

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, ET AL,	.	Docket Number: CA 95-1865
	.	
Plaintiff,	.	
	.	
v.	.	Washington, D.C.
	.	April 10, 2000
DONNA SHALALA,	.	10:00 a.m.
	.	
Defendant.	.	
	.	
. . . . .	.	

TRANSCRIPT OF PRELIMINARY INJUNCTION  
BEFORE THE HONORABLE GLADYS KESSLER  
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff:	JONATHAN W. EMORD, ESQUIRE CLAUDIA A. LEWIS-ENG, ESQUIRE Emord & Associates, P.C. Burke Professional Center 5282 Lyngate Court Burke, Virginia 22015 (202) 466-6937
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Court Reporter:

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dictation.

## P R O C E E D I N G S

1  
2 THE COURT: We are ready for our next case which is  
3 Durk Pearson, et al, versus Donna Shalala, Civil Action  
4 Number 95-1865. Would counsel please identify themselves for  
5 the record.

6 MR. EMORD: Jonathan Emord on behalf of the  
7 plaintiffs, Your Honor.

8 THE COURT: And with you is?

9 MR. EMORD: Claudia Lewis-Eng.

10 THE COURT: All right. For the defendants?

11 MS. STRAWN: Good morning, Your Honor. Susan  
12 Strawn for the government, and with me is Patricia Kaeding,  
13 of FDA.

14 THE COURT: Okay. This is here for a preliminary  
15 injunction and a request for expedition. I have read the  
16 papers, everybody. I have to say I have a clear recollection  
17 of struggling with the dispositive motions several years ago.  
18 I thought that this was one of the more difficult cases I  
19 had had.

20 The Court of Appeals came out differently than I  
21 did, although I actually think they may be right. And  
22 certainly whether they are right or not their opinion  
23 governs, I make that clear, and we are back now with the  
24 plaintiffs requesting expedition.

25 This is the plaintiffs' motion, so we will start  
26 with Mr. Emord. I have read the papers, everybody. I don't  
27 think that this is nearly as complex legally as the  
28 dispositive motions were the first time around. I  
29 would hope that in fifteen or twenty minutes at the most that  
30 the basic arguments could be made by each side, and I will  
31 undoubtedly have some questions.

32 Mr. Emord, please.

33 MR. EMORD: Thank you, Your Honor.

34 Your Honor, on April the 20th, 1999, this court  
35 issued its mandate to the Food and Drug Administration to  
36 implement the Pearson decision. That decision was handed  
37 down January the 15th, 1999.

38 Directly following the issuance of that mandate we  
39 waited for a time to see if the Food and Drug Administration  
40 would, within a reasonable period, issue an order authorizing  
41 the claims with the disclaimers that the court recommended,  
42 or at least publishing in the Federal Register --

43 THE COURT: Recommended or perhaps suggested would  
44 be more accurate, I think.

45 MR. EMORD: All right. The Food and Drug  
46 Administration did not publish any notice in the Federal  
47 Register revoking the rules that were invalidated by the  
48 United States Court of Appeals.

49 Those rules were invalidated. The court didn't  
50 simply remand the case for further rulemaking. It  
51 invalidated the rules based on a determination that those  
52 rules violated the First Amendment.

53 In particular those rules were the outward  
54 manifestation of the Food and Drug Administration's  
55 interpretation of the statute as it applied to the claims,

1 and the court held that interpretation invalid under the  
2 First Amendment.

3 Now when the court invalidated the rules it did so  
4 based primarily --

5 THE COURT: Let me interrupt you for a minute.

6 MR. EMORD: Yes.

7 THE COURT: Because I was -- I wanted to get the  
8 exact language of the Court of Appeals. They certainly  
9 invalidated the four regulations, but they did remand to me,  
10 with instructions for me to remand to FDA, for  
11 reconsideration of appellant's health claims.

12 That is an important distinction. They did not  
13 remand to me and then to FDA with order that the four health  
14 claims be put into effect. They clearly contemplated the  
15 word reconsideration, meaning that FDA should rethink its  
16 position.

