IN THE SUPREME COURT OF THE UNITED STATES

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BUCKMAN COMPANY, :

Petitioner :

v. : No. 98-1768

PLAINTIFFS' LEGAL COMMITTEE :

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Washington, D.C.

Monday, December 4, 2000

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:03 a.m.

APPEARANCES:

KENNETH S. GELLER, ESQ., Washington, D.C.; on behalf of the Petitioner.

IRVING L. GORNSTEIN, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; on behalf of the United States, as amicus curiae, supporting the Petitioner.

MICHAEL D. FISHBEIN, ESQ., Philadelphia, Pennsylvania; on behalf of the Respondent.

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P R O C E E D I N G S

(10;03 a.m.)

CHIEF JUSTICE REHNQUIST: We'll hear argument now in Number 98-1768, the Buckman Company v. the Plaintiffs' Legal Committee.

Mr. Geller.

ORAL ARGUMENT OF KENNETH S. GELLER

ON BEHALF OF THE PETITIONER

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

The plaintiffs in this case are people who underwent back surgery in which particular medical devices were used. They brought this suit under State law to recover for injuries allegedly caused by their -- by these devices, but this is a very unusual form of State law product liability action. The plaintiffs don't claim that these devices were in any way defective. There's no claim here of manufacturing defect. There's no claim here of design defect. The plaintiffs also don't claim that the surgeons who used these devices did anything wrong. There's no claim here of medical malpractice.

Instead, the plaintiffs' sole claim in this case is the following. They assert that the Federal Food & Drug Administration was deceived into giving regulatory clearance to these devices, that, absent this deception,

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these devices would never have been on the market, and that, if the devices had never have been on the market, they wouldn't have been used in their surgeries and they wouldn't have suffered any injuries.

So this lawsuit is, in other words, a direct attack under State law on the decision of the Federal Food & Drug Administration applying Federal law to allow these devices to be marketed in interstate commerce and, if this suit is allowed to proceed, it means that a jury applying State law would have to decide such issues as, what sorts of disclosures have to be made to the Food & Drug Administration in the context of seeking 510(k) approval for a device? What did the FDA know about these specific devices and their intended use? Was the FDA deceived in any way in granting regulatory clearance?

QUESTION: Do they really have to get into all of those issues, because I thought at least one theory of the plaintiffs' case was simply representation as determined on an objective basis and the only thing the jury would have to decide was whether, on an objective basis, the representation that the devices were intended for, what was it, long bone surgery, something other than spinal surgery, was true or false? Why would they have to go beyond that?

MR. GELLER: Justice Souter, they would have to

do that because there's a fraud claim and if you look at the complaint --

QUESTION: Well, that would be a question of intent on the part of the company, but it --

MR. GELLER: It would --

QUESTION: I'm sorry, go ahead.

MR. GELLER: It would be more than that, Justice Souter. If you look at the complaint, for example, at page 21 of the joint appendix, paragraphs 131 and 132 allege not only that a false statement was made but reliance and causation and all the things that you have to prove in order to prove a State law cause, State law fraud action.

So it's not enough simply to prove that a misrepresentation was made in order to recover on it. You would also have to prove whether the misrepresentation was material, whether the FDA knew what was allegedly not told to it, whether the FDA thought that it was relying on the absence of the information, relied on the misrepresentation and then finally, what would the FDA have done if it had been told the truth, the causation theory.

QUESTION: Mr. Geller, why wouldn't it be adequate to show that, that there had been two prior applications that were rejected for use of this device for

spinal surgery?

MR. GELLER: Your Honor, the -- what the manufacturer has to show in seeking 510(k) is, in addition to showing that the device has the physical technological characteristics of the predicate device the manufacturer also has to put down what the intended use of the device is. It's -- the manufacturer under the law is entitled to put down any intended use it wants, as described in the labeling.

What the plaintiffs seem to claim here is that the FDA, is that the manufacturer had to allege not simply that the intended use was for the long bones, which was the manufacturer was entitled to allege, but also, according to the complaint, that once the device got on the market the manufacturer intended that it be used for spinal applications, and that our -- and therefore a State jury would have to determine what would the FDA have done, if it had been told, as the plaintiffs allege the manufacturer should have told the FDA, that once this device gets on the market the intent was to see it used significantly for spinal applications.

QUESTION: But my point was simply that we do have two applications that said the intended use is for spinal surgery and both of those applications were turned down. Isn't that enough to infer that if they had for a

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third time said the same thing they'd be turned down again?

MR. GELLER: Well, I think the opposite, Justice Ginsburg. I think it shows that the FDA was well aware of the possibility of using these devices for spinal applications and when the manufacturer came in, as it was entitled to do, and that now we want to seek 510(k) approval to label these devices for the long bones of the arm and leg, the FDA was well aware that the devices had some possibility of being used for spinal applications. After all, I think the mistake here --

QUESTION: So you're saying in effect that there would be an issue of whether the FDA was complicit in the deception itself?

MR. GELLER: Absolutely, what did the FDA actually know about the use of these devices, and that's in our view not an inquiry that should be made under State law. In fact, one of the --

QUESTION: We know -- I mean, as Justice Ginsburg's question suggests it would be fairly easy to prove what the FDA knew about possible applications, but I think, if I understand your answer to her, your answer is, well, that still doesn't simplify the case, because the issue then would become, even on that assumption, did the FDA understand perfectly well that this fraud was nothing

but a fraud, and they winked at it and said, sure, this is an easy way of letting them do what they want to do even though we've said before that we won't let them do it. In other word -- is that in effect what you're --

MR. GELLER: In effect, although whether it was even a fraud at all -- you see, I think one of the problems here is in viewing the intended use statement under 510(k) as a factual representation at all. It's not a factual representation at all. It's simply a request for marketing clearance.

The manufacturer decides by its labeling what sort of marketing clearance it seeks for its devices. The FDA's role is simply to look at the labeling and determine whether there was a device on the market prior to 1976 with those physical characteristics and that labeling.

QUESTION: It's really a misnomer, then, if they're going to use it the way you say they have been and ought to use it, they shouldn't call it intended use. They should have -- it should be called permitted use, or approved use, or something like that.

