IN THE SUPREME COURT OF THE UNITED STATES

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DONNA S. RIEGEL, INDIVIDUALLY :

AND AS ADMINISTRATOR OF THE :

ESTATE OF CHARLES R. RIEGEL, :

Petitioner :

v. : No. 06-179

MEDTRONIC, INC. :

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Washington, D.C.

Tuesday, December 4, 2007

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:11 a.m.

APPEARANCES:

ALLISON M. ZIEVE, ESQ., Washington, D.C.; on behalf of the Petitioner.

THEODORE B. OLSON, ESQ., Washington, D.C.; on behalf of the Respondent.

EDWIN S. KNEEDLER, ESQ., Deputy Solicitor General, Department of Justice, Washington, D.C.; on behalf of the United States, as amicus curiae, supporting the Respondent.

C O N T E N T S

P R O C E E D I N G S

(10:11 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in case 06-179, Riegel v. Medtronic, Incorporated.

Ms. Zieve.

ORAL ARGUMENT OF ALLISON M. ZIEVE

ON BEHALF OF THE PETITIONER

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

The question in this case is whether section 360k(a) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act preempt State-law claims seeking damages for injuries caused by a device that received pre-market approval. Medtronic's view of the pre-market approval process is that it results in an FDA decision that a particular device must be designed, labeled, and manufactured in a particular way. This view is incorrect, and so I want to talk -- begin by talking about what pre-market approval is and what it isn't. PMA is the FDA's permission to market a Class III device. The manufacturer PMA device develops the design and chooses the -- choosing it on its own. After the company submits the application, the FDA evaluates it, based on information submitted, but it does no independent

testing, no product development, no comparison with other products to see if this one is as good as or better than existing products -- or even if it's the best that it can be.

If the information submitted by the company meets the statutory standard, reasonable assurance of safety and effectiveness, the FDA grants PMA, thus permitting the device to be sold. So the FDA approves the design and labeling chosen by the manufacturer, but the agency doesn't require the manufacturer to choose -- to make those choices.

Once on the market, a PMA device may prove to be unsafe, because very often problems and hazards come to light only after the device is in widespread use. So --

CHIEF JUSTICE ROBERTS: Isn't that situation addressed by the requirement that the manufacturer alert the FDA to new information and at least file annual reports, and then the FDA can pull back the pre-market approval if they think these problems require it to do so?

MS. ZIEVE: Well, yes and no. The requirement about submitting adverse event reports and the annual report are intended help the FDA to monitor the device after it's on the market. But the

responsibility and the opportunity to improve the design or labeling or to initiate a recall is really on the manufacturer in the first instance, because the manufacturer is the first one to learn about the problems. The FDA has a more passive role. The FDA receives the information that the manufacturer sends to it --

JUSTICE SCALIA: What if the manufacturer wants to make what you call an improvement? Can it simply market the product with that improvement without further FDA action?

MS. ZIEVE: Depending on whether it is a design or labeling change, the answer is different. For a labeling change, some changes can be made prior to FDA approval. For design changes, any change that affects safety and effectiveness can't be made without a further submission to the FDA.

JUSTICE SCALIA: Even if it is designed to improve safety and effectiveness?

MS. ZIEVE: That's right. And in that way a PMA device is no different from the 510(k) device that this Court considered in Lohr, because with respect to those devices as well, any change that would have a significant effect on safety and effectiveness had to await a new submission and a new --

JUSTICE SCALIA: Right, but those devices had not been -- they were just grandfathered. They had not been specifically approved as safe and effective by the FDA. Right?

MS. ZIEVE: Right. But the question isn't what the level of pre-market scrutiny is. The question is what requirements are imposed on the manufacturer at the end of the process when the device enters the market.

JUSTICE KENNEDY: Well, before that decision is reached, let me ask you this -- under State law, either generally or specifically under the law of the State that you are trying to invoke here, does the jury -- does the finder of fact weigh the potential risks of injury and illness against the probable benefits to the health of the patient? Is that one of the things the jury does? In other words, suppose this was a very important device, but it had a one-percent risk. Does a jury consider that when it determines whether that's been negligently sold?

MS. ZIEVE: Well, the standard in New York is whether the product is unreasonably hazardous. I think the term "unreasonably" takes into account --

JUSTICE KENNEDY: Alright, now isn't that exactly what the FDA measured in the PMA process? The

FDA is specifically charged with weighing the risks against the probable benefits.

MS. ZIEVE: That's right. And in that way, the State law is mirroring--

JUSTICE KENNEDY: So the jury is doing the same thing that the FDA did.

MS. ZIEVE: Yes. And as this Court said in Lohr and in Bates, when the State law mirrors the Federal law, there is no preemption.

JUSTICE KENNEDY: Well, but that was under the expedited 510(k). That's different than PMA, because in PMA there's a specific way.

MS. ZIEVE: What the FDA does before the product reaches the market is different in the PMA context as opposed to 510(k). But when it comes to comparing the State and Federal requirements -- which I think is what you are getting at -- Lohr's analysis and the analysis in Bates v. Dow Agrosciences didn't turn on how rigorous the FDA requirements are, but are they parallel to the State requirements.

JUSTICE SCALIA: What was the State requirement there? I mean, what was the Federal requirement there? It was simply that the device had been on the market before the law became effective. Right?

MS. ZIEVE: The design requirement in Lohr?
JUSTICE SCALIA: Yes.
MS. ZIEVE: It had to be substantially equivalent in safety and effectiveness to a device that was grandfathered in, that's right. But Medtronic argued in that case that it couldn't change the design of that product without filing another submission to the FDA, and that that was why there's preemption, and that's the same argument that's made here --
JUSTICE SCALIA: Well, but the point is that the -- to follow up on Justice Kennedy's question -- the point is that the FDA in Lohr had never made a determination of weighing the risks against the benefits, as they do for the issuance of PMA's. And so the jury was not replowing the same ground that the FDA had already plowed in Lohr.
MS. ZIEVE: I don't think that goes to preemption under 360k(a) which looks for a specific Federal requirement, a State device requirement, and then looks at -- compares the two to see if there are counterparts.
JUSTICE GINSBURG: Ms. Zieve, how does it -- how does it compare with another process that the FDA looks at very closely, I think even more closely than new devices -- new drugs. New drugs also go through a very

long testing period. Is there -- and the FDA gives its approval, and the drug is marketed, and it turns out it has risks people didn't anticipate and there's a tort suit. Is there -- is there a defense to the manufacturer, "I followed to the letter the permission that the FDA gave me"?