17 MR. EMORD: No question about it, Your Honor. They  
18 contemplated reconsideration of the claims. However, they  
19 ruled those rules invalid. Those rules were its prohibition  
20 of the claims, and the invalidity was predicated on the fact  
21 that the agency lacked empirical evidence sufficient to  
22 satisfy the First Amendment standard.

23 The First Amendment standard is a condition  
24 precedent to government suppression of any commercial speech.

25 It must satisfy that burden of proof in order for it to  
26 suppress speech.

27 The court held that the empirical evidence  
28 necessary to establish a basis for suppression, consistent  
29 with Ibanez and consistent with the progeny of In re R.M.J.,  
30 was that the agency have empirical evidence to show that the  
31 harms it recited were real and that the restriction would  
32 elevate those harms to a material degree.

33 At the time of the Court of Appeals' decision, that  
34 empirical evidence was not present. To this day that  
35 empirical evidence is not present. The Supreme Court -- the  
36 First Amendment to the Constitution under obviously the  
37 Supremacy Clause, Article 6, Clause 2, is the supreme law of  
38 the land.

39 Agency construction to the contrary, and  
40 administrative convenience to the contrary notwithstanding,  
41 this agency may not, as a matter of constitutional law  
42 suppress these claims based on the invalidity of these rules,  
43 the constitutional invalidity of these rules.

44 The rules were merely the outward manifestation of  
45 the agency's interpretation of the statute. These rule  
46 makings --

47 THE COURT: Are you saying that the entire  
48 preclearance structure of the statutes, that that whole  
49 approach to the regulation is essentially unconstitutional in  
50 this case?

51 MR. EMORD: No. Not at all. That was not even an  
52 issue in the appeal, not at all.

53 THE COURT: I am well aware it wasn't, and that is  
54 why I asked you that question, because that is the  
55 government's argument. The government's argument is that you

1 cannot put these labels out there without having them  
2 precleared under the applicable statutory tests and  
3 constitutional tests, but without having them precleared by  
4 the government.

5 And I mean I am simplifying their argument, but  
6 that is step one, and step two is that they are going through  
7 that process, and step three of their argument is that they  
8 are not taking unduly long, and I guess their final step  
9 four is that they have made a promise to you, albeit only  
10 after great pressuring by you, appropriate pressuring by you,  
11 that they have made a promise that they will get them out in  
12 the 539 days I guess it is, which is actually a year and a  
13 half.

14 MR. EMORD: Actually, they have made no commitment  
15 to authorize the claims or allow them. They have made a  
16 determination that by October the 10th --

17 THE COURT: A decision will be made.

18 MR. EMORD: A decision will be made.

19 THE COURT: Right.

20 MR. EMORD: However, Your Honor, there is an  
21 important distinction that needs to be made here. These  
22 rules were not a product of the health petition, health claim  
23 petition process that they cite as a basis for their  
24 argument.

25 These rules were a part of a rule making ordered by  
26 Congress in the NLEA for ten specific nutrient disease  
27 relationship claims. Under that rule making that was  
28 pursuant to that statute, they made a determination not to  
29 authorize these claims predicated on an undefined significant  
30 scientific agreement standard.

31 The court held that standard invalid. They  
32 actually held that the interpretation of the statute was  
33 invalid, and that was the rule that the agency relied upon to  
34 disallow these claims.

35 Now so what we have is a distinction that is very  
36 important. The statutory provisions that they are relying on  
37 arose out of the FDA Modernization Act with respect to the  
38 time table, the 540 days, and the Nutrition Health Alliance  
39 decision, both of which post dated this proceeding and were  
40 not subject to attack in this proceeding.

41 In this proceeding we were looking at the separate  
42 statutory provision, the NLEA provision for FDA to review ten  
43 separate nutrient disease relationship claims, of which the  
44 four we sought to make were a subset of that ten.

45 THE COURT: Let me ask you something. In the Court  
46 of Appeals' argument, was any reference ever made to the 2nd  
47 Circuit decision?

48 MR. EMORD: In a footnote, there was a reference  
49 made to the 2nd Circuit decision, and it was distinguished.  
50 If you look on footnote four, the decision is distinguished  
51 in that footnote.