MR. GELLER: Absolutely, Justice Scalia. I think intended use is a misnomer. It's a term of art in the food and drug law, and I think the statute and the regulations are as clear as can be, it is simply a request for marketing clearance by describing how you intend to

label your device. It is not at all a factual representation as to how that device will actually be used off-label once the device is on the market, which is, I think, one of the many problems with the plaintiffs' claim here.

But the point that I was simply making is the sorts of inquiries that a State judge or jury would have to make if this State law claim were allowed to proceed are inquiries that would delve heavily into the intricacies of the Federal regulatory process and, in addition, in addition to prevail on their claims the plaintiffs would have to convince a State jury that these devices should never have been on the market and were not lawfully on the market, even though the FDA has decided as a matter of Federal law that the devices are lawfully on the market, so to rule for plaintiffs, a jury under State law would have to essentially disregard and nullify a binding decision of the FDA.

Now, our position is that a claim such as this, which essentially amounts to an attack under State law on a binding determination by a Federal agency is both expressly and impliedly preempted by the Federal food and drug laws.

QUESTION: Mr. Geller, I'm sorry, may I ask you just to go back one step, and that is to the issue of

whether the plaintiffs' cause of action really is an attack, at least on its face, on an FDA decision, because the FDA decision, as I understand it, is a decision to allow the devices to be marketed for the long-bone use, and their cause of action, as I understand it, is that in fact, as a result of this lie, this fraud on the FDA, it was, in fact, allowed to be used, or it was possible to use it, I guess is the neutral word, on the spine.

MR. GELLER: Yes.

QUESTION: But that is not attacking a decision of the FDA because, in the sense that the FDA, as I understand it, says yeah, we'll permit it for the purposes of long-bone use.

MR. GELLER: No, I think --

QUESTION: And that's as far as the FDA decision went, wasn't it?

MR. GELLER: That's a mis -- I think that's a misunderstanding --

QUESTION: Okay.

MR. GELLER: -- Justice Souter, of the process. What the FDA does is permit it to get on the market, and it can only be marketed for long-bone use. It can only be marketed for the intended use described in the labeling, but once it's on the market, it's quite clear that surgeons are entitled, in the exercise of their medical

judgment, to use those devices for --

QUESTION: Oh, it's true, and the surgeons are not liable to the FDA --

MR. GELLER: That's --

QUESTION: -- but is it fair to characterize the FDA decision as being a decision to permit it's use for the spine --

MR. GELLER: The FDA --

QUESTION: -- as opposed to permit its use for the intended purpose?

MR. GELLER: The FDA decided that these devices were entitled to be on the market, labeled for long-bone use. There's no question that they were lawfully at all times on the market, labeled for long-bone use.

QUESTION: And labeled for long-bone use means, doesn't it, that the -- or implies, doesn't it, that the FDA's approval was for long-bone use --

MR. GELLER: Yes.

QUESTION: -- and only for long-bone use?

MR. GELLER: No. It means it could only be --

QUESTION: It may not have had a right to go after the doctor who used it for some other purpose, but the extent of the FDA approval didn't go beyond long bones, did it?

MR. GELLER: No, Your Honor. It means it can

only be marketed for long-bone use. It can be used for any purpose whatsoever once it was on the market, consistent with independent medical judgment. The claim here --

QUESTION: Well, to the extent that it's used for more than long bones, hasn't the FDA in effect washed its hands of it?

MR. GELLER: But it is not inconsistent in any way with the FDA's decision. The FDA decided here that the -- that this 510(k) satisfied the statute in the sense that the device was similar, substantially equivalent both in its characteristics and its intended use to a predicate device. It therefore was entitled to be on the market. In fact, it had a right to be on the market. At all times it was lawfully on the market. The plaintiffs --

QUESTION: Mr. Geller, is it -- explain to us, if you would, the practice of the FDA with regard to authorized drugs and devices. If it is authorized, is an off-label use always allowed --

MR. GELLER: Yes.

QUESTION: -- by the FDA?

MR. GELLER: Yes. The FDA --

QUESTION: In fact, it's rather common?

MR. GELLER: Absolutely. In fact, many drugs and devices --

QUESTION: For instance, the use of, what is it, the cholesterol-reducing drugs for memory enhancement and that sort of thing is perfectly okay, even though it's authorized only for the cholesterol?

MR. GELLER: Absolutely. The statute is quite clear. Congress made it quite clear that the FDA has no control over the practice of medicine. All it does is approve drugs and devices to be marketed for particular purposes. Once they're on the market, physicians and surgeons are entitled to use the devices for any purpose consistent with their own medical judgment, and off-label --

QUESTION: Now, I assume these plaintiffs would have a cause of action against the physicians who made the judgment that it's okay to use them for the spine?

MR. GELLER: If that failed --

QUESTION: If, indeed, they're not safe for the spine?

MR. GELLER: If that fails to satisfy some State law duty of care.

In fact, Justice Souter, you can imagine a situation where a manufacturer here sought approval for these devices for a purpose of labeling them for long bones, and had absolutely no intent that they be used for anything else, a manufacturer with a perfectly clear heart

here, contrary to what they allege about these defendants. The device would have been on the market in exactly the same way these devices would have been on the market. The physicians and surgeons would have used them in exactly the same way these devices were used. The plaintiffs would have suffered exactly the same injuries.

So the flaw here is that these devices were entitled to be on the market. Once the intended use that was described in the 510(k) application was consistent with an intended use for devices such as these prior to 1976 --

QUESTION: No, I think -- I mean, I think I --

MR. GELLER: Okay.

QUESTION: -- get your point. The only issue that I was trying to raise was how we ought to characterize it. Should we characterize it as -- should we characterize their intent as inconsistent with the FDA approval, as distinct from consistent with a use that the FDA would not affirmatively take steps to stop, and that --

MR. GELLER: It is consistent --

QUESTION: That characterization might have an effect on the way we view --

MR. GELLER: My view, Your Honor, it -- what happened here was perfectly consistent with the FDA --

with the scheme and the FDA's decision here.

The FDA's decision here was that these devices had a right to be on the market because they satisfied 510(k). What happened thereafter, it may have been a marketing violation if they were marketed for other purposes, but it was in no way a fraud on the FDA, which is the allegation here, to seek approval. It is perfectly lawful -- let me say it this way.

It is perfectly lawful, perfectly consistent with the statute, perfectly protective of the public health, to seek approval under section 510(k) for a device by saying it has intended use A, even though you hope, expect, intend that once the device gets on the market it would be used primarily, or even exclusively, for use B. That's perfectly consistent with the Federal statutory scheme.