MS. ZIEVE: Under the common law of most or all States, compliance with Federal law is a defense on the merits, and it is not usually dispositive, but in some States -- in some States it is.

JUSTICE GINSBURG: So it would certainly be at least the same here, right? That compliance with the Federal law would be a defense on the merits.

MS. ZIEVE: Absolutely. I don't think that the PMA is irrelevant to the tort suit. It's just not sufficient for preemption under 360k(a).

JUSTICE GINSBURG: Is there a reason -- as I understand it, tort suits are not preempted with respect to new drugs. Is there a reason to treat the two differently -- the new medical devices and the new drugs?

MS. ZIEVE: Well, there is no express preemption provision in the Food, Drug, and Cosmetic Act with respect to drugs.

JUSTICE GINSBURG: So that's the difference. So the question is what does the express preemption

provision mean?

MS. ZIEVE: Right. But I think in trying to figure out what the express preemption provision means, it's actually useful to consider why there's none for drugs and there is one for devices. And the reason is because drugs were regulated by the FDA since 1938. Devices weren't regulated until 1976. So, in those intervening 38 years, States had stepped in and started to do some regulation on their own to fill that regulatory void.

California is the most notable example, and the one discussed the legislative history. So, when drafting the medical device amendments and coming up with the system for pre-market scrutiny, the question arose, well, what about California? What about other States that are regulating good manufacturing practices? Or California had a PMA scheme of its own. And so the legislative history makes clear that Congress, faced with this dilemma, decided California shouldn't be able to continue to regulate devices in that way. It shouldn't be able to pre-screen devices once the FDA had stepped in and filled the Federal void.

And that's why you didn't need an express preemption provision for drugs. The States weren't doing that in 1938, but because the government -- the

Federal government waited so long to regulate devices, it was necessary to say what are we going to do about these State regulations?

JUSTICE SCALIA: Does that mean that, under the Food and Drug regulation, the States can issue their own regulations that contradict the Federal approval?

MS. ZIEVE: Well, they couldn't issue regulations that contradict the Federal approval because of the express preemption provision. But without it, California --

JUSTICE SCALIA: No. No. I'm talking about drugs. Not medical devices. You say that --

MS. ZIEVE: That would be a conflict preemption question.

JUSTICE SCALIA: Well, no. I mean, you can comply with both. It's just additional -- you have to go further to comply with the State rule, so there's no conflict. It's easy to --

MS. ZIEVE: Well, if there's no conflict, then there would be no preemption.

JUSTICE SCALIA: Then the States can issue regulations that go beyond -- beyond what the FDA says in drug matters? I would be surprised if that's the case.

MS. ZIEVE: Well, if there's -- the only

basis for preemption with respect to drugs is conflict preemption. So, if your question incorporates that there's no conflict, then there would no preemption. But --

JUSTICE SCALIA: And is that the only basis here? Conflict -- there's no conflict? It's all okay under the Medical Devices Act?

MS. ZIEVE: Well, here, if there is not a specific Federal requirement that is the counterpart to a State requirement, there is no preemption. That's what -- that's the language that Congress wrote and --

JUSTICE SCALIA: They can add additional requirements so long as -- and I suppose they can do this by regulation -- so long as these additional requirement do not prevent complying with the Federal requirements? So long as there's no conflict, the States can add additional requirements under the Medical Devices Act? That's not my understanding of it.

MS. ZIEVE: No. That --

JUSTICE SCALIA: It is field preemption, isn't it?

MS. ZIEVE: No, I don't think so. The -- when the FDA has spoken directly to a question, then the States cannot impose requirements that are different from or in addition to what the FDA has stated.

JUSTICE GINSBURG: Take a --
JUSTICE SCALIA: Different from --
JUSTICE GINSBURG: Take a concrete situation where the FDA is asked: We'd like to make this improvement. And the FDA says no, we don't think that enhances safety. And then there's a tort suit based on the failure to make that improvement. Wouldn't the FDA rejection of permission to make that improvement -- wouldn't that at least be preemptive?
MS. ZIEVE: If the -- if 360k(a) ever preempts tort claims, I think that would be a situation, but if -- only if the tort claim is -- is specific in that way, that you -- that the company failed in its duty of care because it didn't design the device in the specific way that the FDA had rejected.
JUSTICE SCALIA: Well, that's not the way I would -- the jury has to say that?
I mean, in fact --
MS. ZIEVE: Well, that --
JUSTICE SCALIA: In fact, that's what's going on, but it could have been safe if -- if they had made the change that the FDA rejected. But the case goes to the jury and that's, in fact, what's going on.
MS. ZIEVE: Well, the --
JUSTICE SCALIA: The trial is, you know, had

he -- had he made this change, it would have been safe, but he didn't make the change and, therefore, you, ladies and gentlemen of the jury, should hold the company liable.

MS. ZIEVE: Well, if that's the theory of the case, I think that's basically the one-inch/two-inch hearing aid wire of Justice Breyer's example in Lohr.

JUSTICE SCALIA: So it just --

MS. ZIEVE: But most tort claims --

JUSTICE SCALIA: It just has to be the theory of the case. We have to look at each jury verdict and decide whether that was the basis on which the jury made the decision.

MS. ZIEVE: Well, it's -- it's not actually that hard, because most tort claims are --

JUSTICE GINSBURG: I thought your response was it wouldn't go to the jury if the FDA had said no, you cannot make this, and the plaintiff's point is you must make it in order to make this device safe.

I thought your answer to me was that the FDA regulation -- the FDA's action in refusing to allow the change to be made would be preemptive and you wouldn't give it to a jury to second-guess that determination by the FDA.

MS. ZIEVE: Yes. That's right. And I

thought, Justice --

JUSTICE SCALIA: Yes under State law, but you -- you don't say that Federal preemption requires that; you say that by the grace of New York State, that may be the situation, but New York State can change that law, as far as you're concerned, right?