52 THE COURT: On the issue of ripeness?

53 MR. EMORD: Yes. Because the court there kicked  
54 out most of the challenge on ripeness grounds, and that  
55 challenge therefore was not affected by the decision in the

1 court's case.

2 THE COURT: But our Court of Appeals did note that  
3 the 2nd Circuit held on the merits that the 540 days time  
4 limit was not an unconstitutional prior restraint.

5 MR. EMORD: Correct. It noted that the 2nd Circuit  
6 so found. Now here, and this is very important. The Court  
7 of Appeals' decision, if you read it carefully you can see,  
8 for example, from 659 to 660 of the decision, and I will  
9 quote a segment here:

10 "While we are skeptical that the  
11 government could demonstrate  
12 with empirical evidence that this  
13 claim is similar to the ones we  
14 have suggested above would  
15 bewilder consumers and fail to  
16 correct for deceptiveness, we do  
17 not rule out that possibility."

18 The point here is that they remanded the case to  
19 the agency to develop empirical evidence, one way or the  
20 other, showing whether there would be deceptiveness or not.  
21 But as a matter of constitutional law, they ruled that these  
22 rules were invalid because the agency did not have that  
23 empirical evidence, did not satisfy its burden of proof,  
24 which is a condition precedent to suppression of speech under  
25 the commercial speech standard.

26 The government may not suppress speech and later  
27 decide whether it has evidence. Government must have the  
28 empirical evidence first, must meet its First Amendment  
29 burden of proof.

30 There is a long history of precedence, Supreme  
31 Court precedence establishing that it is the government's  
32 burden of proof to suppress speech. It is their burden in  
33 the first instance.

34 This statute may not be interpreted in a manner to  
35 conflict with the First Amendment without necessarily  
36 invalidating the statute. It is not necessary here. Why is  
37 that so?

38 It is not necessary here because the provision that  
39 the agency relies --

40 THE COURT: Let me interrupt you, Mr. Emord. Do  
41 you think in remanding to the agency for reconsideration that  
42 the Court of Appeals meant to preclude the FDA, which is the  
43 agency with the appropriate and relevant expertise, but meant  
44 to preclude them from considering what I gather from both  
45 your sets of briefs is a large number of new articles and  
46 peer review articles on the merits of the four health  
47 claims?

48 A lot has happened since you first filed your  
49 request with FDA.

50 MR. EMORD: Certainly not. As a matter of fact  
51 they can consider that at any time with regard to any of the  
52 food claims they have authorized, and so forth. At any point  
53 in time they can look at the science and reconsider their  
54 decision.

55 The fact is though that they are putting the cart

1 before the horse. The court here held these claims at worst  
2 potentially misleading on the scientific record that was  
3 before the court. At worst, potentially misleading.

4 Under the Supreme Court precedent, potentially  
5 misleading speech may not be suppressed outright but must be  
6 authorized with disclaimers if disclaimers can correct for  
7 misleadingness.

8 The agency's position has never been, even to this  
9 date, that there is no scientific evidence to support the  
10 claims. The agency's position has been that that scientific  
11 evidence is not conclusive.

12 The court's recommended disclaimers all begin with  
13 that recognition. The court's recommended disclaimers inform  
14 consumers that the claims are inconclusive.

15 THE COURT: Do you think that the Court of Appeals  
16 intended to limit the FDA to its preexisting record, or do  
17 you think that the Court of Appeals contemplated the  
18 development of -- again, what I gather from your respective  
19 brief is now a massive new record?

20 MR. EMORD: The Court of Appeals expressly stated  
21 that the rules were invalid, that that determination was  
22 invalid. They didn't -- they didn't say that it is invalid  
23 pending the development of further rulemaking. They said it  
24 was invalid as of that point of time, and they remanded to  
25 the agency to develop the empirical record.

26 They wiped out the prohibitions on this speech, and  
27 they gave it back to the agency and said, look, agency, you  
28 go ahead and look at the record, but as a matter of  
29 constitutional law, you have the burden of proof and you may  
30 not -- this government may not suppress protected commercial  
31 speech absent empirical evidence.

