent device, and that is a regulation at 807.81, which instructs manufacturers to submit new 510(k) applications for new devices when it decides to alter a preexisting device.

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But that doesn't preempt the Lohrs' device design claim either, because that regulation doesn't require to use the terms of the statute, doesn't require Medtronic to do anything here, let alone anything bearing on the Lohrs' claims. The Lohrs' --

QUESTION: I'm not sure I follow you there. Why doesn't that indicate that the statute requires the device being currently manufactured and marketed be like the one that was previously manufactured --

MR. WOLFMAN: Well --

QUESTION: -- and why isn't that a requirement?

MR. WOLFMAN: Your Honor, I want to be clear on this. That is a requirement in the literal sense of thee word and in the terms of the statute, but it's not a requirement that has any bearing on device design, and as Medtronic has conceded --

QUESTION: Well, it has to be of the same design as the previous device.

MR. WOLFMAN: It does --

QUESTION: So why doesn't that relate to device design? I don't quite --

MR. WOLFMAN: It only relates to its substantial equivalence. It doesn't have to do with what the Lohrs would be claiming in the suit, which is that the design is faulty. It was only to show that the device was

equivalent --

QUESTION: But isn't there a claim --

MR. WOLFMAN: -- to what was on the market --

QUESTION: Isn't there a claim that the device should have been designed differently?

MR. WOLFMAN: That is correct.

QUESTION: And therefore, wouldn't it be in -- would it not violate the requirement that it be the same?

MR. WOLFMAN: Well, but again, the requirement, here, is simply that it be the same not for any reason --

QUESTION: Right.

MR. WOLFMAN: Not for any purpose of its design, and as Medtronic has conceded, there needs to be some subject-matter congruence. Even if they -- Medtronic doesn't go as far as the FDA regulation, which we claim is entitled to deference, the device specificity regulation, even if they don't go that far, there needs to be some subject matter congruence.

The subject matter of the 510(k) process was only to show equivalence, that it be the same device.

QUESTION: Right, to show that it was the same, and she says it ought to be difference. I don't quite -- really, I'm not quite catching your argument.

MR. WOLFMAN: But her claim is as to the design. The purpose of the substantial equivalence process was not

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to clear anything about the design.

The premise of Medtronic's argument, starting from its question presented in its opening brief, is that this design was authorized by the agency. That is simply not correct. All the agency found was that there were devices that were on the market in 1976 that are similar to the device that was marketed.

QUESTION: But the statute doesn't talk in terms of three universes of design, manufacture, labor -- and it may talk about labor, but so far as design and manufacture, the statute does not make those distinctions. The statute allows a certain device to be marketed, period.

MR. WOLFMAN: That is --

QUESTION: Or doesn't.

MR. WOLFMAN: That is precisely right, and that's our point, although many things under the act -- for instance, the requirement that manufacturers register with the agency, they're all requirements, but to make any sense out of the statute you have to at the very least concede some subject matter congruence between the State law requirement and the Federal law requirement, and what we're saying is that to be sure, on the State law side Mrs. Lohr's claims would concern the safety of the design of that device, but it does not do so on the Federal law

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side.

Let me turn for a moment to the manufacturing defect. The FDA -- the MDA imposes no requirements regarding the manufacture of pacemaker leads, nor is the Lohrs' claim, even if you assume that it doesn't have to apply manufacturing requirements to pacemaker leads, nor is the Lohrs' manufacturing-defect claim different from or in addition to the FDA's good manufacturing practices or GMP regulations, which is the basis for their claim of preemption with respect to manufacture.

Let me use a few examples to show that. Assume that the plaintiff claimed under State law that a device failed because it was constructed by untrained personnel. The most relevant GMP simply states, and it is at 820.25(a), and it states, and I quote, all personnel shall have the necessary training to perform their assigned responsibilities adequately.

Now, getting back to some of the questions posed by Justice Scalia, it's very clear that her claim would not be different from or in addition to that. It would be simply a claim that the training in that case was not adequate.

It's -- in other words, the GMP's just set out very basic guidelines for the proper manufacture of any consumer product, certainly not the level of specificity

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necessary to preempt, and that's really the problem with all the arguments the company's making. They're at a level of generality that is so high that it essentially wipes out not all State tort law but all State law.

