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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA
JULIAN M. WHITAKER, ET AL. DOCKET NUMBER: CA 99-3247
.
Plaintiff, .
.
vs. . Washington, D.C.
. October 28, 2002
DONNA E. SHALALA, ET AL . 10:00 a.m.
.
Defendant. .
. . . . . .
TRANSCRIPT OF MOTIONS HEARING
BEFORE THE HONORABLE GLADYS KESSLER
A UNITED STATES DISTRICT JUDGE
APPEARANCES:
FOR THE PLAINTIFF: JONATHAN EMORD, ESQUIRE

FOR THE DEFENDANT: DRAKE CUTINI, ESQUIRE
THE COURT REPORTER: SUSAN PAGE TYNER, CVR-CM
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United States District Court
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SUSAN PAGE TYNER, OFFICIAL COURT REPORTER

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P R O C E E D I N G S
THE COURTROOM CLERK: This Honorable Court is now
in session. Judge Gladys Kessler presiding. Please be
seated and come to order.
THE COURT: Good morning, everybody. This is the
case this morning of Julian Whitaker, et al, versus Donna
Shalala, et al. And, of course, that caption dates from
1999 when the case was filed. This is civil case number 99-
3247.
First of all, would counsel please identify
themselves for the record. Plaintiff.
MR. EMORD: Jonathan Emord on behalf of the
plaintiffs, Your Honor.
MR. CUTINI: Drake Cutini on behalf of the
defendant.
THE COURT: And who is going to be arguing for the
government?
MR. CUTINI: I will, Your Honor.
THE COURT: And could I have your name again,
please?
MR. CUTINI: Drake Cutini.
THE COURT: How do you spell it?
MR. CUTINI: D-r-a-k-e C-u-t-i-n-i.
THE COURT: Okay. This is here as everybody knows
on cross motions for summary judgment, and I really do feel

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constrained to begin with a general apology. I know how old the motions are, and I want to assure everybody that I never forgot about the case. Each time that I picked it up, I did find the issues so difficult and complicated that obviously I never could get it done, and that is why I have set it for a hearing this morning. I have reread all of the papers, and I do find the issues to be very difficult in this case. So Mr. Emord, let's start with you please, and I do have to warn counsel about one thing, and that is that I am still recovering from a really bad cold, so you all have got to speak up and please speak into the mike.

MR. EMORD: Thank you, Your Honor.

THE COURT: That I can hear.

MR. EMORD: Very good. Would you like me to give you a brief factual background, or should I go directly into the legal argument in the case?

THE COURT: Oh, I think you can go into the legal argument.

MR. EMORD: All right.

THE COURT: And because it has been so long since the papers were filed in this case, if any new either events or cases have happened, you need to update me. I don't

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think there are any new cases. Certainly not from our Circuit, but if there are, of course, I need to know about it.

MR. EMORD: There is a new Supreme Court decision, Western States -- Thompson versus Western States Medical Center, 122 Supreme Court 1497, 2002. This case asked the court to determine whether or not the Food and Drug Administration is suppressing in a manner more extensive than is necessary truthful and non-misleading speech by refusing to process a health claim under the Dietary Supplemental Health Claims Provision, and insisting that instead it be processed under the more restrictive, more costly drug process. Between the Health Claim Provision in section 343(r)(1)(B), and the drug provision in 355(d), there is no question but that the drug provision is more complex, more burdensome, more costly. That is indeed how Congress designed it. Congress understood at the time of the passage of the Nutritional Labeling Education Act that nutrients, because of their long history of safety, as components of foods in the food supply, were substances that could be afforded a lesser degree of scrutiny before truthful information could be applied, whereas drugs, which are typically patented, synthetic compounds, would require more

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exacting scrutiny, and that had been the history preceding the adoption of the NLEA. Now NDA approval is only sought for patentable substances, and we are dealing here with a nutrient that is

unpatentable, Saw Palmetto, the extract of the American dwarf palm fruit.

There is great economic benefit for patentable compounds to pursue the drug approval process. Congress has specified a twenty-year period of protection, patent protection, and then FDA adds on to that an additional five years.

In this instance there is evidence in the record of a $58 million estimate by an economist, Paul Reuben, for the cost of pursuing a drug application for Saw Palmetto, and in addition --

THE COURT: Mr. Emord, I don't have any doubt about those facts, and of course they are interesting, but I don't really know that they are legally relevant. I have to deal with this complex statutory structure as it exists, like it or not, and I think that that is what we had better focus on this morning.

MR. EMORD: Okay. Well, clearly under the language of 343(r)(1)(B), the language in issue, quote: "Expressly or by implication characterizes the relationship

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of any nutrient to a disease or a health-related condition."

Clearly the claim in this case, the Saw Palmetto claim, falls within the plain meaning of that language in that it is a nutrient, Saw Palmetto. We are characterizing the relationship of that nutrient to a health-related condition, BPH, and it plainly falls under the clear express meaning of Congress as to what that language means.

Now preliminarily I think it is important to note that we are under canons of statutory construction that in an issue of constitutional importance, such as this First Amendment issue, we are required to construe the statute in a way that renders it constitutional.

And in that regard, it is clear from the Western States Medical Center case that the court makes it unambiguous that you must interpret the statute so as to reduce the burden on protected speech.

You cannot interpret the statute in a way that enhances or maintains a restriction on speech beyond that reasonably necessary. And in this case let me quote exactly what the Supreme Court said, because it is a rather direct and profound statement of import to us now.

