OFFICIAL TRANSCRIPT

PROCEEDINGS BEFORE

THE SUPREME COURT

OF THE

UNITED STATES

CAPTION: FOOD AND DRUG ADMINISTRATION, ET AL., Petitioners v. BROWN & WILLIAMSON TOBACCO CORPORATION, ET AL.

CASE NO: 98-1152 c.1

PLACE: Washington, D.C.

DATE: Wednesday, December 1, 1999

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IN THE SUPREME COURT OF THE UNITED STATES

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FOOD AND DRUG ADMINISTRATION, :

ET AL., :

Petitioners :

v. : No. 98-1152

BROWN & WILLIAMSON TOBACCO :

CORPORATION, ET AL. :

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Washington, D.C.

Wednesday, December 1, 1999

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 10:02 a.m.

APPEARANCES:

GEN. SETH P. WAXMAN, Solicitor General, U.S. Department of Justice; on behalf of the Petitioners.

RICHARD M. COOPER, ESQ., Washington, D.C.; on behalf of the Respondents.

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PROCEEDINGS

(10:02 a.m.)

CHIEF JUSTICE REHNQUIST: We'll hear argument first this morning in Number 98-1152, Food and Drug Administration v. Brown & Williamson Tobacco Corporation.

General Waxman.

ORAL ARGUMENT OF GEN. SETH P. WAXMAN

ON BEHALF OF THE PETITIONERS

GEN. WAXMAN: Mr. Chief Justice, and may it please the Court:

Following the most extensive rulemaking in its history, the Food and Drug Administration concluded that nicotine in cigarettes and smokeless tobacco is highly addictive and has three other strong pharmacological effects on the body as a sedative, a stimulant, and an appetite suppressant. The FDA found that the manufacturers know this, that they know that consumers predominantly use their products to obtain these effects, and indeed that they engineer their products to deliver the precise doses of nicotine that consumers need to obtain its powerful effects.

The question presented in this case is, whether given those findings, the FDA validly concluded that these products are drug-delivery devices under the Food, Drug and Cosmetic Act. The Act defines drugs and devices to

include, quote, "...articles (other than food) intended to affect the structure or any function of the body...," and the FDA found that nicotine is intended to do so in four quintessentially drug-like ways. Like No Doz, nicotine acts as a stimulant. Like Valium, it acts as a sedative. Like Dexatrim, it suppresses appetite, and like Methadone, it's used to satisfy an addiction.

The FDA also found that cigarettes and smokeless tobacco have the classic characteristics of articles subject to regulation by the FDA. They are taken within the human body. They deliver a pharmacologically active substance to the bloodstream.

QUESTION: Although they're not marketed, are they, as products to treat or prevent disease or cure disease and so forth?

GEN. WAXMAN: Traditionally, they are not, and it is our submission that that does not in any way --

QUESTION: Well --

GEN. WAXMAN: -- affect the definition of whether they --

QUESTION: Okay, but --

GEN. WAXMAN: -- are drugs or devices.

QUESTION: -- then the statute goes further and contemplates that devices, if approved by the FDA, have to be safe and effective, and is it the position of the

Government that the use of tobacco is safe and effective?

GEN. WAXMAN: The -- the FDA is --

QUESTION: I take it not. So, you know, it just doesn't fit.

GEN. WAXMAN: Well, I -- may I respectfully dissent --

QUESTION: Okay.

GEN. WAXMAN: -- and explain why?

QUESTION: Yeah.

GEN. WAXMAN: The Act requires that with respect to devices -- and what we're talking about here is a combination product which the FDA, beginning with the 1990 amendments, was authorized to regulate, that is, a product that -- that combines drug components and device components, but this combination product regulated under the agency's device authorities must be found and marketed under conditions, distributed under conditions that the FDA finds to be reasonably safe and effective for its intended uses.

With respect to devices that preexisted the enactment of the 1976 device amendments and the 1990 combination product amendments, the Act contemplates and requires that after the FDA asserts jurisdiction and regulation over a particular device, but not before, the FDA will engage in a classification process for the

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devices which is explained in great detail in the Act at Section 360(c), 360(d), and 360(e), and in that classification process, which will take place with respect to these products, the agency will be required to determine what controls and under what conditions these articles may be marketed and distributed with reasonable assurances of safety and effectiveness.

Now, at this point -- we have not gotten to the classification point yet, but at this point, where the agency has determined in response to petitions and in response to the overwhelming scientific data that it can and should assert certain regulatory controls, it has determined to -- to regulate these products as restricted devices under its authority given to it in 1976 and reflected in Section 360(j)(E).

QUESTION: So your answer is we don't know yet.

GEN. WAXMAN: The answer is the agency --

QUESTION: We don't know.

GEN. WAXMAN: The agency --

QUESTION: That's basically what you're saying.

GEN. WAXMAN: The agency has made -- and the agency is required to make --

QUESTION: I understand that. Now, do you -- but the question, as I understood it, was do you think there is any prospect of the agency being able to make

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such a statement --

GEN. WAXMAN: The agency --

QUESTION: -- under any classification that this stuff is safe?

GEN. WAXMAN: The agency not only thinks, but the agency has explained in very considerable length in its Final Rule that it -- it believes at this point that it will be able to make determinations with respect to both effectiveness and safety.

With respect to effectiveness, it has found that for at least one of the four known pharmacological effects, that is, addiction, that cigarette smoke and the nicotine in cigarettes is in fact quite effective for sustaining addiction, and it may also find through the classification process that it is effective for the other chemical effects, that is, to -- to provide sedation, stimulation, and

weight --

QUESTION: It does have all of the harmful effects that -- that is the purpose of -- of its distribution.