QUESTION: But from what you say, if the FDA chose to be much more specific simply by issuing different and more specific regulations, it could then wipe out State tort law.

MR. WOLFMAN: Well, again, we say that requirement doesn't encompass State damages actions, but that is correct, Your Honor, and let me use an example.

For instance, in the area of tampon labeling, the agency has acted specifically. It says the tampon box must contain this warning. To be sure, if the State said, we not only want this tampon label but we want three more paragraphs, that would be in addition to that.

But to appreciate the breadth of Medtronic's argument, Medtronic would claim that no State could enforce and no plaintiff could sue for injuries based on a tampon injury even if the claim was that the Federal warning had just been omitted.

QUESTION: I don't know, Mr. Wolfman -- I don't know if you know this, know the answer to this, but I wasn't certain when I read the FDA regs where they say the FDA has to have established specific requirements

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applicable to a particular device, suppose what they had in their building section was, every building used to manufacture an implant must have a smoke detector every 3 feet in the ceiling. That's highly specific, but it applies to all devices. I would have thought that was specific within the meaning of the reg, but I've heard it argued no, no, you have to have a special section called, buildings used to make tampons, building used to make hearing aids --

(Laughter.)

QUESTION: -- buildings used -- that would seem to be a ridiculous interpretation of this, but have you any light to shed on that?

MR. WOLFMAN: Yes, I do, and I think that is the -- what you posit I think is a correct interpretation of the statute. By and large, when the agency --

QUESTION: The regs. The regs.

MR. WOLFMAN: Yes. Your interpretation saying that that might be ridiculous if they had focused very specifically on the need for smoke detectors at particular intervals, that might be sufficiently specific even though it applied to devices generally.

QUESTION: So --

MR. WOLFMAN: However, what the agency has done as a general matter is focus specifically with respect to

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devices as in tampons and then otherwise just step back and generally regulate it.

QUESTION: Mr. Wolfman, I -- what I don't understand is, if you say that requirement means specific requirement at one point in the preemption provision, why doesn't it mean specific requirement throughout the preemption provision, never mind elsewhere in the act?

The preemption provision reads, except as provided in subsection (b), it may establish or continue in effect with respect to a device intended for human use any requirement -- okay, no State can impose any requirement. Does that means specific requirement?

MR. WOLFMAN: I'm -- yes.

QUESTION: General requirements are not eliminated, only specific requirements.

MR. WOLFMAN: Yes, and in this case --

QUESTION: And then further down, which is different from or in addition to any requirement applicable under this chapter. That also means specific requirement. If it's different from a general requirement under this chapter, it's okay.

MR. WOLFMAN: Well --

QUESTION: You can have a State -- a State provision so long as its specific, which contradicts a general Federal requirement, or imposes --

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MR. WOLFMAN: That's right, and it makes sense. Let me use an example, if I might.

QUESTION: So, requirement you're willing to accept as meaning specific requirement wherever it is used in that preemption provision.

MR. WOLFMAN: Well, that's right, but let me use an example of how that played out in the regulatory process.

For instance, there are labeling requirements that simply say, the applicable ones here say that the device ought to have a label, should have a label that lists all warnings, contraindications, and such forth, very broad. Now --

QUESTION: What requirement is that? That's the Federal requirement.

MR. WOLFMAN: That's the Federal requirement.

QUESTION: Does it require -- does it apply only to tampons, or does it apply to a lot of other devices?

MR. WOLFMAN: It applies to that particular one. 801.109(c) applies to all prescription devices.

QUESTION: Well then, it's not covered by this anyway so we don't have to talk about it, because you said that any requirement which is different from a requirement applicable under this chapter.

MR. WOLFMAN: Well, the --

QUESTION: That requirement is not a specific requirement --

MR. WOLFMAN: But let me --

QUESTION: -- so it doesn't even come within in it.

MR. WOLFMAN: Let me explain further. That is correct, but let me explain how that is worked out.

QUESTION: You really think it's correct?

MR. WOLFMAN: Well --

QUESTION: I can't imagine that you want to read it that way.