Now, what you can't do is market it for use B, but it's perfectly appropriate, under the statute, to represent to the FDA and put in your labeling that it has intended use A.

QUESTION: And the marketing, you can't market it for use B.

MR. GELLER: You cannot market it.

QUESTION: That's part of which statute?

MR. GELLER: That's part of the food and drug

laws. That may well be misbranded or adulterated if you market it for use B when it only has intended use A, but when you do that you violated the marketing regulation. It's in no way a fraud on the FDA, which is what the allegation is here.

QUESTION: If it helps bring you to the argument on implied preemption, which I'm anxious to hear --

MR. GELLER: Yes.

QUESTION: -- let me just ask you this question. Suppose a consultant like your client here, in assisting the labeling of a drug or device, does not disclose a side effect, and the side effect is not on the label, and somebody's injured because they have the side effect, and the allegation is that they knew about the side effect and deliberately withheld it. Is there a cause of action under some States, under this State?

MR. GELLER: No. I --

QUESTION: Is there implied preemption --

MR. GELLER: Our position --

QUESTION: -- and if so, why should that be?

MR. GELLER: I think it should be, Justice Kennedy, because Congress ultimately made a decision that there is not to be a private right of action for violation of the Federal Food, Drug, and Cosmetic Act, that all violations of the act or suspected violations are to be

enforced by the Food & Drug Administration in its ultimate discretion.

This is section 336 and 337 of the act. The FDA is to decide whether there is a violation and, if there is a violation, the FDA is to decide whether it's a significant enough violation to cause some sort of penalties to be imposed, and this was a very, very important part of Congress' scheme.

Unlike many other regulatory statutes, the securities laws, the antitrust laws, Congress here decided there should not be a private right of action and the reason is because you're dealing here with the public health. There may well be misrepresentations to the FDA in an application and yet it's important to have the device remain on the market for the public health.

QUESTION: Mr. Geller, suppose the case was one in which the FDA decided that the misrepresentation, assuming there was one, was sufficient to justify taking it off the market. Would a person who was injured during the period it was on the market have any remedy at all, either State or Federal?

MR. GELLER: Well, obviously it's not this case, but --

QUESTION: No, I understand that.

MR. GELLER: -- I would say no because of the

Congress' decision not to provide -- you cannot bring a cause of action that enforces the Federal Food & Drug laws. Now, there may well be a State -- as in Medtronic --

QUESTION: Even though the Federal agency might have found there was, in fact, exactly the violation?

MR. GELLER: Absolutely, because there's too great a danger I think, Justice Stevens, that a State court might impose a remedy that is completely inconsistent with the remedy that the FDA itself would have decided was appropriate in that situation.

And here, you know, this is a -- this is the contrasting situation, if I could, and I'd like to save some time for rebuttal, but this is a situation in which all of the allegations of so-called fraud in the plaintiffs' complaint here were presented to the Food & Drug Administration not on one occasion but on at least two occasions.

Thousands and thousands of pages of documents that allegedly documented this fraud were presented to the FDA in a citizens' position, and when the FDA was reclassifying bone screws. The FDA decided not to do anything. It obviously didn't feel itself defrauded. It decided not to take these devices in any way off the market, and yet the plaintiffs' fraud claim here would

have the potential to completely undermine this entire statutory scheme by allowing State courts and juries to second-guess the decision of the FDA to allow these devices to remain on the market to protect the public health.

If there are no further questions, I'd like to reserve the balance of my time.

QUESTION: Very well, Mr. Geller.

Mr. Gornstein, we'll hear from you.

ORAL ARGUMENT OF IRVING L. GORNSTEIN

ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE, SUPPORTING THE PETITIONER

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

The respondents' fraud on the FDA claim is impliedly preempted for two reasons. First, it conflicts with the Federal Government's exclusive authority to enforce the act's prohibitions against fraud on the FDA and second, it conflicts with the FDA's decision clearing the devices at issue here for marketing.

Now, as to the first point, the act expressly gives to the Federal Government exclusive authority to enforce the act's prohibitions against fraud on the FDA, and the claim here conflicts with that allocation of authority because it asks the States to impose on an

individual an obligation not to defraud the FDA.

Now, in this area of preeminent Federal concern, there is no room for that State rule. It is up to the Federal Government to decide whether the FDA has been defrauded and, if so, what to do about it, and that is particularly true when the question is whether the FDA's own internal decision-making process has been corrupted through an act of fraud.

Now, as to the second point, the --

QUESTION: And would you give the same answer Mr. Geller did? Assume the FDA concluded that its processes had been corrupted by the acts of fraud, and so forth and so on. Is there any way the FDA could give a remedy to people who were injured by that fraud?

MR. GORNSTEIN: The people who were -- there would not be an injury for the fraud, but there would be whatever other claims --

QUESTION: You mean, there would not be a remedy for the fraud?

MR. GORNSTEIN: For the -- there would not be private damage actions for the fraud on the FDA.

QUESTION: So the category of people who might exist -- I'm not suggesting that's this case, but who might have been injured by that fraud would have absolutely no remedy?

MR. GORNSTEIN: The only remedies they would have are the other remedies that State laws affords if the product was --

QUESTION: But I -- they're preempted.

MR. GORNSTEIN: Well, let me just continue. The fraud claim is preempted, but if there is negligent design, negligent manufacturing, failure to warn, common law malpractice, all of those claims are available, but insofar as they would be asserting an essential element of the claim would be that the FDA was defrauded, that is an area of exclusive Federal concern, and the State common law cause of action would be preempted.

QUESTION: What happens if the --

QUESTION: What's the Federal provision on fraud on the FDA? What is that?

MR. GORNSTEIN: 331(q)(2) is the prohibition against fraud, 21 U.S.C. 331(q)(2), which I don't think is included in any of the materials here.

QUESTION: That's --

MR. GORNSTEIN: And the exclusive enforcement is 21 U.S.C. 337(a), which with certain limited exceptions gives the Federal Government exclusive authority to enforce the act's prohibitions.