32 They don't have that evidence now. They don't have  
33 the empirical evidence to even show that the claim is  
34 misleading.

35 THE COURT: Doesn't that get you precisely into the  
36 2nd Circuit opinion?

37 MR. EMORD: No.

38 THE COURT: And holding, which is that the agency  
39 can reasonably take the 540 days to develop the record and  
40 reconsider?

41 MR. EMORD: No. Because we would have then an  
42 endless loop in which the agency could continuously look at  
43 new evidence over and over again and never reach a final  
44 decision.

45 These claims were submitted to the agency in 1993  
46 in the instance of the first three claims, and in 1996 in the  
47 case of the folic acid claim, and they were thoroughly  
48 evaluated over a far longer period than 540 days.

49 This agency has been dragging its feet the entire  
50 time. They have been dragging their feet since this decision  
51 was handed down.

52 We waited, and we waited a good long period before  
53 we came to this court expecting the agency to take action.  
54 We wrote to the agency repeatedly. Not until this case  
55 started did they even indicate that they would implement the

1 decision, and not until the eve of this hearing, the last  
2 week, did they first say that they would decide it by October  
3 the 10th.

4 This agency is involved in a serious failure to  
5 respect and implement this decision. This is no ordinary  
6 decision. It is a decision of constitutional import. The  
7 gravity of it is extraordinary.

8 We believe that --

9 THE COURT: How do you answer the government's  
10 argument that -- I think they argue that either a third or a  
11 quarter of the delay was due to your request that they keep  
12 the record open and allow you all, meaning all of the  
13 plaintiffs, to submit a lot more information for the  
14 record?

15 MR. EMORD: That argument is misplaced, because we  
16 have always argued to the agency consistently that the  
17 invalidity of these rules prevents the suppression. They can  
18 develop the record. They can find empirical evidence. Upon  
19 finding empirical evidence, if that evidence shows the claims  
20 to be inherently misleading, and the disclaimers that the  
21 court recommended to be ineffectual, they can suppress them,  
22 but they cannot put the cart before the horse. Without  
23 evidence they cannot suppress these claims.

24 This is what we have argued to them. Yes, we are  
25 participating --

26 THE COURT: They can't have evidence, Mr. Emord,  
27 until they develop a record.

28 MR. EMORD: Oh, they have an enormous record, Your  
29 Honor. Absolutely extraordinary record on each of these  
30 claims, and they have asked for the latest science concerning  
31 these claims, and the point here is --

32 THE COURT: But that record is --

33 MR. EMORD: -- that the claims are not absolute.

34 THE COURT: Excuse me a minute.

35 MR. EMORD: I am sorry.

36 THE COURT: That record is as -- the massive record  
37 is as a result of the proceedings that they started and held  
38 subsequent to the Court of Appeals' opinion.

39 MR. EMORD: No. That is not true. The massive  
40 record that they have developed is over the seven year period  
41 prior to it. The information that they cite to you in the  
42 decision, the numbers that they put there, that is a very  
43 small subset of the mass quantity of scientific evidence that  
44 is of record in this -- in the Court of Appeals' record.

45 The point here is, these claims, even if  
46 established by FDA, the science were established, the science  
47 does not establish -- even if you look at the science it  
48 would not establish that the claims were inherently  
49 misleading.

50 At best it would establish that the evidence is  
51 inconclusive. The Court of Appeals' disclaimer says that  
52 very thing. There is no potential for misleadingness unless  
53 the FDA does something that is herculean, and that is show  
54 that there is no scientific evidence to support the claims  
55 which it cannot do.



1           So when all is said and done, after the FDA reviews  
2 all of this evidence, it must either find that that  
3 scientific evidence completely eliminates the 200 plus  
4 articles on antioxidant vitamins, the extraordinary quantity  
5 of evidence on the omega 3 fatty acids, the extraordinary  
6 scientific evidence of fiber.

7           They have approved claims for these in foods in  
8 common form. Their position has been that the elements in  
9 those foods in common form are emersed in other elements that  
10 may effect disease risk, too.

11           The point here is, Your Honor, we should not be  
12 left in a situation where we endlessly await the agency's  
13 final, and then perhaps later final, and then perhaps  
14 later final decision as to what the science is. This has to  
15 end.