MS. ZIEVE: Can -- I'm sorry. Can change which law?

JUSTICE SCALIA: New York State can let it go to the jury, despite -- despite what the FDA has done. You've said that it's simply a defense under New York State law and the law of most States. But it doesn't have to be a defense under New York State law.

MS. ZIEVE: I think that's a different point. Generally --

JUSTICE SCALIA: I thought that was the point Justice Ginsburg was inquiring about.

JUSTICE GINSBURG: I was asking you, if it was -- as a matter of Federal law, if the FDA says -- rejects --

MS. ZIEVE: Yes.

JUSTICE GINSBURG: -- a proposed change, can a State court say, well, we think the FDA was wrong in rejecting that, so we're going to let it go to the jury. I thought the question I was posing to you is, isn't

Federal law preemptive in that situation, when the FDA says you can't do it and the personal injury lawyer wants it to convince the jury that they had to do it?

MS. ZIEVE: Yes. In a situation where the FDA has said you are required not to market this specific device and the State -- the plaintiff is seeking to impose a common law duty that you must market that specific design, then you would have counterpart State and Federal regulations, but the --

JUSTICE GINSBURG: How about the --

MS. ZIEVE: The relevance of --

JUSTICE GINSBURG: Another variation -- the FDA says you must include X in this device or we won't give you the pre-market approval. And so the manufacturer puts X in, and then there's a lawsuit that wants to charge that putting X in made the device dangerous.

Would the FDA's insistence that X be put in take X out of any State court's tort litigation? That is, wouldn't -- if the FDA says you must have it, a State court couldn't put to a jury whether you should have eliminated it?

MS. ZIEVE: Yes. I think that's Justice Breyer's two-inch hearing aid fix, when the Federal government says you must and the State law duty says

that you cannot.

But the -- that's not how tort claims are litigated as a general matter. First of all, PMA's don't say you must have this design feature. There's --

CHIEF JUSTICE ROBERTS: Right. I thought that was your -- your theory was a little more nuanced. In other words, they don't require you to market a particular catheter. And you -- what I understood you to be arguing is that there may be a better design and that it was negligent for the manufacturer to market a particular design, even though they're allowed to; they don't have to.

MS. ZIEVE: Exactly.

CHIEF JUSTICE ROBERTS: They should have made the change to make it safer, right?

MS. ZIEVE: That's right.

CHIEF JUSTICE ROBERTS: Well, if that's --

MS. ZIEVE: And if you look at the joint appendix --

CHIEF JUSTICE ROBERTS: Well, if that's what happens, what, as a -- what's going to happen for patients at a time when your theory comes up, the manufacturer looks at it and says, well, maybe this is a better device; we don't want to risk these tort suits, so we're going to stop selling our old device that's

been approved, but now we have got to get FDA approval of the new device and that might take forever or at least a year, let's say. And what happens to patients in that year? They've got no device.

MS. ZIEVE: Well, first of all, if the device is reasonably safe and effective, then the company is just not going to stop marketing it because of tort suits. And we know that because --

CHIEF JUSTICE ROBERTS: But your theory is that although this device has been approved, here's a better one. And it's negligent on the manufacturer's part to market a device, even though approved by the FDA, when there's a better one that would reduce the risks.

MS. ZIEVE: Right. But we know that manufacturers don't respond by taking devices off the market, because PMA has coexisted with tort suits since 1976. For instance, recently --

CHIEF JUSTICE ROBERTS: What do you want them to do if you think it's negligent for them to market the approved product? Don't you want them to take it off the market?

MS. ZIEVE: Well, I -- they should make their devices as safe as they can be. And if a tort suit points out that this device is not reasonably safe,

then the manufacturer --

CHIEF JUSTICE ROBERTS: Well, it's not that it is not reasonably safe. It's that another design would be safer. And you think that's a basis for negligence because you say, yeah, the FDA approved it, but that doesn't mean they required the manufacturer to market that device.

MS. ZIEVE: That's right. And 360k looks to requirements. It's not a matter of policy what the effect of tort suits is. The question is what are the requirements imposed by the PMA, what requirements are imposed by State law.

JUSTICE SCALIA: Of course, this is all a little unrealistic. It is not as though some expert agency of the State has conducted a very scientific inquiry and decided that there's something safer than what the FDA approved or that it's negligent to issue what the FDA approved.

What's going on is simply one jury has decided that in its judgment, there was a safer device that should have been used; and because of the judgment of that one jury, the manufacturer is placed at risk in selling a device that scientists at the FDA have said is okay.

I find that extraordinary.

MS. ZIEVE: Well, any one of us might have drawn the line differently. But the line Congress drew was when there is a specific Federal requirement, we looked for a device counterpart State requirement. And where they don't exist, there is no preemption.

JUSTICE BREYER: I thought that was something a little different than that. The question that I have which might be helpful to me, if you can answer it, is -- that's meant seriously -- I'd be helped by knowing what the specific design defect is that you claim? That is, in what respect was this catheter -- and I'd like you to refer to the details of the catheter -- in what respect, what material or what shape or what -- what it is about this catheter that you as the plaintiff think was designed defectively, if you can tell me?

MS. ZIEVE: There's not a lot of discovery about the design of the catheter.

JUSTICE BREYER: I know. But you must have a theory.

MS. ZIEVE: The general theory is that the design was unreasonably safe because the catheter should not have -- should have been strong enough --

JUSTICE BREYER: What is it about the design that you are saying is not safe? That is, you can't go

into the court without having in your mind, as the counsel, that some kind of specific thing that was wrong with this catheter, other than just using the words "design." I mean, how was it designed badly? What part of the design is not right?

MS. ZIEVE: The strength of the balloon and the way in which --

JUSTICE BREYER: You are saying the material of the balloon should have been of a different material or a different thickness; is that right?

MS. ZIEVE: Or designed to burst in a different way.

JUSTICE BREYER: What does that mean? How do you design something to burst?

MS. ZIEVE: I don't know how you design a balloon. But there -- Medtronic has --

JUSTICE BREYER: Well, if you don't know how you -- how to design the balloon, what are you basing the design claim on?