GEN. WAXMAN: There -- there is no question.

QUESTION: Right. What about the second?

GEN. WAXMAN: No question.

QUESTION: What about the safety?

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GEN. WAXMAN: Now, with respect to safety, the Act requires that safety or, with the case of device, reasonable assurance of safety be determined in the classification process by means of a weighing process that is specified in the statute and was outlined by this Court in Rutherford in which the agency weighs not with respect to the world at large, as the Respondents claim, but with respect to the -- the public that consumes these products, the risks versus benefits of using -- of making these products available versus taking them off the market.

Now, in its rulemaking, the agency was careful to say that it was not making a final determination about this, but based on all of the evidence that it had reviewed to date, both the scientific data with respect to the properties of nicotine and the properties of these devices and the epidemiological and behavioral science data about why people use it and at what stage they use it, it made a determination that on balance, the appropriate means of regulating this product was twofold.

One, because almost all people who become addicted smokers or addicted users of smokeless tobacco begin when they are children or adolescents -- and the data is overwhelming on this -- the -- the distribution or sale to those people should be prohibited. They are likely to be unsafe for those people for all purposes --

QUESTION: I want to know to whom --

GEN. WAXMAN: -- and second --

QUESTION: -- to whom it should not be prohibited --

GEN. WAXMAN: I'll -- I --

QUESTION: -- because it would be safe.

GEN. WAXMAN: I thought you would, and I'm coming --

QUESTION: That was my only question. I didn't --

GEN. WAXMAN: I'm coming right to it.

QUESTION: Okay.

QUESTION: You really take an awful long time to answer that.

GEN. WAXMAN: Well, with -- with -- I apologize, but with all due respect, Mr. Chief Justice, the agency made a determination with respect --

QUESTION: Well, yeah, but --

GEN. WAXMAN: -- to two categories of people.

QUESTION: But when -- when a member of the Court asks you a question, it's better to give the answer first and then explain, rather than give the answer after a fairly long explanation.

GEN. WAXMAN: The -- the short explanation is that for a portion of the population, that is, those under

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18, the agencies made a preliminary safety-ness or reasonable assurance of safety-ness determination that a ban was required.

With respect to persons over 18, the majority of whom the agency found are in fact addicted to these products, the agency concluded that a ban would be more dangerous to these people than allowing these people, most of whom are addicted, to continue to use the products pending a --

QUESTION: But it's --

GEN. WAXMAN: -- final review.

QUESTION: It -- it just -- it -- it strains credibility to say that these products can be safe in light of the findings. I just don't understand how anybody could stand here and say fine, they're safe, so we'll permit them to be used.

I think the conclusion under the statute is if they are covered, they have to be -- it has to be banned.

GEN. WAXMAN: Well, but with all respect, Justice O'Connor, the agency, first of all, has made only a preliminary determination with respect to safety, and it has made it clear that if during the classification process, which requires the convening of panels, including representatives of the manufacturers and the scientific industry, that there are no controls or restrictions that

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could make it safe, taking into account the balance, a ban may be required of these products, and you may have the result that the agency, which has concluded that that might --

QUESTION: And do you think -- do you think it's clear that Congress intended that under this Act?

GEN. WAXMAN: What I --

QUESTION: I mean, we certainly operated for a long time with the understanding that it wasn't covered --

GEN. WAXMAN: Well, the --

QUESTION: -- and this is a very recent phenomenon, and it just -- it doesn't fit very well under the structure of the statute.

QUESTION: An understanding, I might add, that -- that had been conveyed to Congress by -- by the heads of the FDA on numerous occasions when Congress had various pieces of legislation dealing with tobacco before it. It seems to me Congress enacted these statutes on the assumption of the state of the law that -- that they had been assured by the agency itself existed at the time.

GEN. WAXMAN: Well, with respect to the prior statements and the long assumption or assumption that didn't exist, I think in order to go back and understand what the Congress may or may not have concluded in 1938 -- and this Court has said many times that this is a statute

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that was not directed at particular articles, but rather laid out general principles and definitions and intended the agency to apply its regulatory authorities to those definitions where appropriate -- the agency, to be sure, has stated repeatedly before Congress and in the courts and in the public many times for a long period up until 1995, that it did not believe that it had sufficient jurisdiction to regulate tobacco products absent claims made about the effects that those products would have on the body, and in order to understand why that was so, I think it's -- it's probably best to look at what caused the agency to change its mind.

This is an agency that is required to act on the basis, first of all, of scientific data, not general understandings, and, second of all, an agency that is required to act with respect to not uses, but intended uses, and since 1938, the agency has had in place a regulation that explains that -- that the manufacturer's intent is to be determined based on the totality of the circumstances and it is the intent that a reasonable fact-finder would impute to the manufacturer based on all of the objective evidence.

Now, in 1995, the agency heard overwhelming evidence and concluded, number one, that there was an absolute scientific consensus that nicotine is a highly

addictive substance.

QUESTION: That certainly wasn't the first time that that scientific consensus evolved, was it?

GEN. WAXMAN: Well, it -- it actually --

QUESTION: The Surgeon General's warning date -- dates back to the early '60s.

GEN. WAXMAN: Mr. Chief Justice, in 1994, the chief executive officers of virtually all of the Respondents sat 500 yards from this courtroom and testified under oath that -- that nicotine in cigarette products and smokeless products was not addictive and that they did not engineer their products to manipulate nicotine levels and --

QUESTION: As far as the former is concerned, nobody believed them.

QUESTION: Nobody believed them.