16           And while we fully respect that the agency should  
17 investigate the science, and we participate in that, and are  
18 participating in that scientific development, the fact of the  
19 matter is that this agency, like every other agency of the  
20 federal government and state governments, may not suppress  
21 protected commercial speech on the theory that evidence will  
22 arise.

23           It may only do so upon empirical evidence. It must  
24 establish that the harms it recites are real, and that its  
25 restriction will alleviate those harms to a material degree  
26 as a condition precedent to suppression.

27           That was the Court of Appeals' decision. That was  
28 the Supreme Court's unbroken line of decisions from In re  
29 R.M.J. forward, and this is why the Court of Appeals  
30 invalidated the prohibition.

31           It didn't just remand. It invalidated the  
32 prohibition and remanded to the FDA -- to this court and then  
33 to the FDA for further rulemaking on the issue of empirical  
34 evidence, allowing the agency to develop the record, but not  
35 allowing the agency, as a matter of constitutional law, not  
36 allowing this agency to continue to violate the constitution  
37 on the assumption that some day empirical evidence will  
38 arise.

39           THE COURT: Mr. Emord, if they didn't want the  
40 agency to develop a record, and then of course to consider  
41 what was in that record, and we are talking about a pretty  
42 massive record, then why didn't the Court of Appeals simply  
43 say on the existence of the record before them at that time  
44 we conclude that there is no justification for the agency's  
45 position, and therefore we remand with the specific order to  
46 the agency to put these health claims into effect? In other  
47 words, to allow the plaintiffs to use these health claims on  
48 their labels.

49           It seems to me that your position is basically  
50 inconsistent, and you know that I don't mean this in any kind  
51 of a personally insulting way, but these are difficult  
52 administrative law issues.

53           If they remand for agency consideration, then the  
54 agency has to do its job. And unless you can show that the  
55 agency is acting in bad faith-- they may be very slow. I am

1 certainly not going to argue that one with you, although they  
2 have been doing a lot more than you suggest.

3 But let's assume that they are being very slow.  
4 But if the case is remanded for the agency to reconsider and  
5 to develop new evidence, then they have got to be allowed to  
6 do their job, and that is what they are doing right now, with  
7 only six months to go by the way.

8 MR. EMORD: Had the court merely remanded it, Your  
9 Honor, I would agree with you entirely on this point. But  
10 the court invalidated the prohibitions. It held them  
11 unconstitutional.

12 That is a definitive determination that cannot be  
13 ignored or avoided. The unconstitutionality of the  
14 prohibitions renders them of no legal force and effect, and  
15 the court remanded the matter to the agency to develop an  
16 empirical record to determine whether, in fact, it had  
17 sufficient evidence to meet the First Amendment burden of  
18 proof.

19 Having not met it, it cannot suppress these claims.  
20 It cannot suppress these claims for the very same reason the  
21 court determined that it couldn't suppress them based on the  
22 record before it, because the empirical evidence was not  
23 presented.

24 The agency has presented no empirical evidence to  
25 this court. The agency presented no empirical evidence to  
26 the Court of Appeals. It may not continue a violation of the  
27 First Amendment without the empirical evidence.

28 What it is doing -- the Court of Appeals took an  
29 extraordinary step by writing, specifically crafting the  
30 disclaimers it believed would correct for this  
31 misleadingness, and then said to the agency, we don't rule  
32 out the possibility that you might find that these  
33 disclaimers don't work, but in the first instance they  
34 crafted those disclaimers.

35 And so as a matter of constitutional law, we have a  
36 determination in which the speech in issue is protected  
37 commercial speech because it is not inherently misleading.  
38 It is, according to the court, potentially misleading, which  
39 means that the speech may not be conveyed without  
40 disclaimers.

41 The court crafts the disclaimers and then says to  
42 the agency, we do not rule out the possibility that upon  
43 empirical evidence you may show our disclaimers  
44 insufficient.

45 They contemplated in that very action that those  
46 disclaimers would be put to use. They invalidated the  
47 rules, and they allowed the claims to be made with  
48 disclaimers.