THE COURT: And I am sorry, but I am not familiar with that case, and you are going to have to give me just a

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little summary of it, please.

MR. EMORD: It is a drug compounding case, Your Honor, in which -- drug compounding is what pharmacists and doctors do when a mass-produced drug is not appropriate in a particular case, either due to allergic reaction or some other predisposition of the individual patient.

What happens in those circumstances is that pharmacists, for example with children, will put something in it that will make it more palatable, and so they take a

mass-manufactured drug, they modify it, and it becomes something that the child can consume, or the other person who has an allergy or whatever can consume it.
And so the court looked at arguments frankly that were somewhat similar to those here, that unless the drug approval processes is required for these products, the problem will arise that there will be a circumvention of the drug approval process. We will not be able to assure safety for these substances that are made on an individual basis.
The court rejected those arguments in a five to four decision, and forgive me if I am speaking too blithely about the details of the decision. It is a detailed decision. I commend it to you.
But in pertinent part, in a passage that is clearly applicable beyond the scope of the case, the court

wrote:
"In evaluating the final prong of the Central Hudson test --"
-- and that is that means ends prong, which is principally in issue here --
"-- we have made clear that if the government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the government must do so."
And so it is, Your Honor, consistent with the canons of statutory construction, before we even get into the question of whether there is legislative intent and so forth, it is the case that we have two statutory schemes.
One that is far more restrictive on speech, and in fact in this case is prohibitive of the speech that we wish to make, and another, the health claims approval process, which clearly is available, can be used, and appears by the plain language of the statute to apply to just this circumstance.
Now it is important to note that in statutory construction, our Court of Appeals in Pearson did pass upon the -- did recognize the plain meaning of section 343(r) at 164 Fed.3rd, at 652, and that is in the Pearson

decision.
There they said that section 343(r):
"Creates a safe harbor from designation as a drug for certain dietary supplements whose labels or labeling advertise a beneficial relationship to a disease or health-related condition."
If the FDA authorizes a label claim under 21 USC, section 343(r), the product is not considered a drug under 21 USC section 321.
A health claim eligible for processing --
THE COURT: Of course that is only if the FDA has authorized the health claim, and that is the point here,

that FDA is not authorizing the health claim because, as I understand their argument, they believe that Saw Palmetto is a drug, and therefore must be regulated and handled under the fare more restrictive positions.
MR. EMORD: Yes. They take that position. But Saw Palmetto is a dietary supplement by definition under the Act. It meets the content requirements.
THE COURT: By what definition? By --
MR. EMORD: By --
THE COURT: Do you rely -- I don't want to say exclusively, but is your major reliance on 343(r)(1)(B)

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as what you view as the definition for a dietary supplement?
MR. EMORD: No. The definition for a supplement we look at is 321(f)(F), and there it defines essentially, if we can summarize:
"A food or food extract."
In this instance, Saw Palmetto has been consumed for hundreds of years by Native Americans, and Saw Palmetto extract is clearly within the definition of a dietary supplement in 321(f)(F), an extract of a food or a food component.
THE COURT: But again, and forgive me for interrupting you all of the time, everyone. I think I usually explain that all my interruptions are not meant to throw anybody off their track, but to try to focus on my concerns.
Again, FDA argues that the definition of drug and the definition of a dietary supplement are not mutually exclusive, and there is some overlap of those definitions, and indeed in Pearson Judge Silberman seemed to acknowledge that there was an overlap in those definitions.
MR. EMORD: There is indeed overlap, Your Honor. Indeed, any time a health claim is approved, a dietary supplement bears what is the definition of a drug in that it is expressing an intent to either prevent, treat, mitigate

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or cure a disease.
Every health claim the FDA has approved for food or a dietary supplement involves prevention and treatment of disease.
The government contends that it only involves prevention. But there is no clear dividing line between prevention and treatment. In a chronic ailment, for example, Your Honor, every instance of prevention is arguably an instance of treatment.
I would be -- you know, I would be flabbergasted if the government could give --
THE COURT: I don't understand that argument.
MR. EMORD: Okay. The ideology of a disease that is chronic usually requires a long history of disease progression before there is overt expression of that disease.
Let's take for example heart disease. We now know that heart disease may begin very early in life. For example, in the teen years or younger there may be the

beginning of the buildup of plaque in the blood vessels. So it is that something that would retard or stop the buildup of plaque would constitute a treatment for heart disease just as it would be a prevention of heart disease.

Distinguishing between the two reveals that, in

fact, you cannot, because there are drugs approved for the prevention of the buildup of plaque, and there are drugs approved for the treatment of heart disease. And there are dietary supplements -- B-6, B-12, and folic acid, for the reduction of the risk of heart disease predicated on a lowering of homocystine levels. It also addresses an independent risk factor, and slows down or prevents that. There is no clear dividing line, and the attempt to do that is not only alien to the statute, but as you point out, the Court of Appeals knew there was overlap, and indeed there is. And it is only through the health claims approval process that you can make these treatment or prevention claims. The plain language of the statute --

THE COURT: Let me ask you this question, and I am not sure that the two sides focused on this so much in their arguments. If we concede that there is an overlap between the definitions, and I think both sides would concede that almost everything turns on which definition Saw Palmetto is said to fit -- either it is a drug or it is a dietary supplement with vastly different constitutional implications in terms of labeling and regulation -- then it seems to me that we get to the issue of FDA's making the determination

of which definition fits Saw Palmetto. Isn't that an issue which, under the APA and a vast amount of case law, I am required to defer, at least fairly substantially, to the expertise of the FDA?