MR. WOLFMAN: Let me explain how it is worked out in terms of its application. That pre- -- that -- those regulations essentially preexisted the MDA, because they applied both to drugs and devices.

Then the FDA later ruled a couple of years after the MDA was enacted that on the date the FDA issued regulations specifically with respect to the labeling of hearing aids, then and only then state law with respect to hearing aid labeling that was different from or in addition to Federal hearing aid requirements would be preempted.

Let me say this, that if, indeed, both sides of the equation are acting at the general level, which is what your question is getting at, whether there might be

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preemption doesn't need to be answered here, but at the very least they need to be acting at the same level.

QUESTION: Why do they have to? Why can't Congress say to the agency, agency, we passed a general statute that makes sense for you to administer, and we delegate to you the authority to interpret these words in a reasonable way, and if you have to interpret them differently when they apply to the State than the Federal Government, so be it.

MR. WOLFMAN: Well, let me tell you --

QUESTION: It's common, isn't it, in State --

MR. WOLFMAN: That is correct, Justice Breyer, and I suppose I should amend my answer. If, in fact, the FDA had issued preemption regulations which had that interpretation this would be a different case, and I'm not suggesting that that might not be entitled to deference under Chevron.

What I am suggesting is, certainly the FDA's determination at the very least that the State and Federal sides of the equation ought to be acting on the same level of generality is certainly permissible construction of this statute, and it makes sense in light of why you want preemption.

I mean, right now the labeling regulation simply says you should have the adequate warnings and

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contraindications. That says very little about whether it's important to regulate specifically warning labels on hearing aids because of particular problems with respect to hearing aids.

QUESTION: I don't want to waste your time, but just for the record, unless you have a third case, Hillsborough County, which you cited as an example where we've deferred to the agency's interpretation of whether a statute preempts the State, Hillsborough County related to an agency regulation as to whether the agency regulation was intended to preempt, assuming the agency had preemption power, and Lawrence County, the other case you gave me, is not a preemption case. It's an agency saying what funds distributed by the agency can be used for. It's really not preemption.

Do you know of another --

MR. WOLFMAN: Those are the cases --

QUESTION: -- because I really don't know of a case in which we've deferred to the agency as to preemption of State law.

MR. WOLFMAN: Well, I don't have -- those are the two cases I have. I think Hillsborough County is very strong in our favor. It basically says --

QUESTION: An agency reg, the issue was whether the agency reg was intended by the agency to preempt, as

it could be.

MR. WOLFMAN: Those are the cases I have, Your Honor.

QUESTION: Okay.

MR. WOLFMAN: In sum, as we've gone through the three claims at issue here, there simply is no tension between the lower State law claims and any Federal requirements applicable to the model 4011 lead.

No preemption here is not only demanded by the text of 360k(a), but it's consistent with the act's purposes. On the heels of a series of public health tragedies, and against a backdrop in which tort claims such as the Lohrs' were commonplace, the MDA was enacted to provide protections that only a few States had provided previously.

To abrogate State law in areas where there are no specific applicable Federal requirements, as Medtronic seeks here, does, as the FDA has said, to make consumers worse off than if the MDA had never been enacted in the first place. Section 360k(a) does not permit that result.

We ask the Court to reverse in part, to affirm in part, and to hold that none of the Lohrs' claims are preempted.

QUESTION: Thank you, Mr. Wolfman.

Mr. Kneedler, we'll hear from you.

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ORAL ARGUMENT OF EDWIN S. KNEEDLER

ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,

IN SUPPORT OF LORA LOHR, ET VIR.

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

The United States agrees with the Respondents Lohr that summary judgment should not have been granted for Medtronic, but our position differs somewhat from both petitioner and respondents in this case.

First, we do not agree with respondents' broad submission that the act's preemption provision does not speak at all to common law tort claims. In our view, the word requirement in section 521(a) of the act encompasses duties imposed by State common law, as well as duties imposed by State statutory or regulatory law.

Conversely --

QUESTION: Is your argument there that, assuming a consistent usage within the section, the Federal requirement is described as being a requirement imposed under this chapter?