QUESTION: I mean --

(Laughter.)

GEN. WAXMAN: At the -- with all due respect, at the time the Surgeon General issued his report in 1994, the Surgeon General found that there was not sufficient evidence to conclude that nicotine was addictive. It was only in 1988 that the Surgeon General did find that it was addictive, and it was largely in the early and mid-'90s that there became a consensus that this product was

addictive.

The agency also found and acted in 1996 --

QUESTION: Excuse me. What -- why is the addictiveness alone necessary for the FDA's jurisdiction? Wasn't it clear from the early '60s? Indeed, wasn't it clear in 1938? Wasn't it clear much earlier than that? States began -- some States had -- a number of States banned cigarettes as early as 1900, and -- and those other harmful effects, whether the addiction was obvious or not, were surely well known, and wouldn't they alone have been enough to require the FDA to come in? Do you need addiction as well?

GEN. WAXMAN: No, no, no. What you need, Justice Scalia, are intended effects. It's just not -- it's not just effects on the structure or function of the body. It would have been unfair and implausible to charge the manufacturers with the intent that people use cigarettes and smokeless tobacco to get cancer and die from emphysema.

QUESTION: Not to get cancer, but to have an effect on the body and the very same effects on the body that are now being described in detail by the addictive mechanism. People have always smoked to get relaxation or to keep going under pressure. We -- we may have hit some question about the strict chemical mechanism by which the

effect is achieved, but certainly from the beginning, there couldn't have been any doubt that people were taking these things for their effect on the body and that they were being sold for people for that purpose.

GEN. WAXMAN: Well, I -- with all due respect, Justice Souter, there were -- I -- I -- I can't place myself back in -- in 1938, but reading some of the materials that the Respondents have submitted and others, there were -- it was generally understood that people smoked because it was soothing or because it gave them status or --

QUESTION: That's an effect on the body.

GEN. WAXMAN: Yes.

QUESTION: It's an effect on the body.

GEN. WAXMAN: And with respect to that, again, I -- without repeating myself, this is an agency that is mandated and expected to act on the basis of scientific evidence. That's just the way the FDA works, and I think -- you know, in fact, the easiest way, at least for me, to see what's different now than -- than was -- than was then -- then -- and it is not our submission that all of a sudden in 1996 something changed. Maybe the agency could reasonably have regulated this in 1985, but if you look at actually the case that --

QUESTION: Well, Mr. Waxman, can the agency

regulate the movie industry that produces horror movies because so many people go to it to get scared and get the adrenalin pumping? Suppose the studies show that?

GEN. WAXMAN: Well, Justice O'Connor --

QUESTION: I mean --

GEN. WAXMAN: -- no -- no one has ever seriously suggested that the FDA exercise regulatory jurisdiction over horror movies or guns or bayonets or --

QUESTION: Well, 30 years ago --

QUESTION: But why not?

QUESTION: Thirty years ago --

GEN. WAXMAN: But --

QUESTION: -- no one would have suggested they exercise jurisdiction over cigarettes.

GEN. WAXMAN: And -- and they would not reasonably have done so. What the -- and the reason -- what the agency does in response to a petition when deciding to exercise its regulatory controls, is to look at the language of the statute and see whether it's covered and then to do what all other administrative agencies and indeed courts do --

QUESTION: When -- when --

GEN. WAXMAN: -- which is to look --

QUESTION: When in your -- when in your view, what year, what time, could the agency reasonably have

regulated cigarettes as a drug?

GEN. WAXMAN: That's a -- that's a -- that's a particularly hard question, Justice Kennedy, because I'm -- I'm really not conversant with when the data became what. I -- one of the things I've struggled with is the agency's 1980 determination that is included as the last document in the Joint Appendix in which --

QUESTION: Well, I interpreted your remarks as saying it would not have -- I think I heard you right that it could not reasonably have regulated tobacco as a drug in 1938.

GEN. WAXMAN: '8. Oh, for sure. I -- I don't think there's any dispute about that.

The agency -- in response to the horror movie question and the gun question, the agency looks first to the language of the Act, the definitional sections and the operative provisions, to see whether or not this is something that with respect to subsection (c) is intended to affect the structure or any function of the body. It then does what all agencies do and what all courts do, which is to look at the practice, that is, does this article and do its intended effects resemble the kinds of articles and intended effects that have always been regulated, the same process that this Court 150 years ago explained in Trinity Church.

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QUESTION: Well, that's fine, but addiction is not the only one. There are other effects that were clear, at least from the Surgeon General's report, harmful effects upon the body. You did not need addiction in addition to that, and the only novel scientific findings you've brought to our attention that antedate the Surgeon General's report are the scientific findings of -- of addiction, although frankly most people suspected that before then anyway.

So why at the time of the Surgeon General's report, which, you know, resulted in a requirement to be posted on cigarette packages -- Caution: The Surgeon General has determined it to be harmful to your health -- why wasn't that fully enough at that point for the FDA to -- to regulate --

GEN. WAXMAN: The agency --

QUESTION: -- although they claim they could not?

GEN. WAXMAN: Right, and they still claim that based -- that the fact that cigarette smoking is known to cause cancer and emphysema and other dread diseases, does not give it jurisdiction to regulate a product. There are many products that are very, very dangerous to health that the FDA does not have jurisdiction to regulate. It has jurisdiction --

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QUESTION: For example --

GEN. WAXMAN: It may be wrong, but it's --

QUESTION: For -- General Waxman, what -- I was trying to see if there was an analogy to something else that the FDA regulates, that is, something that is purchased for its pleasurable effects that has these dreadful, harmful effects, and is -- is there anything that isn't being put forward as a cure?