MS. ZIEVE: As I said, the design claim in this case was not significantly developed. Perhaps it would help to talk about the design claim in Horn v. Thoratec, for example, which was another PMA device --

JUSTICE GINSBURG: What about the label? I mean, this is the suit that you're pressing? So you

said we really don't know what the design defect was. How about the label? That would be the other thing.

MS. ZIEVE: The labeling claim is that the label was -- inadequately warned or was misleading because although at one place it lists among 12 precautions not to inflate the balloon above the rated burst pressure, which was eight, at another place it says to -- it has a chart that shows inflation up to 13 atmospheres, and at another place in the instructions, it says inflate to the nominal pressure, which is --

CHIEF JUSTICE ROBERTS: Well that's just like a car speedometer. I mean, the speedometer goes up to 120 miles an hour, but that doesn't mean you are supposed to drive it that fast.

MS. ZIEVE: But the car doesn't come with a chart that shows you safe usage up to 100 miles either. And the instructions --

JUSTICE KENNEDY: Was Medtronic free to alter this label without the FDA's consent?

MS. ZIEVE: Yes. Under 814.39, Medtronic could make changes to strengthen the warnings or clarify the instructions without prior approval. And there's one other part of the label that --

JUSTICE KENNEDY: What's the citation for that?

MS. ZIEVE: 21 CFR 814.39(d).

JUSTICE BREYER: Let me tell you why I asked my question, because I don't want to leave -- you leave with an unfavorable impression in my mind on your issue without your having a chance to see.

What's worrying me is that, of course, it's a terrible thing when somebody is hurt in these kinds of accidents. And the lawyers are trying to help. So the lawyers will think, look, there's a problem here. There must be. My client was seriously hurt. And he's not supposed to be.

And then they'll work backward from that and say well if he was hurt, there must be something wrong with the design.

So every time there is an accident or something bad happens, the lawyers assert a design claim and they gear up discovery.

And in my mind, could Congress have intended that kind of thing when what they're trying to do is have a group of experts really look into this and decide whether it should be marketed or not. That's what's bothering me. And that's why I would like you to respond to that.

MS. ZIEVE: Of course, it -- I freely admit that at trial if the plaintiff couldn't articulate the

design theory any better than I did here, the plaintiff is not going to lose on the design claim. But there are other cases where there is quite a clear theory about what the design defect is.

There are cases where the product has been recalled because of a design defect; and in those cases, could Congress have really intended to protect the manufacturer from liability? After all, the Dalkon Shield disaster where tons of people were hurt because -- women were killed and injured because of a design defect, was the impetus for the bill.

I would like to reserve the balance of my time.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Olson.

ORAL ARGUMENT OF THEODORE B. OLSON

ON BEHALF OF THE RESPONDENT

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

I think that the key, central focus of this case was touched upon by Justice Kennedy's question. Congress made a decision that it wanted to balance reasonable safety and effectiveness of lifesaving devices with the availability of lifesaving devices to the public.

They did so by vesting this responsibility in the experts, the expertise, the judgment, and the processes at the FDA.

And preemption of potentially conflicting, confusing, and burdensome State law requirements is essential to this scheme.

JUSTICE GINSBURG: Why, Mr. Olson, is it more essential to this scheme than the new drugs? I would think that if everything that you said about new devices would apply in bold letters for new drugs, because the testing procedures are much longer, are they not?

MR. OLSON: They're similar, but they're also quite different, Justice Ginsburg. The principal difference is this preemption provision that is the fundamental issue in this case. Section 360k(a)(1), that similar provision was not put by Congress in the new drug --

JUSTICE GINSBURG: Well, there's an argument that what it was intended to do was to cut out State pre-market approval, where States like California came in when there was a Federal void and said we shouldn't let the manufacturers put out whatever they'd like. Let's have a pre-market approval.

And the argument is, as you well know --

it's presented in Senator Kennedy's brief, that's what we meant to do with the preemption provision. Nothing more.

MR. OLSON: If there was such a State pre-market approval process, it would be something like the Federal process which would involve a very detailed application which would have everything about the design, the manufacture, and the warning labels in it. Then California would come up with different requirements, presumably or potentially, than what the FDA had decided was a reasonable balance between safety and effectiveness and availability. And so therefore, there would be different requirements.

And, as Justice Breyer pointed out in his concurring and dissenting opinion in the Lohr case, if a State jury or a State court comes up with those different requirements, it is the same problem: Different States, different requirements under different circumstances.

And it would be quite anomalous for Congress to have given more power to juries in individual ad hoc cases which don't do the weighing, Justice Kennedy -- they can't do the same amount of weighing because their focus --

CHIEF JUSTICE ROBERTS: What if the FDA

hasn't done it? How are newly discovered flaws dealt with? I mean, say we have this catheter, and the FDA didn't look at the possibility of allergic reactions to the balloon plastic, and all of a sudden it turns out to be a serious problem.

How can you say that that's preemptive?

MR. OLSON: This is a continuous process. Information must be given by the manufacturer. There is a process by which doctors report consequences to the FDA. Citizens may report information. This is a continuous jurisdiction --

JUSTICE KENNEDY: Is the manufacturer free to continue to sell the device after newly discovered risks --

MR. OLSON: Yes --

JUSTICE KENNEDY: -- pending the FDA's acting on the same information?

MR. OLSON: Yes, Justice Kennedy. And let me explain why I think that is important to this case.

If the -- that information is then in the possession of the FDA. The FDA can suggest to the manufacturer -- it can require the recall. It can change warnings. It can do all of those things. But what it is doing, because it's continuously involved in the process --

JUSTICE KENNEDY: Mr. Olson, we know it takes time for the FDA to act. Let's assume that we know it's going to take six months for the FDA to do this. The manufacturer knows that there's a real problem. He can continue to sell in the face of the knowledge of the real problem?

MR. OLSON: What I'm suggesting is that the FDA can act as promptly or as slowly as necessary --

JUSTICE KENNEDY: I was asking you about the manufacturer's duty pending the FDA's action.

MR. OLSON: It's dependent upon the manufacturer providing information to the one centralized agency --

JUSTICE STEVENS: Mr. Olson, suppose the manufacturer did not provide information. Would the preemption nevertheless exist?