49 The agency -- we waited months. The agency did not  
50 develop any empirical evidence. It only started on April 4th  
51 to hold a hearing on the subject matter. It planned -- it  
52 had planned to do extensive rule making, which would have  
53 lasted years. Then this hearing arose, and suddenly, October  
54 the 10th, 2000, becomes the date. That is  
55 progress. It is a movement down from years to months. But

1 it is still a violation of the First Amendment.

2 We do not rule out the possibility, nor did the  
3 court, that the agency may prove disclaimers effective, but  
4 that was the court's decision.

5 Thank you, Your Honor.

6 THE COURT: All right, thank you. Let me hear from  
7 the government, please.

8 MS. STRAWN: Good morning, Your Honor.

9 THE COURT: Good morning.

10 MS. STRAWN: Your Honor, I believe I can be  
11 relatively quick, because Your Honor has already amply  
12 summarized the government's position.

13 THE COURT: I don't know about amply.

14 MS. STRAWN: I believe that you are correct.

15 Basically I want to make two points and then address a couple  
16 of things that Mr. Emord said.

17 The first point is as Your Honor pointed out, FDA  
18 is complying with the mandate of the Court of Appeals. The  
19 mandate was to reconsider the health claims, not to approve  
20 them.

21 The Court of Appeals -- I think it is important to  
22 note that the Court of Appeals specifically stated that the  
23 appellants at that point were not challenging the  
24 prescreening requirement, and therefore the court was not  
25 ruling on the prescreening requirement, and the court did  
26 note the Nutritional Health Alliance decision out of the 2nd  
27 Circuit which upheld that requirement.

28 My second point is that the agency is complying  
29 with the mandate without unreasonable delay. And with  
30 respect to the concern that I think Your Honor expressed  
31 about the agency being prodded to move as a result of this  
32 case, Ms. Kaeding just pointed out to me that FDA notified  
33 the plaintiffs before this action was filed that the agency  
34 would give them a date certain to rule on their claims after  
35 the record was closed and the public meeting was held, both  
36 of which occurred after this action was filed. So the  
37 agency's decision to give a date certain was not predicated  
38 on this action.

39 With respect to what Mr. Emord is arguing, and I  
40 have to give him credit, he argues it well, regarding the  
41 need for empirical evidence before the agency can ban the  
42 claim, I think that is precluded by the 2nd Circuit, and I  
43 will just read to you from the 2nd Circuit's opinion:

44 "The 540 day prior restraint is  
45 sufficiently narrowly tailored.  
46 It grants a limited but reasonable  
47 time within which the FDA can  
48 evaluate the evidence in support  
49 of labeling claims -- so that a  
50 court can determine whether the  
51 regulated speech is, in fact,  
52 truthful and non-misleading as  
53 required by the first prong of  
54 Central Hudson."

55 That is exactly what the agency is trying to do

1 here, and to require the agency to develop empirical evidence  
2 and to satisfy its burden of proof in advance of any action  
3 to prove the claim, or to, you know, prohibit the claim,  
4 would do away with the entire prescreening requirement, which  
5 was not at issue.

6 THE COURT: I am concerned about one thing. Is it  
7 correct, as Mr. Emord argues, that the Court of Appeals  
8 considered the case under one statute governing FDA, namely  
9 -- I guess it is the NLEA, and that your argument now  
10 primarily relies upon a different provision of the FDA  
11 statutes?

12 MS. STRAWN: Are you referring to the 540 day  
13 requirement?

14 THE COURT: Yes.

15 MS. STRAWN: It is correct that, in fact, the  
16 claims that plaintiffs wish to make were originally initiated  
17 by Congress, not by the petition process. And the 540 days  
18 is a Congressional limitation on the petition process.

19 I think -- our argument, though, is that the 540  
20 days provides by analogy a reasonable time. In fact the time  
21 limit that Congress put on the agency to evaluate these  
22 claims was, I believe, longer than 540 days originally, so in  
23 effect not, you know, a binding restriction in the way that  
24 it would be if these claims had come in by the petition  
25 process.