GEN. WAXMAN: Well, the -- the answer is yes, there are. I'm sure I can't recite anywhere near all of them, but if you look at a recent example, the FDA had regulated and permitted to be marketed a drug, I think, called fenfluradine, which was used to reduce weight in obese persons for a short period of time, and when it became known to the FDA that it was commonly being used with another drug that also starts with "fen" and was producing an alarming incidence of mitral heart valve failure, the FDA contacted the manufacturer, undertook certain studies. The manufacturer withdrew it from the market.

Many of the drugs that either are now or at some point have become listed as controlled substances, were regulated by the FDA long before they became controlled and are still regulated by the FDA --

QUESTION: But -- but -- but --

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GEN. WAXMAN: -- to the extent that they have accepted medical uses, but --

QUESTION: But "fen" whatever it was, was marketed as a means of altering your body chemistry. The -- the manufacturer said take this and your body chemistry will be altered, so you -- you can eat just as much and not -- and not gain weight.

GEN. WAXMAN: That --

QUESTION: The difference here is that -- that this is not what -- what the cigarette makers advertised. So what you really need is an example where it -- you know, it isn't advertised on that basis, but -- but people enjoyed using it, and the reason they enjoyed using it happened to be that chemical change which was not advertised.

GEN. WAXMAN: Justice Scalia, we have cited in our brief -- and I can recount them here -- many, many instances of products that the FDA has regulated based on their intended effects to the -- on the body that aren't claimed, and it has been the FDA's consistent interpretation since 1938 that intended use does not equate to claimed use.

It is certainly true that most manufacturers claim the uses that they intend their products to be made for, but it would be the highest irony if you had a

product like tobacco that every -- and everyone knows what it is used for -- and today everyone knows that it has intended effects on the body that completely escape regulation -- a claims requirement would allow a manufacturer, for example, of Prozac, just to sell Prozac and not make any claims about it, or sell any drug as a generic drug and make no health claims, or sell Valium and say it -- it's soothing --

QUESTION: General --

GEN. WAXMAN: -- and there would be no regulation.

QUESTION: I mean, I accept your argument, and I -- I guess it would be fair to say that I accept your argument on every one of the technical points that has been raised here, but it still does not resolve the case in my mind because I have, I guess, a Chevron Level II basic question.

I agree with you. I think this is a Chevron case, and I agree with you that -- that the -- that the -- the -- the agency has a potential role here in -- in completing or clarifying a statutory scheme that is not totally clear.

Where I have my trouble, when we get to Chevron II and -- Part II, and say, is this reasonable, is not

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with respect to any one of the technical problems that have been raised and I think in -- in large part answered by you, but in the totality of them.

Number one, there's -- there's no question that the paradigm examples of FDA regulation is regulation of substances that are put forward for purposes of -- of health or -- or curing disease or whatnot, even though there are exceptions.

Number two, it seems to me the paradigm way that the FDA goes about it is on a claims-made basis. There are exceptions to it, and you're entirely right under -- under intended use, but most of the time what's going on is a response to a claims-made kind of scheme.

Number three, for a long period of time, the agency, for whatever reason, said we have no jurisdiction over this. It said that despite, at least in my judgment, the fact that they could certainly bring cigarettes within the definition of "drug" even if they weren't sure of the mechanism.

Number four, the agency at this point at least is saying we will regulate, but right now it seems to us that there is a balance of goodness in favor of cigarettes, so we're not going to ban, and that seems in traditional practice to be a kind of unusual analysis.

And finally, given this -- this, in effect,

absence of FDA jurisdiction, the Congress has gone in, not with a global regulatory scheme, but with a lot of congressional statutes that attack various parts of the cigarette problem.

When you take all of that together, what bothers me about the Government's position is that it does not seem to me that it is reasonable at this point for the Government to construe its statutes in a way that asserts regulation. It's the -- it's the global problem, not the technical problems, that bother me.

GEN. WAXMAN: Justice Souter, I think in the time remaining, I guess the best way that I can answer the question is to posit the following.

The tobacco company's principal submission is that their product, contrary to the testimony they gave a few years ago, is so dangerous, that if the FDA has to regulate it -- and they concede that there is nothing in -- in the statute or in any of these later specific statutes that either precludes or preempts the FDA from exercising the authority that it has, but it is now so dangerous that if the FDA regulates, it will have to ban, and that is a ridiculous public health result that Congress never could have intended.

Now, first of all, the FDA has construed and it is in the rulemaking --

QUESTION: Why is --

GEN. WAXMAN: -- what --

QUESTION: Why is -- why is that? I -- I don't -- what do you mean, "so dangerous"? All it has to be is dangerous, harmful to human health.

GEN. WAXMAN: It is -- it -- there are --

QUESTION: That may well be -- that may well be the result with respect to alcohol, too, and, you know, we tried a ban of that and decided forget about it.

GEN. WAXMAN: The FDA regulates alcohol in every respect except in which it appears as a food.

I -- I won't characterize. I'll let -- Mr. Cooper can characterize his own argument very ably, but the question that the FDA put is in light of all of this evidence and in light of the plain language of the definitions and the -- the striking similarity and the characteristics of this --

QUESTION: But we know we can't just go with the plain language of the definitions because they would lead infinitely out. You'd be regulating clothing --

GEN. WAXMAN: And --

QUESTION: -- if you simply went by the -- the definition alone.