MR. KNEEDLER: Right, applicable under the act, and the Federal act does not impose -- this point does not derive from the word requirement the fact that the Federal act only addresses statutory regulatory requirements. The Federal act only gives the FDA that authority. But

that -- so it's the applicable under this chapter rather than the word requirement that gives rise to --

QUESTION: But there's also the reference in there, in referring to the requirement at the State level as being imposed by a State or political subdivision, and particularly the reference to political subdivision doesn't sound like something that would cover a common law rule, even a recovery rule, does it?

MR. KNEEDLER: Well, perhaps not, but it's State or political subdivision in common law.

QUESTION: That's true. That's true.

MR. KNEEDLER: And common law derived from State courts, the State supreme court or whatever --

QUESTION: But that would at least leave a question, and since preemption gives the presumption against preemption, I would suppose anything that was no clearer than that would not have a preemptive effect.

MR. KNEEDLER: Well --

QUESTION: So we would construe it in a way that would not result in preemption, isn't that fair?

MR. KNEEDLER: That may be one possible construction, but we believe, particularly read against Cipollone and the use of the requirement there, and just the nature of State law, State law we believe would also encompass duties imposed by the --

QUESTION: Why would that be a permissible construction? I mean, you would need -- your argument is not that it only includes the common law, is it?

MR. KNEEDLER: Right.

QUESTION: Your argument is that it includes both the common law --

MR. KNEEDLER: Right.

QUESTION: -- and statutory law.

MR. KNEEDLER: Right, law from whatever source.

QUESTION: And to cover the statutory thing you would have to include or any subdivision.

MR. KNEEDLER: Political subdivision, that's correct.

Conversely, we do not agree with Medtronic's broad submissions that the mere fact that its pacemaker lead received 510 -- went through the 510(k) process and was found to be substantially equivalent altogether preempts respondents' State law claims.

The Federal act preempts a State requirement only if it's different from or in addition to a Federal requirement applicable under the act. The basic requirement for Class III, indeed, its defining characteristic under the act's definition, is that it goes through the extensive premarket approval process with one exception.

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In this case, the finding of substantial equivalence as part of the 510(k) process served to exempt the Medtronic lead in this case from the PMA requirement. In other words, the only purpose of the substantial equivalence determination in this case was to render inapplicable to the device under the Food & Drug Act the premarket approval characteristic.

The substantial equivalence determination is not itself a requirement under the act for purposes of preemption. It is rather -- it has the opposite effect. A finding of substantial equivalence to a preamendments device has the effect of taking a Class III device outside of the PMA process and putting it in the same category as a preamendments device.

QUESTION: Temporarily, if this statute works eventually the way Congress intended.

MR. KNEEDLER: Right, until a premarket approval application is called for under the regulations.

But what Congress did with respect to devices that were on the market before 1976 and those that came along after but were essentially like those was not to require a premarket application even if they're in Class III until the FDA called for such an application, and the FDA has not done so, so I think it's beyond question that devices marketed before 1976 were, and continue to be, the

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subject of State law tort suits for defective design.

We think it follows under the scheme of the act that devices found substantially equivalent and therefore removed from the premarket approval process fall into the same category and can also be subject, properly subject to State law defective design --

QUESTION: To establish that, it seems to me you have to say that there's no requirement as to the design of those products.

MR. KNEEDLER: That's correct, and we believe that's true.

QUESTION: But there is one, isn't there?

MR. KNEEDLER: No, and if I may, there are several points there. The design does not come from the act. It is not a requirement imposed by the FDA. It's not a requirement under this chapter. The design originates with Medtronics, and the FDA doesn't approve it. It's --

QUESTION: The obligation to follow that design originates from the statute. Yes, the design originally was made by somebody else, it wasn't designed by the Government, but the Government says you have to follow the design that was used pre-'76.

MR. KNEEDLER: But Justice Scalia, the same is also true for a pre-'76 device. A pre-'76 device could

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not be design -- could not be altered in its design in a major way without also going through the 510(k) process, and yet again, it's clear that despite that fact, that limitation on changing the design, that a preamendments device can be subject to a State law tort suit, so the requirement --

QUESTION: Why is that clear? How do we know that?

MR. KNEEDLER: There's nothing -- there's no requirement at all with respect to design imposed on the -- on a preamendments device.