26 But by analogy, and I think what some of the  
27 unreasonable delay cases of the D.C. Circuit say is that you  
28 look to the statute, you know, or at some analogous type  
29 mandates to discover whether or not the delay is reasonable,  
30 and I think that the 2nd Circuit has held that that is  
31 reasonable.

32 It might also be reasonable if the science were  
33 tremendously greater than normal. It might be reasonable to  
34 ask for more time or less time. But I think in this case the  
35 540 days is a good analogy, and the agency is complying with  
36 that.

37 THE COURT: What is your position on one or two  
38 questions that I asked Mr. Emord, and that is, do you think  
39 that the Court of Appeals contemplated that its opinion  
40 contemplated the development of a new record by the FDA after  
41 the remand?

42 MS. STRAWN: Yes, Your Honor, I do, certainly.  
43 Certainly on the issue of disclaimers. I mean the Court of  
44 Appeals specifically referred to the idea that the agency  
45 might develop empirical disclaimers -- or I am sorry,  
46 empirical evidence that disclaimers don't work in certain  
47 situations, or do work in others. It remanded to the  
48 agency to come up with disclaimers that would work.

49 I think in order to come up with disclaimers that  
50 work, you have to have an understanding of the current state  
51 of the science, otherwise you don't know what it is that you  
52 want consumers to understand.

53 THE COURT: Does your administrative proceeding  
54 thus far focus on the science, or did it focus on consumer  
55 perceptions, or both? I thought that it was just on the

1 science.

2 MS. STRAWN: They are doing both simultaneously.  
3 There have been focus groups on disclaimers that have been  
4 held, and the public meeting, which was last week, I believe,  
5 also was -- had a panel that dealt with disclaimers, and the  
6 agency has been reviewing evidence with respect to the  
7 implementation of disclaimers.

8 THE COURT: All right.

9 MS. STRAWN: With respect to the -- to Mr. Emord's  
10 argument that, you know, this could be a never ending  
11 process, I don't think that there is any evidence that the  
12 agency has said it will issue a final decision.

13 That said, you know, obviously the FDA is in a  
14 position of protecting the public health, and if at some  
15 later point science comes in and there are studies done that  
16 impact on these disclaimers one way or the other, certainly  
17 Mr. Emord -- assuming that that agency were to deny the  
18 claim, for example, certainly Mr. Emord would be entitled to  
19 bring to the agency's attention new science that supported  
20 the claim, and likewise someone else, or the agency could  
21 address the claims again on the basis of new science that was  
22 unsupported by the claim.

23 So I think that that is within the agency's  
24 prerogative. That does not impact on the fact that there  
25 will be a final decision and that the record will close.

26 But to go back to Mr. Emord's main argument about  
27 the burden of proof at this point, if the government is  
28 required to show by empirical evidence that a claim is  
29 misleading before it takes action, then all claims could be  
30 made at this point, and the agency would be in the position  
31 of having to go forth and do rule makings on, you know,  
32 whatever claims might be out there.

33 I mean, you know, I could claim if I eat this pen  
34 it will prevent my cancer, and the agency, you know, would  
35 have to go back -- would have to go out and develop empirical  
36 evidence that that was not the case in order to ban the  
37 claim.

38 And that is not the law, and that is not what the  
39 2nd Circuit held, and that is not what the Supreme Court has  
40 held in regard to prior restraints.

41 So to conclude, I would just conclude that I just  
42 think that the court's mandate is clear, that the agency was  
43 to reconsider the claims, and that the agency is in fact  
44 doing that in a timely manner.

45 THE COURT: All right, Mr. Emord, did you have  
46 anything else you wanted to add?

47 MR. EMORD: Thank you, Your Honor. On Ms. Strawn's  
48 last point, we don't contest that empirical evidence is  
49 necessary to support a claim in the first instance. We filed  
50 that empirical evidence, and the court determined that at  
51 worst it was potentially misleading. Therefore, it was  
52 protected commercial speech.

53 We did not challenge the prescreening process, nor  
54 is it applicable in this context. This is a NLEA driven  
55 direct nutrient disease relationship claim review under

1 their now invalidated significant scientific agreement  
2 standard.