GEN. WAXMAN: Justice Souter, when -- when one is talking about a drug or a device that delivers a drug

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to the body, like a cigarette or a syringe, there is no problem applying the literal meaning, but in any event, the FDA went way beyond applying a literal meaning and looked at great length to the extent to which these devices -- and their intended effects resembled things over which they already regulated. But my point is if they are right, if these products, because they are dangerous, must be banned, and the FDA cannot work with Congress to -- to accomplish an amendment to the statute that would, like so many other product-specific amendments, like saccharine, that have been enacted to enable the FDA to continue to regulate in accordance with its public health mandate, then two things will happen. One, we will have an inability of this agency with the paradigmatic responsibility to, for example, require them to use a filter or add a substance that would make these things less causing -- less able to cause cancer or less addictive, and, number two, we would have them remain as if not the only -- virtually the only finished product that is ingested in the body that is regulated and inspected by no Federal agency and yet is so dangerous.

May I reserve the balance of my time?

QUESTION: Very well, General Waxman.

Mr. Cooper, we'll hear from you.

ORAL ARGUMENT OF RICHARD M. COOPER

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ON BEHALF OF THE RESPONDENTS

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

The Solicitor General was not entirely accurate in stating our position. We do contend that the tobacco-specific statutes preclude FDA from exercising jurisdiction, and that's an argument independent of the Food, Drug and Cosmetic Act arguments.

I want to pick up on the answers to the questions from Justice O'Connor and Justice Scalia. As to the scope of FDA jurisdiction and the need for addiction, I'm going to read from the passage in the Final Rule, page 44678, FDA speaking. The nature of a product's effect on the structure or function of the body, therapeutic or nontherapeutic, beneficial or adverse, thus, does not determinate FDA's jurisdiction. The relevant inquiry is simply whether a product has an effect on the structure or any function of
the body.

So they don't need addiction. Their position is that any effect, even an adverse one, brings a product within the Food, Drug and Cosmetic Act.

QUESTION: But only if there's an intent. Isn't the key --

MR. COOPER: Yes, has to -- yes. There has to

be an intent, but for them --

QUESTION: And isn't that the key question in the case?

MR. COOPER: Yes. Well, it's one of the key questions, Justice Stevens, but for them --

QUESTION: But would you concede there is an intent?

MR. COOPER: I do not --

QUESTION: Would you lose if you did concede there's an intent?

MR. COOPER: No, there's not an intent here.

QUESTION: But if you did concede there was an intent, would you not lose?

MR. COOPER: I think not because the -- because, again, the tobacco-specific statutes would preclude FDA jurisdiction.

QUESTION: So you think there had been a partial repeal of the FDA?

MR. COOPER: No. I think when the -- I think the -- as in Estate of Romani, the issue of FDA jurisdiction had not been determined favorably -- in favor of jurisdiction prior to the enactment of the tobacco-specific statutes. So it's a question of harmonizing the statutes, reading them together, and these statutes cannot be harmonized consistent with FDA

jurisdiction.

QUESTION: Your position, if I understand it, is that although there may have been Chevron play in the joints originally in the statute after there's other legislation which has to be taken into account, step one of Chevron is no longer passed.

MR. COOPER: Yes, with an addendum that there are then multiple statutes, most of which are not administered by FDA, so that deference under Chevron would not be appropriate, and even at Chevron step one, before the enactment of the tobacco-specific statutes, we still have the Food, Drug and Cosmetic Act not being able to accommodate these products.

QUESTION: But I still want to know. Do you think that those statutes amended the Food, Drug -- the Food Act?

MR. COOPER: They did not amend it.

QUESTION: So your basic position is that even if none of those statutes had been passed, you would still not be subject to the statute because you did not have the requisite intent because you didn't advertise the cigarettes as being addictive.

MR. COOPER: Because when you --

QUESTION: That's really your basic position.

MR. COOPER: Well, there's more -- there --

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that -- that's part of our position. There's more to it than that.

These products simply, as Justice O'Connor noted, don't fit into the Food, Drug and Cosmetic Act. There's an array of health and safety statutes in this country. The Food, Drug and Cosmetic Act is unique among them in that it requires, as to drugs and devices, the weighing of benefits to health against risk.

QUESTION: Well, but, again, if --

MR. COOPER: There's no --

QUESTION: -- that's your basic argument, you don't need all these -- these later statutes.

MR. COOPER: We don't need them, but they're very helpful to us.

QUESTION: Well, I don't think they're --

[Laughter.]

QUESTION: It seems to me, they're totally irrelevant --

MR. COOPER: No. I --

QUESTION: -- because they don't directly answer the question --

MR. COOPER: I would --

QUESTION: -- and you may be right on the basic question because they didn't advertise this product the way they -- the way they claim you intended it to be used,

but I thought the heart of your argument was that there's no intent because there's no claim that had these -- these positions.

MR. COOPER: Our argument has multiple parts.

I would submit that the tobacco-specific statutes are the most relevant because they're the ones that tell us how Congress has dealt with tobacco and health, how Congress wants these products --

QUESTION: Yes, but the problem with that -- let me just get it right on the table. The problem with that is it seems to me at least theoretically possible that until 1990, say, you had no intent to make this stuff addictive and there was no evidence, objective evidence of such an intent, but in 1994 or '95, such evidence -- you changed your minds, and you then decided on a new marketing strategy with this intent, and then -- and then for the first time became under the statute. It seems to me, that's at least theoretically possible.

MR. COOPER: It's -- it's contrary to the facts, however.

Let me read a passage from the 1964 Surgeon General's report.

QUESTION: Well, that's just to the addiction.

MR. COOPER: Yeah.

QUESTION: I'm only focussing on intent, the

intent of the companies marketing the product. Is it not possible that the intent was different in 1985 than it is today?