MR. EMORD: No. Because in our construction precedent, our Court of Appeals has said that in the case of a clear statutory definition -- and here we are arguing that that statutory definition, expressly or by implication, characterizes the relationship of any nutrient to a disease -- any nutrient to a disease or health-related condition. That health claim definition is clear and unambiguous, and as a result our Court of Appeals has ruled that quote:

"In the case of a clear statutory definition, there is no occasion for deference."

And in addition, in this case, deference to the agency means suppression of the speech for the reasons -- the factual reasons we have discussed -- because it is unpatentable, because the costs are extraordinary. So the effect is to condone what will, in fact, be a mass suppression of that speech, which under the canons of statutory construction cannot be allowed in the face of our

constitutional precedent, which most clearly and
definitively indicates and states:
"The government must choose the
less restrictive alternative."
Here there is an option of construction. And in
the face of the option for construction we ask ourselves
under the constitutional standards, what is the less -- what
is the lesser restrictive of the two?
And clearly the health claims approval process is
the lesser restrictive of the two. And therefore, as a
matter of First Amendment law and under the canons of
construction, that method must be chosen.
In addition --
THE COURT: Did you see this as -- or do you
analyze this as at least in part Chevron case where the
court has used the Chevron analysis to determine whether the
statute speaks directly to the definition?
MR. EMORD: Only in this sense, Your Honor.
Paramount is this First Amendment requirement, the less
restrictive alternative. If it was the case that the drug
definition had to apply, then the drug definition as applied
to this speech would be unconstitutional, because it would
result in the suppression of truthful information when there
is a less restrictive alternative available.
The court has been unequivocal, the Supreme Court
--
THE COURT: I don't think Pearson said anything
like that. It did not go that far.
MR. EMORD: Well, to this extent. If the speech
in issue is either truthful or is only at worst potentially
misleading, then the court will not allow it to be
suppressed, because it is protected speech, provided that a
disclaimer in the event of potential misleadingness could
cure for misleadingness.
But they didn't even get there, Your Honor. And
in this case we are talking about a dietary supplement of
long-standing. The government in its brief has mentioned
that in the absence of a health claim, this is a dietary
supplement.
In the absence of any disease, any effect on an
existing disease, it is currently treating this as a dietary
supplement. It is sold in pharmacies throughout the United
States. Is used by millions of Americans presently for what
is termed -- what they allow a structural function claim of
improves prostate health.
We can tell people that the product improves
prostate health under the structure function claim
provisions of the Act, but we cannot tell them why. And
there is the speech suppression.
There is an inherent irrationality to the
government's regulatory scheme. On the one hand they let
this out there on the market as a dietary supplement
currently marketed across the United States with structure
function claims that are allowed for improves prostate

health. But we cannot tell the consumer what it does to improve prostate health.
The court -- our Supreme Court has transcended these efforts, which I think in this case is an effort to circumvent Pearson 1, 2, and 3, and has asked the ultimate question: are you communicating truthful information or potentially misleading information?
In the case of statutory construction, which must necessarily be under this constitutional rubric, we ask ourselves, is their insistence on drug approval in the first instance, does that comport with the First Amendment?
We have Pearson 1, in which the court inverted the normal order in the presence of just such a First Amendment question. Inverted the normal order and answered the First Amendment question first.
Now even if this court does not follow that, under Chevron we cannot move beyond the plain language of the statute to get to the legislative history for this reason. It is unambiguous.
It is unambiguous in my view, and I think in most reasonable minds under an English language definition, to

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construe the association between a nutrient, Saw Palmetto, and benign prosthetic hypertrophy, a health-related condition, not to comport with -- not to come under this very broad definition Congress chose, expressly or by implication, characterizes the relationship of any nutrient to a disease or health-related condition.
That is an immense definition. If Congress intended not to include an effect on an existing disease, one would certainly have expected this language to have been modified with something making the clear. But Congress did not do that.
THE COURT: Doesn't your argument in a certain way play into, if you will, the FDA's argument that that definition is so broad, or it can be read so broadly, that it would essentially undermine into eviscerate, if you will, the drug regulation provisions?
MR. EMORD: Not at all. Because that is an isolated view of one part, just the drug definition. If you look at the act as a whole, only certain substances meet the definition of a dietary supplement. Only certain substances are safe enough to be sold as a dietary supplement.
You see, they give examples of drugs that have severe side effects and say, these are derived from natural elements. That is not at issue. It would never meet the

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definition of a dietary supplement.
These are synthetically derived substances. And in addition, they are not safe enough to be sold as foods or dietary supplements. Under the act there are a number of provisions that provide for restrictions on what can be a dietary supplement, and if we look at those we see that it is impossible for a drug to qualify.
In the first instance we said no product can

satisfy -- no product could be sold as a food or a dietary supplement unless it met the definition of a dietary supplement, either a food, or an extract, an herb, et cetera, under 21 USC section 321(f)(F).

But in addition, under 21 USC section 342(f)(1) --

THE COURT: Wait a second.

MR. EMORD: I am sorry.

THE COURT: Which one?

MR. EMORD: 342(f)(1). A dietary supplement is considered adulterated, unlawful for sale, if it quotes, quote:

"Contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury."

In addition to that, if you synthetically derive something -- the reason why synthetic derivation is

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important is because you cannot patent just the nutrient. You have to synthetically modify it to get a patent.