QUESTION: What would happen if an expert gave fraudulent or negligent, two different hypotheticals,

information to an attorney, and the attorney then made a submission to the court, and the court makes a ruling, and the ruling is against the adversary party, can the adversary party then sue the expert just under State law, and does this happen all the time, or would the courts have in -- throughout the States the same argument that you're making here, oh, we don't want a lot of satellite litigation, we don't want to be deluged? Are there cases on the books that tell us about this, or --

MR. GORNSTEIN: I'm not aware of cases, but we think the same general principle, if a court is defrauded and its judgment permits certain conduct, then the method to go about getting relief from that is to go back to the court and say that that judgment has been secured by fraud, and the same thing is true here.

QUESTION: This theory hasn't been tried?

MR. GORNSTEIN: I have not seen that theory tried, Justice Kennedy.

Now, the second reason that there's preemption here, and this is a second and independent reason, is that the State law common law claim conflicts with the Federal clearance decision, and the reason --

QUESTION: The what?

MR. GORNSTEIN: The FDA's decision clearing the devices at issue for marketing, and the reason that it

does is that an essential element of this claim is that the devices never should have come to market under Federal law, whereas the FDA has determined that they should, and the fact that there is an allegation here that that decision was secured through fraud does not avert the conflict, because the FDA can reconsider its decisions and withdraw them if it determines they've been secured by fraud, but unless and until it does that, those decisions remain binding and authoritative, and they preempt any conflicting State law claims.

QUESTION: But you're going further. You're saying even if they did find it was procured by fraud, there would still be preemption.

MR. GORNSTEIN: Yes, Justice Stevens, but that's under my first argument and not under my second argument.

QUESTION: Well, you'd say there would be preemption up to the point when the FDA reviews the matter and concludes that it has been defrauded. Then would you say -- I'm just trying to follow Justice Kennedy's judicial analogy. If you went back to a court and the court concluded it had, indeed, been duped, you'd probably then have a private lawsuit.

MR. GORNSTEIN: You probably do, Justice Scalia, and there may not be a perfect analogy here, because --

QUESTION: Because you don't think there would

be a private lawsuit, even after the FDA came to the conclusion that indeed --

MR. GORNSTEIN: That's correct, because the second theory of preemption would be gone, but our first theory of preemption, which is that this is a matter of exclusive Federal control over the decision as to whether there's fraud and what the remedies for that should be, would still be in effect.

QUESTION: In other words -- I'm sorry. In other words, the FDA can do its own fraud prosecution and the FDA can withdraw the drug from the market.

MR. GORNSTEIN: It can.

QUESTION: I mean, those are the reasons.

MR. GORNSTEIN: That's correct.

Now, finally, the final point I wanted to make is that the --

QUESTION: Excuse me. And if that happened, you would not object to a fraud suit at that point.

MR. GORNSTEIN: No. We --

QUESTION: Under --

MR. GORNSTEIN: There would still be a --

QUESTION: Under the implied preemption theory.

MR. GORNSTEIN: On the second implied preemption that I've given, which is that an outstanding Federal clearance decision, there would not be preemption, but --

because that would have been withdrawn, but on the first theory preemption I'm giving, which is that the decision about whether there is fraud and what the remedies for that should be, there would still be preemption of that claim. Now, either one of those theories is independently sufficient to resolve this case.

Now, the final point I wanted to make is that the respondents say that this case is just like Medtronic, and the claims here shouldn't be preempted for the same reasons the claims in Medtronic were not preempted, but there are three basic differences between the claims in Medtronic and the claim here.

The claims there, the State was performing its traditional role in enforcing ordinary duties of care running from the manufacturer to the consumer, whereas here it's seeking to impose an obligation on somebody not to defraud a Federal Government agency. The claims there had an existence that was completely independent of the Federal scheme. This claim is entirely derivative. Without this Federal regulatory scheme you could not have a fraud on the FDA claim.

And finally, the claims there were not preempted by the Federal clearance decision. They all assumed that the devices had been permissibly cleared under Federal law, whereas here, the claim conflicts with the Federal

clearance decision.

If there are no further questions --

QUESTION: Very well, Mr. Gornstein.

Mr. Fishbein, we'll hear from you.

ORAL ARGUMENT OF MICHAEL D. FISHBEIN

ON BEHALF OF THE RESPONDENT

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

We're here to determine whether or not the Food, Drug and Cosmetic Act, or the medical device amendments to that act, prevent the States from recognizing and awarding damages for -- which flow from allowing a device to enter the market through fraud on the FDA. I would suggest to the Court the answer to that question comes from the unanimous -- the unanimous portions of this Court's decision in Medtronic.

In Medtronic the Court was confronted with the question about whether or not the Food, Drug and Cosmetic Act and the medical amendments to the Food, Drug and Cosmetic Act preempt State common law claims which are founded on a violation of Federal requirements, and what the Court said, and said so unanimously, was that there is nothing in Federal law which prevented the States from affording a private damage remedy, one not given by Federal law at all, for violations of the Food, Drug, and

Cosmetic Act, or the medical device amendments to that act, and that was not limited to negligence cause of actions. It was focused on violations of the act.

In the present case, our claim does not derive from some newfangled principle of tort law. Our claim derives from a longstanding principle of tort law which has been in force in this country, in the States, in various forms since they became States, and that is the principle reflected in section 536 and 557(a) of the Restatement of Torts Second --

QUESTION: May I just --

QUESTION: But that's an extraordinary -- this is an extraordinary application of that principle.

MR. FISHBEIN: I don't believe so, Mr. Chief Justice, and I say that for this reason. The tort law does not only go to negligence per se, but tort law says that where one is required to file, furnish, or publish information by statute or regulation for the protection of the public, and makes a misrepresentation in doing so and harm follows from that, that you're entitled to recover damages.

QUESTION: From whom?

MR. FISHBEIN: That is true --

QUESTION: From whom?

MR. FISHBEIN: You're entitled to recover

damages from the maker of the misrepresentation, because that is where the culpable conduct lies.

Now, of course, it's true that that principle is not frequently invoked, because in many cases it's easier to go more directly through other tort principles, but that doesn't change the fact that that is a principle of tort law which is independent of the Federal scheme.

QUESTION: It is, but in ordinary tort law the third party who has been defrauded does not have the power to say authoritatively in any sense, I have not been defrauded. It will be up to the court to say whether he's been defrauded or not.

But here the alleged defraudee is a Federal agency that is empowered to decide authoritatively whether it's been defrauded or not.