MR. OLSON: Yes, Justice Stevens, because in that case --

JUSTICE STEVENS: At least as a theoretical possibility, there could be a newly discovered risk that the FDA never knew about. And, nevertheless, the claim would be preemptive.

MR. OLSON: Yes. And that's a judgment that Congress made, because with the -- the manufacturer then would be violating the law, failing to tell the FDA what

was going on, perhaps committing fraud, and be subject to criminal penalties, recall penalties, civil penalties, and that sort of thing.

The choice is, Justice Stevens, in that situation -- is to allow the agency that has the expertise, that has spent 1200 hours or so on this particular device, according to your opinion in the Lohr case, to make a judgment with respect to whether this product should be on the market or not.

Because as I --

JUSTICE SOUTER: Mr. Olson, that still leaves the -- sort of the hiatus that Justice Kennedy's question was addressed to. And I -- I don't think I understand your answer to it.

His question was what if the manufacturer has learned that there is -- that there's a problem that somebody hadn't anticipated? The manufacturer has told the FDA, and the FDA has not yet acted.

Leave open the question of whether the FDA is slow or whether it just takes time, but there's a -- there's a hiatus here. And an injury occurs because of marketing that took place during the hiatus.

Does preemption still apply?

MR. OLSON: Yes, it does.

JUSTICE SOUTER: Okay.

MR. OLSON: And the reason for that, Justice Souter, is that someone must make a judgment. That -- the information that the manufacturer may have learned may be -- have some aspect of the safety or effectiveness of the device, but it still might be the best product available.

As the government points out in its brief, there are some devices that are used in situations where a child might die. There's a 50-percent mortality rate even with using the device. So there's got to be individual judgments with respect to variations of risk and safety and availability.

JUSTICE ALITO: Do you know whether the PMA process in this case considered the design defects that the Petitioner seems to be relying on?

MR. OLSON: Well, all -- no, I don't know the answer to that specifically, Justice Alito. But I do know -- and this is the application, itself, which is not, unfortunately, in the record, but is available through the FDA. It goes into elaborate detail with respect to the burst pressures. This device -- the label on this device -- and that is in the record at A-174 of the court of appeals' appendix -- specifically says it shouldn't be inflated higher than a burst pressure or atmospheric pressure of -- at 8 atmospheres.

This one was inflated to 10 atmospheres, notwithstanding the label requirements.

So what -- what I am saying is that the elaborate nature -- everything in the label has to be approved by the FDA. The safety indications, the precautions, the hazards, the counter -- counterindications, and that sort of thing, there's a professional judgment there.

My colleague says that well, it's not the FDA's not imposing requirements, because this is a design submitted by the manufacturer. Of course, it's a design submitted by the manufacturer. That's how devices are made.

But the FDA examines every little part of that design -- the way it's manufactured, the way it's labeled, the way it's marketed, the way it's going to be used.

And it can say no, change that part of it, or have you considered this? It's a dialogue between the manufacturer and the FDA.

And then when the FDA is satisfied that it's reasonably safe and effective -- and the word "reasonable" is important. Nothing is perfectly safe. You can make a car weigh a hundred tons, and it might be perfectly safe, but balances have to be made, the same

with drug devices. So --

JUSTICE ALITO: If you look at the file of a PMA proceeding after it is concluded, can you tell exactly which design features and which risks the FDA has considered?

MR. OLSON: No, I don't think you can. What you can do, Justice Alito, is examine -- and Justice Breyer's example of the two-inch versus one-inch wire in the Lohr case is a good example.

The FDA will have examined, and presumably done its job, with respect to every aspect of the design, manufacture, and labeling and marketing of the device.

Now, the choice is between that -- and I think Congress made this judgment quite consciously, because if a -- if a jury comes along in a particular case, examining a particular infant or a particular ill person and the facts of a particular situation, and says well, the device should have had a one-inch nail -- a wire, or it should have had a different tensile strength of the balloon, or something like that, then the manufacturer is in this dilemma.

JUSTICE GINSBURG: Why isn't there -- to -- to take care of that kind of hypothetical where the FDA says this is it, to say that kind of suit can't be

brought. But Ms. Zieve mentioned that there's a category of suits that is simply saying: Manufacturer, you didn't do what's in that pre-marketing approval.

So we're kind of a backup to not doing anything in conflict with the FDA's approval. We're simply saying you didn't follow the labeling requirement, or you didn't follow the design permission that you --

MR. OLSON: I think that if there's a violation of the requirements -- now, it's no -- it's no question that there are requirements, because every aspect of this approval incorporates the design and all of those things.

If the manufacturer fails to comply with those requirements, that's a parallel suit that may be brought.

Now, in this case, the negligent manufacturer -- a claim was made. It was dismissed on summary judgment, which was affirmed by the Second Circuit because there was no evidence to support it. So --

CHIEF JUSTICE ROBERTS: You -- you agree that that was not preemptive.

MR. OLSON: That was -- we agree that was not preempted, and -- and the court of appeals came to

that same conclusion, but affirmed the district court that dismissed it on summary judgment because there was no evidence to support it.

JUSTICE GINSBURG: You would say the same thing for -- for design and labeling if the manufacturer did not do what the FDA approved?

MR. OLSON: That's correct, Justice Ginsburg.

Now our -- the statute, I think, could not be more clear with respect to every aspect of what the Court talked about in the Lohr case. And I think that the analysis that this Court articulated in the Geier case having to do with the airbags, although that was an implied preemption and conflict preemption -- case and this is an express preemption case -- is very illustrative.

The Court went through an analysis of what manufacturers might do if they were required to put an air bag in the car when the Department of Transportation had decided that it wanted a little bit of play in the marketplace with respect to different types of restraints of individuals.

And the Court made it very clear that if a trial court in Kansas or some other place decides that cars must be manufactured in a certain way, that's what

would happen.

And then the judgment of the Department of Transportation, which was considering all of these things and wanting to encourage innovation with respect to restraints -- the same thing is true here.

We want in this country for devices to be as safe and effective as they possibly can be. But we don't want to discourage the marketing of products that might save our lives. And these are -- Class 3 devices are all in the category of life-threatening or life-saving devices here. So we want those available. They may not all be perfect. They maybe work in some situations, not work in other situations, but some expert, centralized, that can take into consideration all of those factors should be the place where that decision is made.