MR. COOPER: The intent is derived from the claims in the marketplace --

QUESTION: Well --

MR. COOPER: -- which have been essentially --

QUESTION: All right.

MR. COOPER: -- the same, and there's a reason for that.

QUESTION: If you rely entirely on claims in the marketplace, it's an easy case. You win. You don't need all these statutes.

MR. COOPER: Well, we can win without them.

QUESTION: Well, but you don't really respond to my question.

QUESTION: Why don't you -- why don't you -- why don't you answer his question which relates not to claims in the marketplace, but to what -- I know some -- some of the literature talks about objective intent. I have no idea what objective intent is, but let's assume--

MR. COOPER: That's in the FDA regulation.

QUESTION: We are --

MR. COOPER: I'm trying to answer the question.

QUESTION: Well, as I understand the question --

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is never mind what the claims were.

MR. COOPER: Right.

QUESTION: Has -- isn't it possible that there was an -- a change in the subjective intent of -- of those who marketed the cigarettes, that only at a more recent date was it clear that it was their intent to make physical alterations --

MR. COOPER: Is it possible that there was a change --

QUESTION: -- in the -- in the bodies --

MR. COOPER: -- in subjective intent?

QUESTION: Yes.

MR. COOPER: Yes. Is there an FDA finding on that? No. Is subjective intent relevant under the statute? I would submit not. The FDA regulation, as you point out, Justice Scalia, requires an objective intent. That's a very unusual term. It didn't say objective evidence of intent. It says an objective intent.

QUESTION: Let me just change it. Supposing the evidence of objective intent didn't surface until 1995.

MR. COOPER: Object -- evidence of objective intent by its very nature must surface in the marketplace. The evidence of objective intent is claims and representations in the marketplace --

QUESTION: Or you could have --

MR. COOPER: -- and it's public.

QUESTION: Could you have aspirin? Couldn't you have aspirin? Everybody knows what it does and you don't need a claim. All you have to say is the word "aspirin." Everybody knows what it does, and would you say there is no intent there to cure headaches?

MR. COOPER: But there --

QUESTION: I mean, isn't claim evidentiary of intent --

MR. COOPER: No.

QUESTION: -- rather than the other way around?

MR. COOPER: I would -- the -- the claim establishes the objective intent. In the case of aspirin, it was established by claims of pain, but --

QUESTION: Fine. If a claim establishes objective intent, hear what they have now, but not previously, is every smoker, no longer being able to kid themselves -- knows that this nicotine through chemical effect, metabolized in the body, creates feelings of tranquility and or calmness and satisfies a craving created by chemical addiction. They know it, the smokers. The manufacturers know it, and nobody can kid themselves anymore, though maybe they could have kidded themselves before 1965.

Now, I take it that under those circumstances,

the FDA says this falls right within the language, the purpose, the precedence, and everything else in the statute.

MR. COOPER: But it -- no, it does not fit within everything else in the statute, Justice Breyer.

The -- the approval process, for example, for drugs and devices requires a finding of effectiveness, and effectiveness, even before the 1962 drug amendments, was an element of safety. If a product does not purport to provide a benefit to health or body functioning or structure, there is nothing to evaluate for effectiveness. There is nothing to weigh against risks --

QUESTION: Sure there is.

MR. COOPER: -- in evaluating safety.

QUESTION: Sure there is. What there is, is there's risk. That is to say, is the word "safety" in this statute supposed to stop the FDA from looking at the real world? What they say is overall we get more safety by letting people smoke for a while because of the addiction in the country, the risk of black market. In other words, suppose aspirin turned out to have a chemical that was very harmful, but it was also addictive. If they discovered that for the first time, wouldn't they have the power to treat these other sections of the statute, looking to safety overall for the public rather than

suddenly withdrawing an additive substance?

MR. COOPER: But we are bound on this record by FDA's findings, and FDA found these products unsafe. And indeed, it said in the -- in the proposed rule at Page 41348 that if these were to be regulated as drugs, they would have to be found safe or found generally recognized as safe

and -- and I quote, "Neither of these outcomes can be viewed as a realistic possibility," close quote, no realistic possibility of finding these products safe.

QUESTION: For an individual, but, I mean, can't they have a remedy that creates safety overall rather than a remedy that will in fact lead to a lot of people being hurt?

MR. COOPER: I submit not. The -- there -- there is no general public health standard under this statute. Section 903 21 USC 393 requires FDA to ensure that drugs are safe and effective, and under Section 360(c)(A)(2)(a), that means for the people who use them, and the statute also requires that there be a reasonable assurance that medical devices are safe and effective.

This Court reviewed the standard for medical device approval in Medtronic. It's a rigorous standard. It relates to the health of the individuals who will use the product.

QUESTION: I guess --

QUESTION: So if it --

QUESTION: I guess on the theory that Justice Breyer is inquiring about, the FDA could -- could approve the -- the sale of -- of cocaine, and in effect adopt the -- the theory of many people who want legalization of drugs; that the overall social benefit of legalizing them will -- will outweigh the individual harm. You'll have much less crime and so forth and so on. I suppose if the FDA has -- can do this kind of a thing with cigarettes, it could do it with -- with marijuana, with any of the other drugs that -- you know, overall it would be better to have a free market in this stuff, and some people would be hurt, but the society at large would be helped. I guess this is the theory we're talking about.

QUESTION: Yes.

QUESTION: You don't disagree with that, do you?

QUESTION: Yes, yes. I thought Methadone -- I thought -- sorry -- cocaine and these drugs are the Controlled Substances Act, a different act. I also thought that Methadone in fact does involve such a theory.