MR. FISHBEIN: I agree with that statement, Justice Scalia, and I think that one of the important distinctions here is that this agency never said one way or the other whether they had been defrauded. There has never been a factual finding, either in connection with the 510(k) clearance premarket notification or subsequently, in which the FDA say we either were or were not defrauded, but if there was --

QUESTION: If the FDA --

MR. FISHBEIN: -- I would agree with you.

QUESTION: If -- supposing the FDA had opened the matter up, said we find we weren't defrauded, would you then have no claim?

MR. FISHBEIN: I think that that presents a more difficult question to --

QUESTION: Well, I'm asking you to fish or cut bait, so to speak.

(Laughter.)

MR. FISHBEIN: I would argue, Your Honor, even under those circumstances, unless we were party to the adjudication, or that was made through a formal notice and comment proceeding, that we were not bound by that. However, I believe that at least in that circumstance there's the argument that allowing a jury to find a contrary fact cuts against what the FDA decided.

QUESTION: Suppose you get a judicial determination that in fact the FDA has been defrauded, does that have any effect on the FDA's approval for the marketing of this device?

MR. FISHBEIN: You mean in private litigation, Justice Scalia, or --

QUESTION: You win this suit, and the basis for your winning it is a determination by the Court that the FDA has been defrauded. Does the FDA have to withdraw the medical device from the market?

MR. FISHBEIN: No, Your Honor, and that's one of the points that we make here, is that --

QUESTION: This produces a very crazy system, doesn't it, where you have a bunch of State courts going around saying that the FDA has been defrauded and has been duped into approving this and the FDA continuing to allow it to go out there? Why would we want a system that allows these contrary authoritative determinations to bounce around?

MR. FISHBEIN: Your Honor, I think we have such a system. Indeed, it's common in our system. Just to use a basic analogy, if I could, the State establishes a law saying you can't -- we're going to put a stop light up at the corner, and you can't run the stop light. The State has the power to enforce that through criminal sanctions and administrative sanctions.

You run through the stop light, the State can either choose or not choose to prosecute you, they can choose or not choose what remedy to afford, but there's no doubt, we all know this from our basic tort law, that the injured individual, notwithstanding the potential exercise of State power, has the right to go into court and recover damages for that violation.

QUESTION: Yes, but this is not that.

QUESTION: That example is quite different. Can

I just suggest why, and I would really like you to focus on it. Here, your claim is not only that they were defrauded, but that the fraud was sufficiently serious, that's responsible for the item being on the market, and so if they keep the item on -- say the FDA had an investigation, you had a jury, everybody agreed there was fraud, but everybody also agreed the fraud was not sufficiently serious to take the item off the market, it was kind of immaterial, that's quite a different case from the red light case.

MR. FISHBEIN: Your Honor, I do not believe that a determination has ever been made that the device should not be kept on the market, and I think that goes to what's involved in a so-called 510(k) clearance.

QUESTION: Well, no. It's involved in your lawsuit, as I understand it. One of the steps in the sort of, the change of causation is that in your argument -- your complaint, if I understand, is, but for the fraud, this item would not be on the market. Is that correct?

MR. FISHBEIN: That's correct, Your Honor.

QUESTION: Okay.

MR. FISHBEIN: And the point I want to make here is simply this. When the FDA receives a 510(k) notification it has to determine -- it only has the power, not to clear the device for the market or not clear the

device for the market. Under 21 C.F.R. section -- I think it's 807.100, the FDA has three choices when it gets a 510(k) market, premarket notification. It can either say that the device is substantially equivalent to a predicate device for the use intended by the applicant, it's not substantially equivalent, or it can ask for more information.

Now, what the FDA did here was exactly what they typically do. They looked at the proposed labeling they were given, which was not accurate labeling because it was not truthful reflection of the intended marketing for this device, which is required under the regulations, but the applicant --

QUESTION: Excuse me. No, you can't say that, that it wasn't a truthful reflection of the intended marketing. I think it's been conceded by Mr. Geller that if they marketed this for the use that you claimed harmed your clients they would have been in violation, wouldn't they?

MR. FISHBEIN: Yes, sir.

QUESTION: So it isn't a matter of what's the intended marketing. The issue is what is the intended use.

MR. FISHBEIN: I agree with that, Justice Scalia.

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QUESTION: And the intended use, according to Mr. Geller, is a term of art, which means the use for which you want FDA approval.

MR. FISHBEIN: I disagree with that, Justice Scalia, and I think that it's clear, and the Government agrees with this position, that intended use not only in this section of the statute but every other place is defined objectively by the manner in which the proponent of the device intends to characterize the device in the market.

And I think it's significant that in the regulations governing 510(k) disclosure -- I believe it's 807.87(e) of title 21, or of 21 C.F.R. -- what the FDA says is, don't just give us the label that's going to accompany this product. You are obliged to give us the labeling sufficient to describe the intended use of the device, and labeling through a series of case law and decisions says that it is not only -- and in your decision in Cordell, in fact, it is not only what is on the product, it is the promotional materials which accompany the product which demonstrate how the product will be characterized in the marketplace which determine intended use, and that is consistent with the legislative scheme. Congress --

QUESTION: Are those promotional materials

attached to the application to the FDA?

MR. FISHBEIN: Frequently they are, Justice Ginsburg. In this case they were not, and my point is simply that it is not sufficient to come to the FDA and say, here is a screw, I'm going to use this as a screw to build crutches, when you know darned well that you're never going to characterize it that way in the market. It's not a crutch screw, it's a bone screw, and --

QUESTION: But the thing that makes this case so peculiar is, a Government agency, a private Attorney General coming in to say that the agency has been defrauded. I don't know of any precedent for a private citizen coming in and saying, Government agency, I'm going to be your champion, you have been defrauded.

It's not like in the SEC. The SEC says, yeah, we need people to help us enforce because we can't go after all those bad actors, quite different from here, saying, agency, you've been defrauded, and we private citizens are going to decide. Is there any precedent, anything like this?

MR. FISHBEIN: I believe that there is, Justice Ginsburg. I think, in fact, your opinion in Medtronic, at least the unanimous portion, says that private plaintiffs can rely upon violations of food, drug, and cosmetic law if they can otherwise do so under State law to recover

damages.

QUESTION: I don't mean the FDA, because as far as I know this is a novel claim. Is there any case where citizen X has successfully maintained a claim for fraud on any three- or four-letter agency that you want to pick?