JUSTICE GINSBURG: Mr. Olson, what about the argument that once you've got this very valuable pre-market approval, even though you could make that device safer, you have no incentive to do that. You have permission to market this product as is. Even if you know that there's a better way to do it, there's a disincentive to try to go through the process and make the change. Why should you, when you have carte blanche to continue without making the change?

MR. OLSON: Well, I think the real world answers that question. The manufacturers of these products are always trying to produce better products that will be safer. They of course have to go through the process to justify to the experts at the FDA that they are indeed safe, or -- and the FDA then may make a judgment that the reasonableness -- if there is a much safer device that doesn't have the risks of the previous device, they can -- they can withdraw the approval of the previous device.

But the FDA may at the same time say well, this one device might be safer under some circumstances but less safe under other circumstances. It might work in this critically ill patient, but not in this critically ill patient. So the marketplace of doctors and patients deserves to have more than one product out there, even though someone might decide this one is safer than the other one. That is the way Congress made this judgment. And --

JUSTICE KENNEDY: If the manufacturer finds just from its own laboratory experiments and not because of any data it's received from doctors and patients that there's a better way to do this, does it have the obligation to notify the FDA?

MR. OLSON: I don't think so,

Justice Kennedy. I think that there may be marketplace incentives and other things that would cause a -- someone in the marketplace to say I found a better way. Someone in the marketplace might say well, it might be better, but it might be prohibitively expensive. There are all kinds of those judgments, and I think that illustrates the point.

The FDA is the right place for these decisions to be made and this balancing process to occur, because an individual, ad hoc, not scientifically trained jury that is not required to consider the consequences for the marketplace as a whole, cannot make those judgments.

As conscientious as a jury might be, that judgment is in for that case and for that patient and might say well gee, it should have been done differently in this particular situation; a one-inch wire might have been better in this particular case. But the --

CHIEF JUSTICE ROBERTS: Mr. Olson, I'm looking at the government's brief on page 4 which says that in the annual reports, the -- the manufacturer has to disclose "unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device."

So presumably that includes any nonclinical

laboratory studies that the manufacturer itself conducted.

MR. OLSON: Yes. I believe that's true, but I think that was a slightly different point than Justice Kennedy's one; if it was -- if it is the same point, I agree with you, that there is an elaborate process of information exchange from the manufacturer and from doctors and from all over with respect to these medical devices. It's described in considerable detail in about six pages in the court of appeals decision, and the Government's brief describes it quite thoroughly as well.

That same balancing, the Government filed a brief last week in this Court in the Warner-Lambert case, that this Court will be hearing, I think in January, which describes in even greater detail than it does in the brief filed here about that balancing process and the importance of the centralized --

JUSTICE STEVENS: Could you clarify one thing for me on that part? Is that a -- as soon as they get the information requirement, or is it an annual requirement that they have to take --

MR. OLSON: That -- what the Chief Justice was referring to was an annual requirement --

JUSTICE STEVENS: Right.

MR. OLSON: -- but there also are requirements -- and I haven't -- can't give you the exact citation, there's a lot of subparagraphs in these sections -- with respect to information that comes into the possession of the manufacturer that's pertinent to adverse consequences or effects of the device that must be given promptly to the FDA.

JUSTICE SCALIA: Mr. Olson, the other side says well, you know, these are all horribles but, in fact, we have had tort suits and manufacturers haven't taken their products off the market. This is all just a Chicken Little kind of a --

MR. OLSON: Well, I don't agree with that, Justice Scalia. In the first place, I don't think we know. Secondly, there are six of the seven circuits that have considered this case, found that those tort suits were preempted. So to the degree to which they are out there, there is one circuit in which they might --

JUSTICE STEVENS: Yes, but of course the FDA took this contrary position some years ago.

MR. OLSON: Yes, it did, and it -- and it learned from experience -- the unique experience that you described the FDA having, in your opinion in the Lohr case, has been brought to bear in this case; and

there's a reasoned explanation for the FDA's -- the Government's position today, as to why it took one position then -- there were some proposed regulations that are no longer on the table -- but there's a reasoned explanation by the agency that you said and quite correctly in my judgment had a unique experience, and unique capability of determining the effect of take -- State tort suits on the process that it's involved in, and that's reflected in the Government's briefs that are filed in this case just earlier.

The fact is that there are specific detailed requirements with respect to every aspect of the device that's approved by the FDA; and any jury, just like any regulatory body, Justice Breyer, will impose a different requirement. The fundamental -- you asked about, what's the basis of this suit, there was some answer to it, but the fact is there's some effort to explain why, if it was designed according to the approval, by the FDA, that wasn't good enough.

There was something wrong with that design that was approved. Something wrong with that label that was approved. And a jury at the end of the day will be expected then to render a different requirement by saying you are liable for damages because you did it the way the FDA approved.

That is a State requirement which is a counterpart to the Federal requirement, and this -- and Congress made it explicitly clear that any requirement that is different or in addition to the Federal requirement is preempted if it has to do with safety or effectiveness of the device.

And if juries require products to be changed, they will by definition be either less safe or less available than the FDA has determined is in the best interests of the public according to the responsibility vested in them by Congress.

Thank you, Mr. Chief Justice.

CHIEF JUSTICE ROBERTS: Thank you, Mr. Olson.

Mr. Kneedler.

ORAL ARGUMENT OF EDWIN S. KNEEDLER,

ON BEHALF OF THE UNITED STATES,

AS AMICUS CURIAE,

SUPPORTING THE RESPONDENT

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

I think it might be useful to begin by focusing on the consequences of Petitioner's argument that the PMA approval of an application does not result in requirements that are preemptive for purposes of the

preemptive provision. Under Petitioner's view, the day after the FDA gave PMA approval to a particular device, State legislatures or State regulatory agencies could adopt laws or regulations that would direct the manufacturer to manufacture or design the product or to give labeling that would conflict with what the FDA had just approved. And we don't think that Congress could have intended, in enacting the express preemption provision here, to allow State regulatory agencies or, even more so, individual juries that could vary, even within a State --

JUSTICE GINSBURG: I thought that you conceded that there would be conflict preemption, that the States could not -- either through a State agency or through a jury -- come up with a requirement that would conflict with an FDA requirement.