No one is going to be $20 million for a drug -- $500,000 for a drug application, $200 million for the science necessary to get approval, and go through that lengthy process without an assurance that you are going to get some money on the other end. It is just common sense.

THE COURT: I understand.

MR. EMORD: So you simply would not be able to afford it for an unpatentable substance. And in that circumstance the substance is synthetically derived, and as a synthetic derivative, it is a new dietary ingredient under the meaning of the act.

If you try to take a new synthetic derivative of some substance -- a drug company, let's say they lost their mind and wanted to go the health claim route. There is no protection for patents and so forth there -- and they went through that process, they would come out on the other side in a competitive dietary supplement market. They could not demand the amount of money for each unit as they could coming out of the drug approval process. No patent protection.

In addition to that, they would be selling a new dietary ingredient by virtue of the act that is prohibited. Any new dietary ingredient -- any substance first introduced

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in the market after October 14, 1994 under section 350(b)(a)(C) cannot be marketed as a dietary supplement unless you prove the safety of it as a food or a dietary supplement.

And that safety cannot be proved for a substance like a synthetic derivative that most frequently involves at least some degree of adverse effects. It is very hard to find any drug on the market today that does not have some adverse effects that are significant.

Here the United States has determined that Saw Palmetto has no serious adverse effects. As we have pointed out, it has been consumed for over hundreds of years by Native Americans, and it is being sold as a dietary

supplement across the United States right now.
THE COURT: But again, the government's argument is that they are very concerned that by treating the symptoms of the condition that successful treatment, or perhaps a better word mitigation of those symptoms, can lull consumers into not seeking medical care when there may be underlying very serious prostate disease.
MR. EMORD: And this, as in Pearson, and as in our Western State Medical Center Supreme Court decision just handed down, the Western State decision, in a circumstance far worse than a safe supplement, in a case of compounded -- individually compounded drugs, the five to four majority

said:
"In an instance where there is a potential for harm here, why not require warning statements? Warning statements, disclaimers to that effect are a less restrictive alternative. We require it."
In Pearson, in a passage in Pearson, the court said, hey, if there is some adverse effect, reveal it with a disclaimer.
In this case we said to the government -- we said to the court --
THE COURT: Pearson was not a drug, and I come back to that, that so much turns on whether FDA has properly categorized this as a drug, and what degree of deference I have to give to that decision?
MR. EMORD: But Your Honor, under Pearson, each of those four claims in issue, in the absence of the health claim definition in the statute, would have been drugs, and those statements would not have been allowed, because all of the statements were prevention or treatment claims. Every one of them.
And so the court there looked exactly at this, a prevention or treatment plan, and it asked itself whether it

was permitted under the health claim definition, and it was knee-jerk then. The government did not even raise these arguments then.
And so the court reiterated its understanding that the statutory section was a safe harbor from drug evaluation. Indeed, if it is not a safe harbor from drug evaluation, the statutory section becomes superfluous. And of course we must give meaning to the statute.
THE COURT: Mr. Emord, let me ask, are you aware of any case in which a court has overruled an FDA classification, or an FDA decision that a particular substance is, in fact, a drug under the statute?
MR. EMORD: No. However, one could argue --
THE COURT: I could not find one either.
MR. EMORD: I couldn't find one, but one could certainly argue in the case of Pearson, where the government contended that these are not appropriate for approval under the health claims statutory section, and thereby default,

because of the prevention or treatment, would only be approvable as a drug claim.
That indeed, the constitutional decision of our Court of Appeals was, in fact, a rejection of the agency's classification. The agency would not permit those substances to be approved with health claims, and in fact took the position that no such claims are authorized under
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our standards, and the only way that would be left to pursue those claims would be under the drug definition.
THE COURT: Did the Supreme Court discuss Pearson at all in its decision?
MR. EMORD: No, not in Western States. And forgive me if my recollection is weak on any footnote reference, but I don't believe that Pearson was referenced in the decision.
THE COURT: Now I want to ask you another technical question. I believe that the FDA used a -- relied upon a different section of the statute in deciding that Saw Palmetto was a drug, and not the section of the statute that is referred to in the safe harbor provision. Am I right about that? And if so, what if any difference does that make?
MR. EMORD: Well, I think they relied upon 321(g)(1).
THE COURT: That is right. They used to 321(g)(1)(B). The safe harbor clause refers to 321(g)(1)(C). And again I am not trying to catch anyone off guard here, but this is so technical, and this is my only time to ask you these questions, I need to know whether you think that makes any difference or not.
MR. EMORD: It does not for this reason. The first section, 321(g)(1) is the drug definition section.
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And without question, anything that is intended for use in the care, treatment, prevention and mitigation of a disease is a drug but for the exceptions to that.
And the exceptions occur later in the statutory provision for health claims wherein it is by virtue of that second act provision that a substance does not become a drug if it has been approved as a health claim.
So it is the greater, the more encumbering provision of the statute is the general provision of intent. It is a drug. But if you go through the health claim approval process and come out on the other side with a dietary supplement with a claim to prevent or to treat a disease, it is, because it went through that process, not a drug.
And in this case, another factor that is rather extraordinarily important to the clients, they sell dietary supplements. To sell a drug is an extraordinary change in operation. Absolutely extraordinary.
Not just the testing, but the fact that it is a whole new market only available through a doctor's prescription. You basically have abandoned your existing business and go into the drug business without enough money to do that.

So in real terms what the government is doing here is an absolute prohibition on the communication of speech.

If this precedent stands, not just in an instance where we are talking about a treatment of Saw Palmetto. I can give you another simple example.