MR. FISHBEIN: I believe in the securities area there is, Your Honor. I can't cite the case, but your -- this Court's recognized --

QUESTION: Where there's a claim for fraud on the SEC?

MR. FISHBEIN: Sure. Where you have a false filing with the SEC and people purchase in reliance on the false information contained in that filing, I think it is actually a statutory cause of action.

QUESTION: That's a -- but that's --

QUESTION: That's fraud on them. I mean, once you have a false -- you made a false statement in a filing that you know is going to be presented to -- in a prospectus that you know is going to be presented to buyers, that's fraud on them, but this is not fraud on your clients. I mean, this is quite a different situation.

MR. FISHBEIN: It is not fraud on our clients, Justice Scalia, but the common law does not require as a tort matter fraud on the clients.

QUESTION: Do you have another example besides the SEC filings, which are, of course, meant to be presented to the investors and therefore constitute fraud on the investors themselves?

MR. FISHBEIN: There was a case, an important case decided by the Third Circuit, not by you, by Justice Becker, called Stanton By Brooks v. Astro Pharmaceutical, which held in the early 1980's that the failure to discharge duties of disclosure in connection with a drug or device rendered the product defective per se under section 402 of the Restatement, and allowed a court to award damages based on the theory that the FDA, had they received appropriate disclosures, would have acted differently and would have protected the plaintiff from injury and therefore which allowed recovery.

There are also other appellate cases within the appellate system which are cited in our brief, Learjet v. Spindlauer, which I think is a Fifth Circuit case, and there are a few others which recognize -- and that case was an aviation case, where a fraudulent -- a license was obtained fraudulently from the FAA, also a case called Hawkins, cited in our briefs, where the -- again a Federal court case, an appellate case, where the court recognized that that kind of misrepresentation changes the whole regulatory calculus, deprives the public of an informed

decision with respect to the product, and that could render the product dangerous and people can recover based on that.

So there is a recognition both in the common law of that, and what I would suggest is that in Medtronic, both explicitly and as a matter of implied preemption which is not dealt with directly in Medtronic, that States are not foreclosed from doing that, because there is no impact here on any function with which the FDA is entrusted.

QUESTION: Well, I found it rather hard to find that in my opinion in Medtronic, which was a separate opinion.

MR. FISHBEIN: Your opinion, Justice Breyer, was the one opinion which didn't go off on the distinction between remedies and requirements and the State --

QUESTION: I mean, I would find it surprising, wouldn't you, that if you have a private right of action, to say in any of the thousands and thousands of State agencies or Federal agencies that what the State did, you see, what these people did is, they got their brief in late. They got their brief in late, violating the Federal -- violating the agency rule, and if they -- doing that, they wouldn't have gotten the approval.

MR. FISHBEIN: Well --

QUESTION: There would be no cause of action there.

MR. FISHBEIN: No, there wouldn't be.

QUESTION: No, all right, so -- and because it would be up to the agency to enforce its own rule, isn't it?

MR. FISHBEIN: No. I would have a different reason for that, Your Honor, and the reason I would advance for that --

QUESTION: Is?

MR. FISHBEIN: -- is that in that particular circumstance the failure to follow Federal law was not something that had to do with the safety of --

QUESTION: No, no, no. Whether it's Federal or State, I don't care. I mean, take any agency you want. Take a municipal council, I don't care. It would just be amazing to me that you'd find somebody getting a private right of action based upon, under ordinary tort law principles, based upon the agency not following its own procedural rules, that the person violated some procedural rule, because you'd say that's up to the agency, and of course my question is, how is this any different, and of course my opinion in Medtronic says that we look to see what the agency wants and if the agency thinks it's preempted, good-bye, and that seems to me in essence what

you have here.

Now, I'm putting it that to you to get an answer, not because I'm wedded to it.

MR. FISHBEIN: There's a couple of embedded questions in there, Your Honor. One, I do believe it's a traditional principle of tort law, not as a matter of implying cause of action but as a matter of negligence per se, or liability per se, that where somebody violates a statute or regulation, regardless of who's in charge of administering that statute or regulation intended for the protection of the public, any harm caused by that is actionable under State law, not because you're implying a, in the case of Federal law a Federal cause of action, but just as a matter of negligence per se.

So the question then is, is this a substantive safety regulation that we're talking about here, or is it a procedural regulation, and I say it's a substantive safety regulation, because the heart of the Federal scheme, and there's hundreds of cases on this regulating food, drug, and cosmetics, is, you are only regulating by -- with respect to what the device or drug is, and that is a function of two things, both what it physically is and what it's conceived to be for marketing purposes, and if you misrepresent to the public what it is, or you misrepresent to the agency what it is, you're undermining

the central safety aspects here.

For -- it's easy to see that in this case, because when the agency was told this was a spinal fixation device and that that's what it was, they said, you can't put that on the market.

QUESTION: There are a number of things. We're on precisely the same track, because in my mind I was thinking substantive/procedural, something like that, and what's fraud, and then if I push it towards -- I can be elliptical because I think we're thinking alike.

The -- if you push it towards the substantive side, then I get into the problem of the agency having a bunch of powers. They could enforce it through injunctive relief, monetary penalties, seizure, criminal prosecutions, withdrawal of market clearance.

And then I think, well, shouldn't that be up to them? I mean, after all, their job is to protect the public from monopoly, and if they think that really this particular misrepresentation is not that serious in light of their basic job, shouldn't it be up to them to decide how to enforce it rather than up to a jury?

MR. FISHBEIN: We don't know here whether they think it's serious or not, so that's the first point, but more fundamentally, insofar as the remedies that you've enumerated are concerned, I do believe that the FDA has

exclusive prosecutorial discretion. I do think that section 337 of title 21 does preempt the ability of States to give, for example, injunctive relief, civil penalties, and to suspend somebody's license to sell these products. I agree with all that.

But what the Federal law doesn't give, and what Congress reserved to the States when it passed the Federal law, it doesn't give anybody the ability to compensate the victims that I represent for the damages that he's sustained as a result of the fraud.

QUESTION: That's because the FDA doesn't want them compensated for this kind of thing because it's decided that the harm to them, which they're not understating, would be outweighed by the need to get this drug on the market to fight the monopolistic advantage that people would have without it being there.