MR. KNEEDLER: But we think that the express preemption provision embodies that very important conflict, or maybe in this context it is best to conceptualize it as field preemption, of the things that are included within the application that is submitted to the FDA and the labeling.

JUSTICE SCALIA: Additional requirements are not necessarily conflicting requirements. You can comply with --

MR. KNEEDLER: Yes, that is -- that is definitely true.

JUSTICE SCALIA: It is clear that Congress didn't want any additional requirements.

MR. KNEEDLER: That's -- that's entirely correct, and if I could just elaborate on that --

JUSTICE BREYER: How are they not conflicting? Go ahead; go ahead -- elaborate.

MR. KNEEDLER: Well, what I was going to say -- to elaborate on the point that I made, Petitioner concedes that if there is an FDA PMA requirement, the State may not impose its own PMA requirement; and that has to be correct, because in the State PMA approval, the State could withhold its approval unless the manufacturer changed the device or changed the labeling in some way to get it cleared through --

JUSTICE GINSBURG: Everybody agrees that far, that the States were not to be in the business of issuing PMA's. The question is does the preemption clause mean any more than that?

MR. KNEEDLER: But it's important to understand why. Congress was not concerned about the PMA in the abstract or as a process; it was concerned about what the consequences of requiring a manufacturer to go through the PMA process were. And that was

precisely because the result of the State PMA process could be to impose different requirements. The labeling should read differently --

JUSTICE GINSBURG: Isn't it -- isn't it --

MR. KNEEDLER: -- the product should be designed differently.

JUSTICE GINSBURG: If you compared drugs, which -- I think you will -- you will concede -- go through a very arduous process, new drugs, why -- maybe you think that the same preemption applies there, although there's no preemption clause.

MR. KNEEDLER: There is -- there is no express preemption clause there. One -- one possible explanation might be is that a -- that a device is a tangible concrete item, an item of commerce that is -- that has extensive design and planning and blueprints in a way that a drug doesn't quite have that same -- that same characteristic. I mean, like other -- like automobiles or something, that they have a tangible aspect and a long lead time in the design and manufacture.

That may be one explanation for why Congress wanted to be especially firm about imposing preemption with respect to federally approved devices.

JUSTICE SCALIA: It was also a different

Congress.

MR. KNEEDLER: It was a different Congress.

JUSTICE SCALIA: How much -- how many years later?

MR. KNEEDLER: This was 1976 when the new drug amendment --

JUSTICE SCALIA: Why would we expect them to come out with the same --

MR. KNEEDLER: Right, and they were only addressing devices in that -- these were not general FDA amendments; they were addressing -- they were addressing the --

JUSTICE GINSBURG: Did anyone -- when this preemption clause was put in the new Medical Device, did the government -- when was the government change? Was it 2004? The government's position, the FDA's position, was 180 degrees different --

MR. KNEEDLER: Well, the government filed a brief in -- in late 1997 taking the position that PMA approval did not -- did not have preemptive effect. That was issued together with FDA's issuance of a proposed rule to the same effect. FDA withdrew that proposed rule seven months later. The government did not address this question again until 2004 in the brief you're referring to in the court of appeals.

And due in large part to examining the very things that I've been talking about, that in FDA's judgment, which this Court in the Lohr case said was entitled to considerable deference, FDA recognized that there would be a serious undermining of FDA's approval authority and its balancing of the risks and benefits, if a State jury could reweigh those -- the balance that FDA had struck in --

JUSTICE KENNEDY: Suppose that a label is approved in a very specific form under PMA, and then a year later, it turns out, unforeseen by anyone, that doctors are just -- many good doctors are just reading it the wrong way and it's dangerous.

Can the manufacturer continue to sell new devices with the same label pending the annual report?

MR. KNEEDLER: Yes. I mean, let me just clarify.

If the -- if the -- there are incident reports that -- that a manufacturer is supposed to give to FDA. There is often a difficult judgment as to whether the injury that is associated with a device is some problem with the device or whether it's some problem --

JUSTICE KENNEDY: Just take --

MR. KNEEDLER: -- with what --

JUSTICE KENNEDY: Just take my hypothetical.

MR. KNEEDLER: And it -- what I was going to say is it's possible that the labeling would be regarded as misleading for some reason. In that event, the manufacturer should apply to -- should submit what's called a supplemental PMA and request that the labeling be changed to clarify that.

JUSTICE KENNEDY: And you could -- can the manufacturer continue to sell the device knowing that the label is being misconstrued by very good doctors pending FDA action?

MR. KNEEDLER: Ordinarily, yes. If there was -- if there was a very serious risk to health and safety --

JUSTICE KENNEDY: Yes, it's very serious.

MR. KNEEDLER: In that event, FDA has a variety of tools that it can take and so does the manufacturer. One of them is what's sometimes called a "Dear Doctor" letter, which is notification -- this is provided for under 360h(a) of the Act -- is a notification to physicians or other users of the product that there may be some previously unrecognized problem or misrepresentation or what could be misconstruction of the label.

JUSTICE KENNEDY: Does the failure to give

that notice subject the manufacturer to liability if the manufacturer continues to sell the device?

MR. KNEEDLER: It would not subject it to State tort liability, no. If there was -- if there was a situation where the manufacturer knew of a serious problem and did not report it to it FDA, that could subject the manufacturer to criminal penalties with respect to FDA for either misrepresenting or withholding information. But that's really the Buckman -- this Court's Buckman decision, that that's the relationship between FDA and the manufacturer, and that's the incentive.

I think someone asked about what incentive does the manufacturer have. The manufacturer has a powerful incentive because of the criminal penalties and other sanctions that can be taken by FDA if -- if the manufacturer does not report something to the FDA. Plus, manufacturers have an important reputational interest, that they don't want to be seen to be flouting possible problems.

JUSTICE SOUTER: Mr. Kneedler, let me ask you to -- a textual question which perhaps would be better directed to counsel for the Petitioner, but let me get your take on it.