If you said prune juice is a cure for chronic constipation, or if you said that it is a treatment for chronic constipation, and you included on the label, be sure to see your doctor, because constipation may be due to other physiological things that you need to see your doctor.

Even though this is commonly accepted and understood by people, that prune juice relieves constipation, that would be an unapproved, in their view, drug claim, that you could never make the statement unless you patented prune juice.

And so even though this is true, and even though it should be out there -- people should have the right to know what foods do to them -- it cannot be said by anyone who makes prune juice.

THE COURT: Except every mother and father and the world, right?

MR. EMORD: Yes.

THE COURT: Well, I want to ask you something else. In your dealings with the FDA, have you, as I believe you did in Pearson, offered various options in terms of a more limited health claim, or a more restrictive health claim?

MR. EMORD: Well, we have said that we would accept any reasonable disclaimer, and we have made that abundantly clear to the government. So if, for example, their true fear is that people would use Saw Palmetto instead of something that treats a really benign condition, benign prosthetic hypertrophy, which is nothing more than an enlarged prostate, and over 50 percent of men aged 60 and older will have it.

In fact the older you get it almost becomes everyone. Every male by the time they are 90, something like 90-some-odd percent of men will have an enlarged prostate.

It is almost a common characteristic of the aging process. But it is not normal. It is pressure on your bladder, and it interferes with -- so we said look, we will accept any representation, reasonable representation that would alert d people.

And in fact, point of fact, when you consider that it is out there on the market right now with its, for prostate help, people are experimenting with it, not knowing exactly what it does, wouldn't it be better to have on the label of the product, go see your doctor.

Go for an annual prostate screening exam. Go to make sure that you only have a slightly enlarged prostate at this point, that you don't have some other medical complications?

We would be willing to accept any one of those things. Our clients want people to see and obtain appropriate medical treatment, and they also have produce liability reasons that support this. They want people to know what they should do.

But by the same token, they want people who have mild benign prosthetic hyperplasia, the first part of the condition, to understand that you don't immediately have to take these drugs with adverse side effects. You can take something that is out of the food supply that will ameliorate those physical conditions.

You should still go to see your doctor. It is a bit like, you know, a drink -- or chicken noodle soup with the flu. It may help you feel a little better. It may have certain physiological effects upon you that are beneficial.

But for heavens sake, you don't want to not go to the doctor if you have the flu. And we would take the same position. We said any reasonable disclaimer alerting people. And this fits completely within our constitutional scheme.

It is more information, not less. It is full disclosure rather than suppression, and it will help

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people to understand their options and yet not avoid treatment if necessary. It gives them the information they need, and that is more than what the government does right now.

THE COURT: All right. Thank you.

MR. EMORD: Thank you, Your Honor.

MR. CUTINI: May it please the court, I am Drake Cutini on behalf of the defendants.

In this case the FDA concluded that plaintiff's proposed claim was actually a claim that Saw Palmetto cures or has a therapeutic effect on a disease, and for that reason it rendered the product a drug, and it cannot be considered as a health claim under the NLEA.

FDA did not prohibit plaintiff from making this claim. It just decided they could not make it in the manner they desired to make it.

FDA's decision on the meaning of the act and the application of the act, the Food, Drug and Cosmetics Act, to plaintiff's proposed claim should affirmed.

Now in 1990 the Food and Drug Administration considered banning from the market over-the-counter drugs, including products that contains Saw Palmetto, and products that contained other ingredients that were sold to treat the symptoms of BPH.

THE COURT: Well, plaintiffs are not claiming that

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they can cure the condition. I believe what they are saying is that Saw Palmetto will mitigate some of the symptoms. That is different it seems to me.

MR. CUTINI: They are all within the drug definition. They claim it can treat the symptoms of BPH, and FDA concluded in its decision that that is within the drug definition, which includes cure, mitigate or treat. It

is not a prevention claim.
In 1990 the Food and Drug Administration found that Saw Palmetto was not generally recognized as safe and effective to treat this disease, and that safety and effectiveness could be shown through adequate and well-controlled clinical studies, which the plaintiffs have not done.
And it could be shown and proven to FDA through the new drug approval process, which is not limited to patentable items as plaintiff suggests.
THE COURT: But it is still a dramatically different process, isn't it, than establishing health claims?
MR. CUTINI: Yes. And it requires prior approval of the safety and effectiveness, and a demonstration that safety and effectiveness is generally recognized to get approval, and that is --
THE COURT: That is a different burden of proof.

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MR. CUTINI: Yes, it is.
But the Food and Drug Administration said in 1990 in their Federal Registry notice that they could also seek to amend the monograph, the over-the-counter monograph, which is a different process from the new drug approval process. But it requires a demonstration of the safety and effectiveness of the product.
So either of those routes could have been chosen, and plaintiffs were on notice of this in 1990 that they could have chosen either of these routes, and they did not do so.
Their statement that they have no notice of these facts so they should be able to submit to material outside of the record is belied by this 1990 Federal Registry notice from the Food and Drug Administration which explained the process for getting approval either through an OTC monograph or through a new drug application for Saw Palmetto.
Now the primary reason given in 1990 by the Food and Drug Administration was that although Saw Palmetto might have provided minimal relief to the symptoms, it was not an adequate or meaningful clinical improvement, and the studies that existed then that were shown to the Food and Drug Administration, were inadequate to establish effectiveness. There were too few participants in the study.