MR. FISHBEIN: Your Honor, they made no such determination in this case.

QUESTION: No, no, that's true, but they say, the way we make these determination is by deciding which remedy to pick, and we pick the lesser ones when we think we want this thing on the market. We pick the greater ones when it should be gotten rid of, and if you leave it up to the jury, of course, that's the same as getting rid of the product.

MR. FISHBEIN: I disagree that it's the same as getting rid of the product. What happened is, the product as bone screws entered the market, I say unlawfully. Now, if the FDA has not revoked the 510(k) clearance it's because the product is still legitimately on the market as a bone-screw product. The problem is here, we have an illegitimate pretextual application which the Government concedes was pretextual and would be improper if the facts we allege are true.

QUESTION: Mr. Fishbein, may I stop you there --

MR. FISHBEIN: Certainly, Your Honor.

QUESTION: -- because I didn't realize that was the Government's concession, and Mr. Geller told us that there was indeed an effort to go to the FDA to complain about this and it was unsuccessful.

MR. FISHBEIN: The F -- we have gone to the FDA and they have not ruled yea or nay, and I believe that their brief concedes that they have not made a determination as to the lawfulness of this conduct in any context, both when the application was received by them, or subsequently, and they take the position that when someone applies for 510(k) clearance they cannot simply list a use, an intended use, in quotes, which is pretextual.

The Government's position, and I think it's

right, is that the use must be bona fide. You must intend, the product must have an intended use, meaning you intend to characterize it in the market for that use.

Now, true --

QUESTION: Shouldn't there be some, even a notion of -- assuming that there could be such a complaint at all, of primary jurisdiction, or exhaustion or something, to let the agency speak for itself? If it doesn't think that it's been defrauded, that should be the end of it.

MR. FISHBEIN: The doctrine of exhaustion I think does not apply here, because that presupposes that the agency has the power to give a remedy that the plaintiffs want and in this case that would be damages, and the agency clearly does not have that power.

The doctrine of primary jurisdiction is a doctrine which enables a court to make a referral to an agency to make a determination of some issue of fact that's germane to the case. Of course, nobody asked for such a referral here and, looking at your recent case, Southwest Marine, Inc. v. Gissone and Rider v. Cooper, it seemed to me that if there was no primary jurisdiction asserted in those cases, one, for example, whether someone had Longshoreman and Harbor Workers Compensation Act status or seaman status, that was not to be referred to

the agency there, that this seemed to me to be an inappropriate case for the exercise of primary jurisdiction.

QUESTION: Mr. Fishbein, even if you say in this case the agency hasn't ruled yea or nay on the particular facts here, do you have at least some other case where the FDA, which has this authority to find that it has been defrauded, has withdrawn something from the market or has imposed some other penalty because the application did not contain uses that were anticipated, although they were not set forth in the application?

MR. FISHBEIN: I know of no such case, Justice Scalia, but that's not our position.

QUESTION: Don't you think that's significant? Doesn't it tend to support Mr. Geller's contention that all the FDA cares about is what use do you want authority to market for, and so long as you set forth that use, you'll have authority to market for it, and anything else, you may anticipate it's going to be used for other things, but that's all we're approving, is this marketed use?

MR. FISHBEIN: But Justice Scalia, that's not the agency's position and that's not what its regulations say. They say that you must furnish the agency with a bona fide intended use, not a pretextual one, meaning that at least as to the use that you're listing to the agency,

you intend to characterize that device in the marketplace in that manner.

QUESTION: You intend to market it for that use, and there is no allegation here that it was marketed for anything except the approved uses.

MR. FISHBEIN: That's not correct, Justice Scalia.

QUESTION: It isn't?

MR. FISHBEIN: The allegation to the complaint here and the factual support here indicate that this device was never, never marketed for long-bone use. It was only marketed for spinal application, and it was marketed -- in fact, the president of AcroMed within a few days of this clearance told somebody that this was -- their application to the FDA was a labeling sleight of hand which in no way changes the intended use of the product.

There virtually is fraud conceded here by virtue of the circumstances. It's an unusual circumstance, I grant. There's not too many people that would be this brazen, but that's what happened here.

QUESTION: There is a contest on that point, as to whether it was marketed improperly. Mr. Geller says it wasn't. Your cite says it was.

MR. FISHBEIN: It was not marketed properly. It

was -- in fact, it was -- we contend that this fraud did not occur by itself but occurred as part of a deal, or a concocted scheme between Buckman and AcroMed as a two-step process. First, they couldn't get it on the market as a pedical screw fixation device, which is all it ever was. So they lied to the FDA, then they got clearance, meaning, it was found substantially equivalent for long-bone use, but they knew they were going to market it the second it got approved for -- not for long-bone use. There's not a person in the United States that ever received this, as far as we can tell, for long-bone application, and --

QUESTION: Mr. Fishbein, are there other State causes of action that your client could pursue that don't raise this problem of having to establish that the FDA called it wrong, a failure to warn, or some other kind of negligence cause of action?

MR. FISHBEIN: The answer to your question, Justice O'Connor, is, as to Buckman, no. As to other defendants, yes, but as to other defendants, why would we bring Buckman in this if we had other solvent defendants? The principal defendant here was AcroMed Corporation. AcroMed Corporation was basically insolvent with respect to this liability and we ended up settling our claims against AcroMed on a limited --

QUESTION: So Buckman is the one that has the assets and therefore you need a different cause of action.

MR. FISHBEIN: They have additional assets, that's correct, and we are attempting to try to recover for our clients all the damages to which they're legally entitled. I suspect even Buckman does not have sufficient assets, because this fraud and its consequences were so widespread and caused so much injury that there's simply not enough money with the potential culpable defendants.

QUESTION: But the cause of action does require the jury to decide, in effect to second-guess the FDA?

MR. FISHBEIN: I disagree with that, Justice O'Connor, and here's why. The FDA did nothing wrong, or nothing that needs to be second-guessed. They were told -- if we look at page 58 of the joint appendix, the FDA asked Buckman, what is the intended use of this device? Page 58 is a letter from Buckman back to the FDA, because the FDA had reviewed this and seen it was a spinal device before.

Now it's being presented as a long-bone device, and Mr. Shlerf of Buckman said, for purposes of this 510(k), this is a long-bone fixation device, and as a long-bone fixation device, the FDA was correct in determining that there were predicate devices on the market which had the same technical characteristics as

this device, and it was okay.