If the only objective in the -- in the

preemption clause were to preclude State PMA in addition to Federal PMA, there would have been no reason to include the phrase -- would there have been any reason to include a preclusion of a requirement that is different from, in addition to a preclusion of something which is in addition to?

MR. KNEEDLER: I -- if it was just -- I think that's a good point. If it was just a question of going through a duplicative State PMA process --

JUSTICE SOUTER: "Addition to" would be --

MR. KNEEDLER: Right. Right. Right.

JUSTICE SOUTER: Okay.

MR. KNEEDLER: And also I think the FDA regulations promulgated when this was put out, soon after the '76 amendments were passed, I think reinforced the conclusion that -- and, in fact, there was a regulation that specifically talks about the application of general adulteration standards in a way that might require a specific label change to be made by a manufacturer, and we think that's basically precisely this lawsuit. It's the application of general tort law that would require the manufacturer or a standard of care under common law that would say that what the manufacturer had done specifically approved by FDA was -- was improper as a matter of State law. We think that

that is in the teeth of the preemption provision. I think Justice Alito asked the question about the issue of whether FDA focused or didn't focus on a particular aspect of the design. We don't think that a preemption test can really realistically turn on that. That would require extensive and intrusive inquiry into what FDA had done. We think that the best way to look at this is what the end product was; what was the application that was finally approved and the labeling associated with it, much like the filed rate doctrine. You look at what was put before the agency and what was approved, not what might have gone into -- into consideration.

CHIEF JUSTICE ROBERTS: Thank you, Mr. Kneedler.

MR. KNEEDLER: Thank you.

CHIEF JUSTICE ROBERTS: Ms. Zieve, you have 4 minutes remaining.

REBUTTAL ARGUMENT OF ALLISON M. ZIEVE

ON BEHALF OF THE PETITIONER

MS. ZIEVE: First of all, it's not our position, Justice Souter, that only State PMA's are preempted. California had good manufacturing practice requirements that were preempted to the extent they were different from or in addition to the Federal requirement.

Some States had hearing aid packaging requirements. There was a State that had a requirement about the strength of prescription glasses, lenses. So it's -- it is broader than just --

JUSTICE SOUTER: And how do you draw the line between those instances and the ones that you say are not preempted?

MS. ZIEVE: Those were specific requirements for devices, and they had counterparts --

JUSTICE SOUTER: They -- they were requirements, in other words, of positive law? They were State regulations?

MS. ZIEVE: Addressed specifically to devices, and they had --

JUSTICE SOUTER: So the --

MS. ZIEVE: -- direct Federal counterparts.

JUSTICE SOUTER: Okay. So the line is simply enactment of positive law versus jury award? That's the line?

MS. ZIEVE: I think that's what Congress was intending.

JUSTICE SOUTER: No, I just want to make sure --

MS. ZIEVE: I think under --

JUSTICE SOUTER: -- what your position is.

That is where you draw the line then?

MS. ZIEVE: Yes.

JUSTICE SOUTER: Okay.

MS. ZIEVE: I'd also like to --

CHIEF JUSTICE ROBERTS: Didn't the Court -- didn't a majority of the Court reject that line in Lohr?

MS. ZIEVE: The holding of Lohr didn't reject it. Five justices disagreed with me, and I don't think you need to agree with me on that point to find for me here. We talked about some examples that Justice Ginsburg offered, in which a State common-law duty could become so specific that it effectively imposed a State device requirement.

I also want to correct the point that manufacturers can't make labeling changes without FDA approval. Again, 814.39(d) allows them to do so. And so the catheter's label, where it says "inflate the balloon gradually to higher pressure up to the rated burst pressure or until the stenosis resolves," the narrowing resolves, to me that's ambiguous as to whether you can go above the rated burst pressure. Medtronic could have clarified that instruction without running afoul of any FDA regulation.

As for the FDA's current views, it is not

actually correct that in Lohr the government gave weight to the FDA's amicus brief. The government gave weight to the FDA's regulation, 808.1(d). That regulation is still in effect, and it hasn't been modified since -- since Lohr was issued.

JUSTICE KENNEDY: What do I read in order to verify your statement that the -- that manufacturers can cure the label without FDA approval? Where do I find that?

MS. ZIEVE: Without prior approval?

JUSTICE KENNEDY: Yes.

MS. ZIEVE: 814.39(d).

JUSTICE KENNEDY: Thank you.

MS. ZIEVE: After FDA approves a PMA, any of the listed changes can be placed into effect prior to the receipt of a written FDA order approving the PMA supplement.

CHIEF JUSTICE ROBERTS: If I could -- I'm sorry -- I've been thinking about your example of ambiguity. You're saying it is ambiguous when they say you can inflate it up to the bursting pressure or until the blockage is cleared?

MS. ZIEVE: Stenosis resolves. Right.

CHIEF JUSTICE ROBERTS: Well, isn't that obviously mean if the blockage is cleared, you don't keep

inflating it to the bursting pressure. You think that doctors read that as saying you can inflate it past the bursting pressure unless -- if the blockage isn't cleared?

MS. ZIEVE: Yes. It says either one. It doesn't say up to a maximum. There is testimony from the doctor in this case that he thought that the label showed testing up to 13. And that based on the directions, he thought that going up to 10 was fine and that it was standard use among the cardiologists.

CHIEF JUSTICE ROBERTS: Even though the label said eight is the bursting pressure?

MS. ZIEVE: The rated burst pressure, yeah.

CHIEF JUSTICE ROBERTS: Okay.

MS. ZIEVE: I also want to mention -- we don't come to this case on a blank slate. We come to it in light of Lohr. The Court has already interpreted Section 360k(a). In finding no preemption in Lohr of any of the claims, the Court looked to the labeling regulation, 808.109, that was applicable to the device there. That is the same exact regulation that is applicable to the device here.

If Medtronic's PMA device complies with 808.109, then it is deemed not to be misbranded, but

that is a moving target. What is adequate instructions for use changes as the manufacturer learns about use of its product in the real world. The same process for making design changes exists in this case as existed in Lohr.

And on the State law side, we really are talking about identical State duties of care, which this Court said their generality -- the majority held that the generality of these duties left them outside the category of requirements that 360k envisioned to be with respect to the devices.

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, Ms. Zieve.

The case is submitted.

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