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That decision, which is in the administrative record of this case, provides a thorough explanation of why Saw Palmetto was not deemed to be generally recognized as safe and effective for treatment of BPH.
The plaintiff's claim, as I think this court has recognized, would permit them to do an end run around the drug approval provisions, which requires prior approval of the general recognition of safety in and effectiveness, and severely undercut the primary purpose of the Food, Drug Cosmetic Act.
FDA denied this claim and concluded that the act does not permit a claim that the substance has a therapeutic

effect on an existing disease as a health claim under the NLEA, and only permits claims that prevent a disease or reduces the risk of contracting to the disease in the future.

FDA's decision that treatment claims cannot be made as health claims under the NLEA is a proper interpretation of the act, and plaintiff's interpretation, as I indicated, would severely undercut the principal purpose of the act.

In considering this claim, the court must consider the Food, Drug and Cosmetic Act as a whole, and not focus on one provision as plaintiffs attempt to. The primary purpose of the act is to ensure that drugs are proven safe and

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effective prior to marketing, not after marketing as plaintiffs seek to accomplish here, that their product goes on the market, and if it is shown not to be safe then maybe the FDA can withdraw it from the market. But the primary purpose of the act is to insure products that are intended for use as drugs, as this one, are approved prior to marketing.

THE COURT: Are you familiar with the Western States case that plaintiff talked about?

MR. CUTINI: No, I am not, Your Honor, but I believe there was only one condition in the statute. It was not cited in the briefs to this case.

THE COURT: Oh, well I think it was decided long after the briefs were completed.

MR. CUTINI: Correct. But because there has been no the suppression of speech here, the only decision that FDA made was that they cannot make the claim they wish to make as a health claim.

They could make it either in connection with a new drug application, or if they seek amendment to amend the OTC monograph, then they could make the claim that way. There has been no prohibition or suppression of that, and so there is no need to even reach the First Amendment analysis.

THE COURT: Well, I don't understand that

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argument. Clearly the result of FDA's decision is that the plaintiffs are not allowed to put certain claims, certain health claims on their Saw Palmetto.

MR. CUTINI: As a health claim, that is correct, but they can put that on there if they are approved either as a new drug, or if they are successfully getting the OTC monograph amended.

THE COURT: I know that. But the plaintiff's whole argument, and again I don't know where I am going to come out on it, but plaintiff's argument is that that is unconstitutional suppression of speech under Pearson, and that I have to reach that issue because the FDA's interpretation of the statute would require suppression of these health claims, and under Pearson, when those health claims can be presented with adequate disclaimers, then the court should always be mindful of the constitutional implications.

MR. CUTINI: Well, the FDA's decision does not requires suppression, Your Honor. It just means that they cannot make it in the way they want to make it. They have to make it under other provisions of the act, not under the health claims provision.
And the claims that they are talking about in Pearson, I don't think that the argument there was presented that there were actually drug claims and that it was

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improper.
THE COURT: No.
MR. CUTINI: The one I am looking at here in the Pearson case was actually a prevention claim, a claim that point eight milligrams of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects, is more like a prevention claim than a treatment claim.
THE COURT: I agree.
By the way, after -- I think after four opinions between me and the Court of Appeals, did those health claims finally get approved by FDA?
MR. CUTINI: Yes. Some were approved, some were denied, and some were denied without a challenge. Some were approved. So I think those issues are resolved.
THE COURT: In all fairness, until Pearson came down I believe the landscape was quite different, I think, and obviously I came out the other way the very first time around in Pearson.
MR. CUTINI: The FDA estimated that accepting plaintiff's argument that they can make these drug claims as health claims under the NLEA, would lead to many, many products seeking approval under that route as health claims without prior approval of their safety and effectiveness under the drug approval provisions, which is the principal

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purpose of the act.
They estimated that up to 50 percent of currently approved drug products are either foods or based on food compounds for which -- which could be approved as dietary supplements, and if they could make drug claims for those, they could be approved -- making claims in the cure, mitigation or treatment of disease without prior approval under the drug approval provisions of the Food, Drug and Cosmetics Act.
Plaintiffs say that, well, a lot of those are not safe, so maybe they can be taken off the market. But the fact is, and it is undisputed, that as the FDA estimated in the administrative record of this case, up to 50 percent of the currently approved products consist of plants or plant compounds, and they could be approved under plaintiff's theory with only a health claim and without prior approval, and they can make claims for that treatment of disease.
And the FDA noted that people that who actually have a disease require, essentially, better protection than those who are just trying to seek to prevent a disease in the future.

They noted that 94 percent of the currently approved prescription drugs and over-the-counter drugs are for drug treatment, treatment for people who actually have

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diseases. And it was important to protect them by requiring prior approval of the safety and effectiveness of products.

Now in the NLEA, Congress provided that a dietary supplement is not a drug solely because a health claim is made under the NLEA, 343(r). In other words, a product with a health claim, maybe even an approved health claim, could still be a drug if other factors led to that conclusion.

So Congress did not make these definitions mutually exclusive, and it recognized that just because something has a health claim it could also be a drug under the act.

In the legislative history of the NLEA, when examples are given of health claims, they are prevention claims. They are not treatment claims -- when examples of specific claims are given by members of Congress.

THE COURT: I know you cite the legislative history. I found the citations less than compelling. It struck me that -- I am not sure that any of the citations at all from your briefs were to committee reports, or from the sponsors, and as you well know, stray comments by legislators who may not fully understand the implications of such a complicated statute I think are less than persuasive with the court.