MR. COOPER: But I don't -- I -- I -- that's not the way the Food, Drug and Cosmetic Act requires drugs and devices to be regulated.

QUESTION: But, Mr. Cooper, suppose -- suppose

that heroin, it wasn't unlawful. Suppose, as in the case of cigarettes, it's lawful. Are you saying if -- if heroin were legalized that the FDA then could not regulate it?

MR. COOPER: If it does not purport to have a health benefit, it's not subject to regulation under the FDCA, but that doesn't mean it escapes regulation. It could be regulated under the Controlled Substances Act, as in fact it is.

QUESTION: But not by the FDA.

MR. COOPER: But not by the FDA.

QUESTION: So, if a product is simply harmful to one's health, then it falls outside of the FDA.

MR. COOPER: There are thousands of products that are potentially harmful or injurious that are -- that's why Congress --

QUESTION: But one that's ingested in the body.

MR. COOPER: Even ones that can be ingested into the body. Household cleaning fluids, for example, can be ingested by children, for example.

QUESTION: Yes, but where the -- where the core use of it is ingesting it into the body --

MR. COOPER: Well --

QUESTION: -- not an accident.

MR. COOPER: Street drugs. Street drugs. If

somebody puts out a street drug and says this will -- is for pleasure, that's not regulated by FDA. That's regulated by the Drug Enforcement Administration.

QUESTION: Well, you're saying then if we legalize marijuana on the theory it has some health benefits for people with certain disease and so forth, you say the FDA could not regulate marijuana?

MR. COOPER: Oh, no. If there's a theory that it's for health benefits, then certainly FDA does regulate it. That's where FDA comes in, where there is a claim of health benefit.

QUESTION: But if the intent of the manufacturers of cigarettes is to provide certain health benefits, why is that different --

MR. COOPER: Well, there's --

QUESTION: -- if there is the intent, which, of course, you dispute?

MR. COOPER: There's no finding by FDA that any cigarette manufacturer has intended to provide a health benefit.

QUESTION: What about some of these so-called --

QUESTION: What -- not the suppressant, the suppressant of -- appetite suppressant and the three or four things they mentioned, relaxant and stimulant and so on?

MR. COOPER: FDA has said that those are effects. It has not said that those are significant enough to be beneficial. There's no such finding.

QUESTION: Well, suppose they made that finding.

MR. COOPER: We'd have a different case.

QUESTION: But they then regulate if -- if they had the same evidence on intent?

MR. COOPER: They would have to have legally sufficient evidence of intent, and --

QUESTION: They say they do.

MR. COOPER: -- that requires a claim.

QUESTION: They say they have such objective evidence, and I didn't understand you to disagree with that finding.

MR. COOPER: Oh. FDA says at page 45194 in the Final Rule that they are not relying on any claims, anything on the package labeling --

QUESTION: Not claims.

MR. COOPER: -- any representations made. They're relying entirely on other kinds of evidence.

QUESTION: Are you saying that if the requisite intent as hypothesized by Justice Stevens were found, that FDA could regulate despite the existence of the congressional statutes that have been enacted?

MR. COOPER: No. I think -- I think those

statutes --

QUESTION: So the statutory argument stands on its own?

MR. COOPER: Yes, it does, and I think it -- technically, you would say it precludes a finding that a -- that a tobacco product is within the jurisdiction of FDA under the definitions.

QUESTION: Could I ask one other question which is -- I mean, I seem -- to me, underlying your basic food and cosmetic argument -- food -- the -- that Act, there were two really basic points, and one you've dealt with, which is the question of, well, what remedy. It doesn't foresee a sense of a remedy, and that's a question of flexibility. And the other thing is what I thought Justice O'Connor asked earlier, which is it will produce a whole lot of bizarre results such as, if you could regulate tobacco, then they could regulate thermal gloves. Have I focussed you on what I'm thinking of?

MR. COOPER: Yes.

QUESTION: Okay. Now, in thinking about that, I wanted to ask you, suppose you got the thermal-glove effect, you know, warm hands, through a pill. You know, somebody said take this pill, it will toughen your skin and bring gloves -- bring blood to your hand. Well, now we're taking it through a pill and now it's going to

affect our metabolism and change the chemistry of the brain or something. Well, is it absurd that the FDA could regulate that kind of stuff if you got it through a pill?

MR. COOPER: With a claim of the type you describe?

QUESTION: Well, that's what I'm interested in. When is the claim part? And I think we've dealt with that. Leave the -- I mean, not that you've -- I'm saying, let's put that to the side for a minute and come back to it if you'd like, but is there anything other than the claim? You know, what they do is they say take this pill, it's metabolized, it affects your brain, creates an addiction, and lo and behold, you've got warm hands if it gets cold in the winter.

MR. COOPER: Sounds like alcohol.

QUESTION: Yeah -- or no. Well, it's -- yeah, maybe it is, and so could they regulate that if it's not a food?

MR. COOPER: As a drug?

QUESTION: Yeah.

MR. COOPER: No. I would -- I would say they could not.

QUESTION: They could not? Why not?

MR. COOPER: There are other statutes. There are other statutes. If I put out --

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QUESTION: Why -- why -- why not in terms of the words of the Act, the purpose of the Act, the limitation which has gotten -- see, I got the limitation by working backwards from the device statute. Do you see what I mean there?

MR. COOPER: Yes, because --

QUESTION: You know, if the device is not, well, this is.

MR. COOPER: I think I understand.

QUESTION: Yeah.