3 But I think it is very important that --

4 THE COURT: The standard wasn't invalidated, was  
5 it? Didn't the Court of Appeals say it had to be clarified?

6 MR. EMORD: That is correct. That is correct, Your  
7 Honor.

8 THE COURT: I gather that they have done that,  
9 although I don't think that either one of you have really  
10 focused on what they have done in clarifying it.

11 MR. EMORD: We dispute that they have clarified it,  
12 Your Honor, but that is for another day I suppose.

13 THE COURT: All right.

14 MR. EMORD: But the court's decision -- there is a  
15 paragraph which I think is absolutely indispensable to proper  
16 evaluation of the case, and that is the paragraph -- and I  
17 have the actual decision before me, I don't have the page  
18 citation.

19 It is -- but the paragraph reads:

20 "The government disputes that  
21 consumers would be able to  
22 comprehend appellant's proposed  
23 health claims in conjunction with  
24 the disclaimers we have suggested.  
25 This mix of information would,  
26 in the government's view, create  
27 confusion among consumers, but  
28 all the government offers in  
29 support is the FDA's pronouncement  
30 that consumers would be  
31 considerably confused by a  
32 multitude of claims with  
33 differing degrees of reliability.  
34 Although the government may have  
35 more leeway in choosing  
36 suppression over disclosure as  
37 a response to the problem of  
38 consumer confusion where the  
39 product protects health, it  
40 must still meet its burden of  
41 justifying a restriction on  
42 speech. Here the FDA's  
43 conclusory assertion falls far  
44 short. See Ibanez, 'if the  
45 protection afforded commercial  
46 speech are to retain their force,  
47 we cannot allow rote invocation  
48 of the words potentially  
49 misleading to supplant the  
50 government's burden to demonstrate  
51 that the harms it recites are  
52 real, and that its restriction  
53 will, in fact, alleviate them to  
54 a material degree.'"

55 The point here is, Your Honor, the court reviewed

1 the evidence. It held as a matter of law that these claims  
2 were, at worst, potentially misleading. Disclaimers are  
3 therefore the focus of the remand necessarily. What  
4 disclaimer? Whether the Court of Appeals' disclaimer, based  
5 on empirical evidence, would be insufficient to avoid  
6 misleadingness.

7 In the first instance, though, the court wrote  
8 disclaimers, and it was the burden of proof then, as it is  
9 now for this agency, not to put the cart before the horse,  
10 not to presume the existence of evidence to justify  
11 suppression, but under the First Amendment they must have  
12 that evidence.

13 This is absolutely indispensable to the protection  
14 of the civil liberty that is our First Amendment. So we urge  
15 this court respectfully that it take very careful heed to the  
16 points pertaining to Ibanez and In re R.M.J.

17 Never has the Supreme Court ever authorized the  
18 suppression of commercial speech predicated on the promise of  
19 evidence. Never has it done so based on a recitation of  
20 facts without empirical evidence since In re R.M.J.

21 The court has required the evidence.

22 Many a case has been before the court in which the  
23 state has argued that it has an important need to suppress  
24 speech. But the court has unequivocally stated that the  
25 government must have evidence, must have empirical evidence  
26 to meet its standard before it may do so.

27 Thank you, Your Honor.

28 THE COURT: Well, thank you everyone. I am not  
29 going to rule today. I knew I wanted to hear from counsel so  
30 I could fully evaluate all of the arguments made. I don't  
31 intend to delay in ruling though.

32 I would hope that I could get a ruling out within  
33 two weeks, and I will do my best to do that, everybody. Your  
34 papers are really clear, and as you can tell I am familiar  
35 with the issues at this point. Thank you very much. Counsel  
36 may be excused.

37 MR. EMORD: Thank you, Your Honor.

38 MS. STRAWN: Thank you.

39 (Whereupon, the proceedings in the above-styled matter  
40 were adjourned.)

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42 CERTIFICATE OF COURT REPORTER

43 I certify that the foregoing is a correct  
44 transcript of the proceedings in the above-captioned matter.

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SUSAN PAGE TYNER, CVR-CM  
OFFICIAL COURT REPORTER

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