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But I did not see cites, I don't believe, from you to, as I says, the congressional committee reports. It certainly -- I am sorry, go ahead.

MR. CUTINI: I am not sure we cited to committee reports. We cited to the House report, the principal House report on the NLEA, and that provides -- and this is in the administrative record at page 736, that:

"The purpose -- the overall purpose of the NLEA is to

promote long-term health maintenance and prevention

of disease by providing information about labeling."

And at page 736 of the administrative record, that report provides that:

"The bill covers only nutrients or substances in food that nourish."

There is no indication in the NLEA that they intended to include products that have a pharmacological effect, which is the effect that Saw Palmetto has, and plaintiffs, in their petition to the agency, compared their product to a prescription drug.

It has a pharmacological effect, and in this House report, Congress indicated that the purpose of the NLEA was

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directed to nutrients or substances that nourish, not

substances with a pharmacological effect.
Subsequent to the passage of the NLEA, the FDA in the Federal Register, in the preambles to both the final rule on conventional foods -- health claims for conventional foods, and the preamble to the final regulation on the health claims in dietary supplements, indicated that a claim for the cure, treatment or mitigation of a disease would not be considered a health claim.
They also indicated that in some instances a prevention claim would not be considered a health claim. That particular discussion is in the administrative record at page 1406.
And sometimes a prevention claim would be a health claim, but not in every instance. So they made this clear subsequent to the NLEA, and Congress has not altered the NLEA in any way, even after these statements by the Food and Drug Administration.
And it is important again to consider the overall purpose of the NLEA, and the overall purpose of the Food, Drug and Cosmetic Act, which is to require a prior approval of the safety and effectiveness of drug products that are used to treat diseases.
The ten specific --
THE COURT: How do you answer the plaintiff's
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plain language argument that its health claim in this instance fits squarely within the language of 343(r)(1)(B)?
MR. CUTINI: Well, what they say is any claim of any relationship between the nutrients or a food and any disease is permitted under that section. And the Food and Drug Administration said you cannot just focus on that. You have to look at the entire purpose of the Food, Drug and Cosmetics Act.
That means that any claim that any product with a food compound, or an herbal or botanical, cures a disease, cures cancer, would have to be allowed. And that would undercut the entire purpose of the Food, Drug and Cosmetics Act, which again requires prior approval before drugs can be approved for the cure, treatment -- cure or treatment of diseases.
And in the NLEA, the Food and Drug Administration made a distinction between medical foods, which are a portion of the Orphan Drug Act that had been enacted in 1988, and those medical foods are foods permitted in the treatment of a disease in very limited circumstances under the careful supervision of a doctor, and it distinguished those types of food used to treat diseases in the NLEA.
And they also indicated very clearly that the definition of a drug and a dietary supplement are not
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mutually exclusive. A product may be a dietary supplement and also a drug, and the Second Circuit has reached the same results.
As indicated previously, there is no First Amendment issue here, because what the Food and Drug Administration has done is simply said that this claim you

seek to make as a health claim renders your product a drug, so therefore you have to try either the new drug approval process or the OTC monograph amendment process. It did not outright suppress that claim. It simply said they cannot make it in the way that plaintiffs seek to make it. And even if this case were analyzed under the Central Hudson factors, however, even though it is not necessary, the decision of the Food and Drug Administration would be upheld. The government has a substantial interest in having drugs proven safe and effective defect before marketing. If plaintiffs can make treatment claims as health claims, they can market their products prior to this approval, and that would undercut the substantial government interest in having these drugs approved, or these products approved before marketing. And requiring that health claims for dietary supplements be prevention only and not be cure or treatment

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claims, directly advances that government interests by protecting the public health in ensuring that all products are approved that are labeled to treat a disease are approved prior to marketing, and they are demonstrated to be safe and effective, and there is no reasonable alternative to requiring prior approval of products that are labeled in the cure or treatment of disease. That is all I have, Your Honor. We rest on our briefs on the rest of this unless the court has specific questions.

THE COURT: Doesn't your argument come down to the argument that Congress did not really mean what it said when it wrote the language of 343(r)(1)(B)?

MR. CUTINI: No. I think you have to consider the context. First of all, the NLEA, the house report that I just read to you, indicates that it was talking about foods in the role of nutrients in nourishment of the body, not in treatment of diseases. The examples given by individuals, although not in committee reports, were prevention claims. There is no indication in the legislative history that Congress intended to undercut the entire, or the primary purpose of the Food, Drug and Cosmetics Act, which is to require prior approval of products that claim to cure or treat a disease.

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So I think you have to read this statute as a whole. You focus on just one section that plaintiff argued means, we can market anything we want, anything with a plant compound, to treat any disease that we want. That would undercut the primary purpose of the Food, Drug and Cosmetics Act.

THE COURT: Okay. Thank you. Just five or ten minutes at the most, Mr. Emord.