QUESTION: Yes, there is. It has -- it cannot change its design. If it changed its design, it would be in violation of Federal law, would it not, without approval?

MR. KNEEDLER: Well, yes. If I could get to the second point, then -- the first point is that it's not -- the design is not a requirement that stems from the FDA, it stems from the manufacturer, but the second point is, the requirement that you're referring to, if it is a requirement, is only a requirement with respect to substantial equivalence, it is not a requirement with respect to actual safety and effectiveness. That --

QUESTION: Why doesn't it work to say that the requirement that's Federal which arguably displaces the

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State doesn't do it at all unless it's a relevant requirement? A requirement about doors doesn't displace requirements about hearing aids, does it?

MR. KNEEDLER: No.

QUESTION: It has to be relevant.

MR. KNEEDLER: Just so, or --

QUESTION: All right. If it has to be relevant, how do we decide the meaning of that word, relevant?

MR. KNEEDLER: Well, I --

QUESTION: Do we then turn to see what this agency says? That's what I --

MR. KNEEDLER: We believe you -- one does, and the -- and I think that is the message of the agency's use of the word specific requirement. What the agency means then is, by use of the word specific is that there has to be a subject matter congruence as it's been referred to here.

QUESTION: You say relevant means, it has to be relevant to safety?

MR. KNEEDLER: No, it has to be -- the relevance -- there has to be subject matter congruence between the State requirement and the Federal requirements. The only --

QUESTION: What they say is, the relevant requirements, those requirements that are relevant in

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relation to a particular claim, State reg or rule, is a reg that is specific.

MR. KNEEDLER: Right, exactly.

QUESTION: Specific in other specific requirements applicable to a particular device.

MR. KNEEDLER: Right, and --

QUESTION: So it must be a specific --

QUESTION: Well, but you don't mean to suggest, do you, that a manufacturing requirement that is very clear and it applies across the board to all medical device manufacturing is not specific?

MR. KNEEDLER: No. No, that is covered. That is a specific regulation applicable to the device. The point is, the specificity comes with whether a particular requirement is applicable to the device, and what's essential to defer to FDA on something like this is, is there a requirement applicable to that device?

If in the good manufacturing practices the FDA had regulated only, let's say, hours of service of quality assurance persons, that wouldn't preempt all manufacturing claims against the agency. One has to look at exactly what the agency has required, whether it has required anything, and whether the Federal -- the State requirements ought to be imposed in the tort action --

QUESTION: Well, but that --

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MR. KNEEDLER: -- covers the same subject matter.

QUESTION: It seems to me that sweeps way too broadly. Suppose the labeling requirement says for thousands of devices, do not use without consulting a physician. That's all it requires. Can there be a failure-to-warn suit?

MR. KNEEDLER: The Federal requirement?

QUESTION: Yes.

MR. KNEEDLER: Yes. Well --

QUESTION: Can there be a failure-to-warn suit in a State court?

MR. KNEEDLER: I think it would --

QUESTION: That's a specific requirement.

MR. KNEEDLER: I think, again, it would depend on whether the agency had intended to -- whether that intended to exhaust the agency's requirement with respect to labeling. It's possible, for example, that the agency could focus on a particular problem in labeling and address that with a particular warning, but not intend to occupy the entire field of labeling in that circumstance. In other words, not to impose anything bedsides the more general, for example, requirements for prescription --

QUESTION: Well, Mr. Kneedler, there are claims here relating to negligent manufacturing and to failure to

warn, and there are FDA requirements in both these areas, so what's left of those claims?

MR. KNEEDLER: Well, as to the -- we agree that those are requirements within the meaning of the preemption provision, but they're not -- but the State law claim is not preempted unless its shown by the defendant claiming preemption to be different from or in addition to the State law claims, and at this summary judgment stage of the case, we don't believe that this Court can confidently conclude that whatever law the case would be presented to the jury on would be different from or in addition to the general State requirements. That would require further proceedings and looking at jury instructions down the road.

CHIEF JUSTICE REHNQUIST: Thank you, Mr. Kneedler. The case is submitted.

(Whereupon, at 11:08 a.m., the case in the above-entitled matter was submitted.)

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CASE NO: 95-754 & 95-886

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

BY Ann Marie Federico

(REPORTER)