There's nothing about our claim that would require a jury to say the FDA was wrong. In fact --

QUESTION: Well, except section 132 of the complaint says, were it not for these fraudulent acts and statements the FDA would not have issued the 510(k) clearances for the screw for any purpose, the devices wouldn't have been introduced into interstate commerce, and plaintiff wouldn't have been exposed.

MR. FISHBEIN: Yes, Your Honor.

QUESTION: I mean, that looks pretty much like second-guessing to me.

MR. FISHBEIN: Actually, it's enforcing what the FDA had previously determined on two occasions, one of which was about 3 or 4 months before that. The FDA made a specific determination that these devices were not substantially equivalent for pedical screw use or spinal use twice, and the consequence of that was that they didn't belong in the market.

So what we're doing here is simply vindicating an explicit regulatory determination made to protect persons in the position of the plaintiff from the kind of harm that occurred here.

QUESTION: But you're also something of an interloper. I mean, under the Government's view the FDA

has various authorities to follow this thing up and may choose not to follow it up.

MR. FISHBEIN: That's correct, Your Honor, but the Government's authority is in its capacity to protect the public through the remedies given to it, and my contention is, and I think --

QUESTION: Well, the Government's authority is also to limit those remedies if it so chooses.

MR. FISHBEIN: I would suggest, Your Honor, that the Government has no power to limit the availability of damage relief and that Congress did not want it to limit the availability of damage relief.

QUESTION: Well, if you say Congress didn't intend to limit damages you're probably right, but the Government -- assuming if Congress felt otherwise it would be true, too.

MR. FISHBEIN: Oh, if Congress said no damages? There's no question that Congress has the power to do that.

QUESTION: No, but specifically, assuming what you say is right, after the event the FDA finds out about this, it says, we want to leave this stuff out there, because it's more helpful than it is harmful, and therefore we give you a wrist slap, you see, and why are they doing that? Because they want the drug out there to

lower price.

Now, you come along and say, I'm going to a jury, and that will make sure it can't be out there.

Now, why doesn't this range of remedies give the FDA just the authority that I mentioned, an authority that you'll take away from them if you go to the jury, however meritorious your case might be here?

MR. FISHBEIN: I think, Your Honor, that Silkwood basically answers that question both in terms of the majority and the dissent in Silkwood, which said that there is an independence here of regulatory restraint and damage recovery which can and should and must peacefully coexist with one another, so that the FDA, or in that case the nuclear regulatory authorities, regulate -- from a public regulatory standpoint they do what they do and the State courts administer a remedy system which may, in fact, have penal aspects to it, because in Silkwood, remember, there was an award of punitive damages. We're not asking for that here.

So I think that the two can peacefully coexist, and it's up to the State system applying State rules -- there are some States that would not allow us to recover here, but there are many others that would, and there's -- I think what Congress made clear in enacting both the Food, Drug, and Cosmetic Act and the medical device

amendments to that act, was that empowering the FDA to have certain nondamage remedies should not usurp the State's power to provide remedies for people who are hurt.

QUESTION: Thank you, Mr. Fishbein.

MR. FISHBEIN: Thank you, Your Honor.

QUESTION: Mr. Geller, you have 2 minutes remaining.

REBUTTAL ARGUMENT OF KENNETH S. GELLER

ON BEHALF OF THE PETITIONER

MR. GELLER: Thank you, Mr. Chief Justice. Just a few things.

First, in response to Justice Scalia's question, there is no precedent for this cause of action. Every court of appeals, with the exception of the court below, has held that the so-called fraud-on-the-agency claims are preempted.

Secondly, I want to address Medtronic, which is the centerpiece of the plaintiff's argument here. This case is completely unlike Medtronic, in part for some of the reasons Mr. Gornstein was getting into. Medtronic was a garden-variety product liability claim under State law, design defect, failure to warn. There was no requirement in Medtronic that the Food, Drug, and Cosmetic Act be construed, there was no suggestion that you had to inquire into any agency determinations, there was no fraud-on-

the-agency claim in Medtronic, and there was no claim of implied preemption in Medtronic.

In fact, the existence of Medtronic suggests, the decision in Medtronic suggests that the plaintiffs have many common law claims available to them if these products were defective, so it's not a case that the Court was confronted with in Medtronic, where the argument of preemption would have wiped out many preexisting State law claims. Here, no claim -- the States would not be ousted of any claim that would have existed prior to the enactment of the medical device amendments in this case.

Third, I just want to focus for the Court's attention at, if you look at page 136 of the joint appendix there's a strong suggestion here that what the plaintiff's label as fraud on the FDA the irony here is, actually was an idea that originated with the FDA to break up this one device into its two constituent parts and to seek 510(k) approval for each, so the notion that a State court years later could conclude this was a fraud on the FDA and enter a judgment that would -- might have the effect of removing the device from the market is completely inconsistent, we think, with Congress' scheme here, which is to centralize enforcement authority with the FDA.

QUESTION: Mr. Geller, I don't understand one

thing about your case.

MR. GELLER: Yes.

QUESTION: I don't want to eat up your time, but do you contend that your client must -- that a bona fide intended use is at least an intended use that you intend to market? Do you --

MR. GELLER: No.

QUESTION: What is bona fide --

MR. GELLER: No, there's absolutely no requirement.

QUESTION: You don't even have to intend to market it?

MR. GELLER: You do not have to --

QUESTION: What does bona fide mean, then?

MR. GELLER: It's not our -- it's not our word, it's the plaintiff's word. What you have -- you're seeking approval to market for a particular -- for a particular use. You can't market for some other use, but there's no requirement under the law that you market for that use.

Many devices and drugs are on the market --

QUESTION: Then why do we have a fraud cause of action, as opposed to a cause -- on the part of the agency, as opposed to a cause of action for failing to abide by the terms of your regulatory applications?

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MR. GELLER: Well, Justice -- if I may answer the question, Mr. Chief Justice.

Justice Souter in making a 510(k) application, you not only have to provide the intended use, you also have to provide many details about the physical or technological characteristics of the device. There may be test results that are presented. There are many occasions where you might actually present fraudulent information but it doesn't relate to the intended use.

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

(Whereupon, at 11:00 a.m., the case in the above-entitled matter was submitted.)

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