MR. EMORD: Thank you, Your Honor. The notion expressed that somehow the drug provision is a viable option here I think is not only

factually incorrect, but belies statements made by the government itself.
In record exhibit number two at 730 the government says, quote:
"Given the time and expense necessary to bring a new drug to market, it is unlikely that manufacturers would seek drug approval from FDA for any product containing a substance that could be characterized as a dietary supplement or a conventional food component."
So they very clearly understand that this is not a
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viable option for us, and they put that in their decision letter in this case.
In addition, the FDA has essentially admitted that it would be almost impossible for a food component to receive drug approval. At 52 Fed. Reg. 28843 at 28845, in 1987 FDA said, quote:
"As a practical matter, food products are not likely to be able to meet the adequate directions for use requirements, or to have disease prevention claims substantiated in a manner necessary for approval of a new drug application."
In addition, FDA concluded in that OTC proceeding, at least in part, that they would not allow Saw Palmetto to be marketed as a drug, because as Your Honor pointed out, the nation that it would lull men into a false sense of security and postpone reexamination by a physician. That is record exhibit to at 729.
And this barrier would exist no matter what, unless we followed Pearson and the First Amendment line where it says that disclaimers are adequate to inform people the need to see a doctor and so forth.
In addition, the notion that -- Your Honor pointed
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out something extremely important that we have not emphasized enough, and that is the difference in the standard of review.
Drugs under substantial evidence have a lot to prove beyond significant scientific agreement under Pearson. There is no question but that this is an extremely significant restriction on speech beyond that which would be under that health claims provision.
And finally -- and I am sorry that I would have so much to say, but I wish to be sure not to exceed the five minutes, but I think it is -- I think it is wrong to suggest to the court that the approved drugs that are relying upon foods, or dietary components, or plants, or extracts from plants are somehow identical or very similar to dietary supplements, or could meet the definition of a dietary supplement.

The reason for that is that in almost every case they are synthetically derived. And as a consequence, they would not meet the definition of a dietary supplement because they would precisely pose those hazards to health that foods and supplements cannot have and be marketed as foods and supplements.

Foods and supplements have to be safe. They are used daily. They are ingested in quantities that are not like those that are typical with drugs, and as a

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consequence, if it is not safe, or if as the act puts it, there is an unreasonable risk to safety, it is illegal to market it.

And FDA tries to argue there is a post-review, pre-review type of check. No. If they went through the health claims approval process and they found substantial evidence to support a conclusion against the United States Pharmacopoeia that Saw Palmetto was unsafe, they could deny the application and it would never be out there with a claim.

But in point of fact, they are allowing Saw Palmetto to be marketed; have for years. They don't go after it on safety grounds, and that is because it is a dietary supplement ingested for prostate health, it poses no serious, as the United States Pharmacopoeia said, no serious adverse events associated with it.

THE COURT: What is your answer to the government's argument that Saw Palmetto is not an item that nourishes the body?

MR. EMORD: Well, I think it is somewhat preposterous, because like all other dietary supplements, it is a derivative from a substance that is a food.

THE COURT: Excuse me, Ms. Kittay. I am in the middle of a motions hearing. Do not bring your matters for the next case before the bar, and try not to disrupt things,

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please.

MR. EMORD: Saw Palmetto is an extract of a fruit, the American palm, dwarf palm, and it has been used by Native Americans for over 100 years as nourishment. In the United States Pharmacopoeia exhibits that we have there, that exact word, nourishment, appears in the exhibit material from United States Pharmacopoeia.

So it is plainly a derivative, an extract from a food, and meet the definition of a dietary supplement. It has to be a nutrient or provide nutrients in order for it to be a dietary supplement.

On the legislative history point, Your Honor's observation I would like to underscore. There is no clear -- to be frank, there is no clear legislative history saying that this was intended only to -- this was intended to exclude an effect on an existing disease. Sure there are prevention examples. We can also give examples of treatment.

They cite a post act point from their own rulemaking to suggest that it is understood that it is not good enough. But if we look at Congress' post act, and even

though I know this is relatively minor, if we're quickly to play the game of looking post act, well very clearly House report 103410 demonstrates that that Congressional committee, which had direct oversight over a nutrient

disease relationship, embraced health claims as treatment claims, because they talked about garlic reducing serum blood cholesterol. FDA has said reduction in cholesterol is an implied disease claim.
They have talked about ginger relieving nausea and stomach distress. Both of those would be considered by FDA as direct treatment claims. They talked about glucosamine sulfate repairing damaged joints.
So Congress -- and there was no -- nothing remarkable in that committee report saying, you know, that we are departing, you know, and this is the Republicans and the Democrats on the full-time committee. It was an understanding that that is what this provision is as our Court of Appeals found, a safe harbor from drug classifications.
Thank you, Your Honor.
THE COURT: Okay. Thank you, everybody. I am absolutely determined to get the case decided. I am not going to tell you that I find the issues any easy. Fascinating, but not any easier. And what's more, I am well aware that Mr. Emord has another very old matter before me which we are also working on.
Something else you had to say for FDA?
MR. CUTINI: I just wanted to point out that in response to the court's question about whether it was

providing nutrition to the body, I mention that to show that the focus of the NLEA was on food and its role in nutrition of the body.
And in the record of this case, the administrative record page 727, the FDA said in its decision that:
"To the extent the effect of
Saw Palmetto was documented
and understood, it is clear
that its effect is pharmacological."
And that is -- then they go on to explain why. And that is not contradicted in the record of this case.
I think also the report that counsel the plaintiff was referring to is the DSHEA legislative report that Congress itself cannot be relied upon as the legislative history for DSHEA, and I think that -- and we explain all that and give the cite where Congress said that in our briefs.
THE COURT: All right. Counsel, thank you very much. Parties may be excused at this time. I cannot promise you a date, except we are working on it.
MR. EMORD: Thank you.
(Whereupon, the proceedings were adjourned.)
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CERTIFICATE OF COURT REPORTER
I certify that the foregoing is a correct transcript of

the proceedings in the above-captioned case.

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SUSAN PAGE TYNER, CVR-CM

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