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IN THE SUPREME COURT OF THE UNITED STATES

- - - - -X
BUCKMAN COMPANY, :
Petitioner :
v. : No. 98-1768
PLAINTIFFS' LEGAL COMMITTEE :
- - - - -X

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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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,

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

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

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

25 MR. GELLER: Justice Souter, they would have to

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

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

5 MR. GELLER: It would --

6 QUESTION: I'm sorry, go ahead.

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

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

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

1 spinal surgery?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 MR. GELLER: Yes.

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

14 MR. GELLER: No, I think --

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

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

19 QUESTION: Okay.

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

1 judgment, to use those devices for --

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

4 MR. GELLER: That's --

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

8 MR. GELLER: The FDA --

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

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

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

18 MR. GELLER: Yes.

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

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

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

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

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

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

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

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

20 MR. GELLER: Yes.

21 QUESTION: -- by the FDA?

22 MR. GELLER: Yes. The FDA --

23 QUESTION: In fact, it's rather common?

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

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

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

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

16 MR. GELLER: If that failed --

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

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

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

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

7 So the flaw here is that these devices were
8 entitled to be on the market. Once the intended use that
9 was described in the 510(k) application was consistent
10 with an intended use for devices such as these prior to
11 1976 --

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

13 MR. GELLER: Okay.

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

21 MR. GELLER: It is consistent --

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

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

1 with the scheme and the FDA's decision here.

2 The FDA's decision here was that these devices
3 had a right to be on the market because they satisfied
4 510(k). What happened thereafter, it may have been a
5 marketing violation if they were marketed for other
6 purposes, but it was in no way a fraud on the FDA, which
7 is the allegation here, to seek approval. It is perfectly
8 lawful -- let me say it this way.

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

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

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

23 MR. GELLER: You cannot market it.

24 QUESTION: That's part of which statute?

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

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

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

8 MR. GELLER: Yes.

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

17 MR. GELLER: No. I --

18 QUESTION: Is there implied preemption --

19 MR. GELLER: Our position --

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

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

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

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

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

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

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

24 QUESTION: No, I understand that.

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

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

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

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

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

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

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

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

8 QUESTION: Very well, Mr. Geller.

9 Mr. Gornstein, we'll hear from you.

10 ORAL ARGUMENT OF IRVING L. GORNSTEIN

11 ON BEHALF OF THE UNITED STATES, AS AMICUS CURIAE,

12 SUPPORTING THE PETITIONER

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

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

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

1 individual an obligation not to defraud the FDA.

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

9 Now, as to the second point, the --

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

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

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

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

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

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

4 QUESTION: But I -- they're preempted.

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

13 QUESTION: What happens if the --

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

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

19 QUESTION: That's --

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

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

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

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

16 QUESTION: This theory hasn't been tried?

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

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

23 QUESTION: The what?

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

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

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

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

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

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

25 QUESTION: Because you don't think there would

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

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

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

12 MR. GORNSTEIN: It can.

13 QUESTION: I mean, those are the reasons.

14 MR. GORNSTEIN: That's correct.

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

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

19 MR. GORNSTEIN: No. We --

20 QUESTION: Under --

21 MR. GORNSTEIN: There would still be a --

22 QUESTION: Under the implied preemption theory.

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

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

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

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

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

1 clearance decision.

2 If there are no further questions --

3 QUESTION: Very well, Mr. Gornstein.

4 Mr. Fishbein, we'll hear from you.

5 ORAL ARGUMENT OF MICHAEL D. FISHBEIN

6 ON BEHALF OF THE RESPONDENT

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

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

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

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

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

11 QUESTION: May I just --

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

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

22 QUESTION: From whom?

23 MR. FISHBEIN: That is true --

24 QUESTION: From whom?

25 MR. FISHBEIN: You're entitled to recover

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

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

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

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

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

24 QUESTION: If the FDA --

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

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

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

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

8 (Laughter.)

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

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

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

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

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

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

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

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

24 QUESTION: Yes, but this is not that.

25 QUESTION: That example is quite different. Can

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

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

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

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

21 QUESTION: Okay.

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

1 device for the market. Under 21 C.F.R. section -- I think
2 it's 807.100, the FDA has three choices when it gets a
3 510(k) market, premarket notification. It can either say
4 that the device is substantially equivalent to a predicate
5 device for the use intended by the applicant, it's not
6 substantially equivalent, or it can ask for more
7 information.

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

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

20 MR. FISHBEIN: Yes, sir.

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

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

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

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

11 And I think it's significant that in the
12 regulations governing 510(k) disclosure -- I believe it's
13 807.87(e) of title 21, or of 21 C.F.R. -- what the FDA
14 says is, don't just give us the label that's going to
15 accompany this product. You are obliged to give us the
16 labeling sufficient to describe the intended use of the
17 device, and labeling through a series of case law and
18 decisions says that it is not only -- and in your decision
19 in Cordell, in fact, it is not only what is on the
20 product, it is the promotional materials which accompany
21 the product which demonstrate how the product will be
22 characterized in the marketplace which determine intended
23 use, and that is consistent with the legislative scheme.
24 Congress --

25 QUESTION: Are those promotional materials

1 attached to the application to the FDA?

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

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

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

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

1 damages.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. FISHBEIN: Well --

1 QUESTION: There would be no cause of action
2 there.

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

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

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

10 QUESTION: Is?

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

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

1 you have here.

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

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

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

1 the central safety aspects here.

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

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

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

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

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

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

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

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

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

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

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

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

11 MR. FISHBEIN: Certainly, Your Honor.

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

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

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

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

4 Now, true --

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

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

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

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

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

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

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

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

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

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

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

8 QUESTION: It isn't?

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

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

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

25 MR. FISHBEIN: It was not marketed properly. It

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

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

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

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

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

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

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

20 Now it's being presented as a long-bone device,
21 and Mr. Shlerf of Buckman said, for purposes of this
22 510(k), this is a long-bone fixation device, and as a
23 long-bone fixation device, the FDA was correct in
24 determining that there were predicate devices on the
25 market which had the same technical characteristics as

1 this device, and it was okay.

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

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

10 MR. FISHBEIN: Yes, Your Honor.

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

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

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

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

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

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

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

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

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

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

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

1 lower price.

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

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

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

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

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

4 QUESTION: Thank you, Mr. Fishbein.

5 MR. FISHBEIN: Thank you, Your Honor.

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

8 REBUTTAL ARGUMENT OF KENNETH S. GELLER

9 ON BEHALF OF THE PETITIONER

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

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

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

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

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

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

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

1 thing about your case.

2 MR. GELLER: Yes.

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

7 MR. GELLER: No.

8 QUESTION: What is bona fide --

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

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

13 MR. GELLER: You do not have to --

14 QUESTION: What does bona fide mean, then?

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

21 Many devices and drugs are on the market --

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

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

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

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

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

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