MR. COOPER: The purpose of the Act, separate from other health -- there are many other health and safety statutes. The purpose of this statute is to regulate products that purport to provide benefits to body structure or functioning. If all --

QUESTION: This does it before.

MR. COOPER: If all a product does is present risks and some other kinds of benefits, non-health benefits, then you can regulate it under the Consumer Product Safety Act

and --

QUESTION: Well, what about Marmola? I mean, why -- why would a pill that keeps your hands warm be different from a pill that makes you look slim and trim?

MR. COOPER: Unless there's a claim that it

keeps your hand warm, nobody would know.

QUESTION: Or -- but is then that -- is it only the claim that makes the difference?

MR. COOPER: Yes.

QUESTION: Only the claim?

MR. COOPER: It's the -- it's the -- and the nature of the claim.

QUESTION: Right, if it's only -- okay.

MR. COOPER: There's got to be a claim, and it's got to be of a -- of a benefit.

QUESTION: Is it good enough to say the claim -- the claim, in our case of the hand-warmers, it keeps your hand warm with Marmola, it keeps you thin, and with cigarettes, what it does is it makes you feel tranquil, stimulated, and cures a physical craving that it created through addiction. That's the claim, okay? Now, under those circumstances, aren't those three things the same? Then we can get to whether there is a claim.

MR. COOPER: If there is a claim of a non-trivial --

QUESTION: No, but I'm -- I'm trying to leave the claim out of it for the moment. I'll -- have we got three similar cases? Marmola, the hand-warming pill, and let's call it the cigarette.

MR. COOPER: And all of which, just so I have

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the question clear --

QUESTION: All of which you're saying in the one case, we keep your hands warm, in the second case, we keep you slim and trim, and in the third case, we keep you tranquil, stimulated, and we cure an addiction, i.e., we satisfy an addictive craving that we ourselves created.

MR. COOPER: I don't think that satisfying addiction is sufficient.

QUESTION: Okay, we got --

MR. COOPER: But if you -- if -- if you have a product that -- that makes a claim to stimulate or to sedate, that's within FDA's jurisdiction.

QUESTION: Okay. Now, if that's so and all we're left with is a --

MR. COOPER: It's not a tobacco product.

QUESTION: No, no.

MR. COOPER: We don't have the tobacco-specific statutes.

QUESTION: Okay, got all that out.

All -- if all we've got left is the claim, now, why isn't it the same as making a claim that everybody who buys the product knows that you want it to do that and you do want it to do that, and so they don't have to read words on a package, they've got the point once you say it's a cigarette?

MR. COOPER: Because the way the Food, Drug and Cosmetic Act has always worked is that the initiative for defining the purpose, the use of the product is with the manufacturer. It's done through the approval process. When the manufacturer submits the application to FDA, it covers not only the product. It covers the proposed labeling for the product, which specifies what the product is to be

for -- is to be used for, and thereby specifies the dimension of efficacy that's to be assessed by FDA.

QUESTION: All right. What -- what do you make of the regulation which has apparently been on the books for decades which we have referred to or the FDA has referred to as objective intent? That seems to be an alternative to a claims-made scheme.

MR. COOPER: No, I say it's the same. It's not objective evidence of intent. It's objective intent, and I say it's a strict analogy to congressional intent. Like congressional intent, it's not what's in somebody's mind. It's what's written on public documents that everybody can see and everybody can know about.

We talk about the intent of --

QUESTION: It is certainly a very obscure way of referring to an express claim.

MR. COOPER: If you -- if you go through the

various sentences in the regulations, FDA says objective intent is determined by the representations of the manufacturer or other vendor. In the absence of such representations, we can look to objective circumstances. FDA very easily --

QUESTION: And the objective circumstances are the subject of Justice Breyer's question. Why are not these objective circumstances subject to FDA notice even though there is no express claim?

MR. COOPER: They come into play only where there is no intended use established by other representations. When the case of --

QUESTION: You mean it's a default rule?

MR. COOPER: It's a default rule.

In the case of tobacco products, we have had for decades, time out of mind, representations that their intended use is for smoking pleasure --

QUESTION: Okay. And what -- what is the --

MR. COOPER: -- and taste and so on.

QUESTION: What -- and I -- I think this has passed over me because I didn't know it was coming. What is the textual basis for your saying it is simply a default rule?

MR. COOPER: Just reading it. I mean, it's in the regulations.

QUESTION: Well, you were just referring -- you were just referring --

MR. COOPER: It's in -- it's in the regulations.

QUESTION: -- to the text. What is -- what is the textual phrase, if you can give it to me?

QUESTION: It's not statutory text. It's regulatory text.

QUESTION: That's -- yeah.

MR. COOPER: This is -- it's in the regulations. The words "intended use" or words of similar import refer to the objective intent of the persons legally responsible for the labeling of the drugs. Next sentence. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article.

QUESTION: Well, "or" does not sound to me --

MR. COOPER: Right.

QUESTION: -- like a default rule. It sounds like an alternative.

MR. COOPER: I'm just -- I'm -- that's how it has been understood for decades. That -- there are many drugs, for example --

QUESTION: You're saying it's been understood is the default.

MR. COOPER: Well, there are many drugs and

devices, some of the most important in all of medicine, that have off-label uses, that are not covered by the representations by the manufacturer, that are widespread, common, foreseeable, and medically necessary --

QUESTION: So your --

MR. COOPER: -- to save lives.

QUESTION: -- your -- your argument, I guess, is if you're going to preserve the -- the concept of off-label uses, you've got to take this default.

MR. COOPER: Yes. Otherwise, all of those products become unlawful -- unlawful.

QUESTION: Okay.

QUESTION: The primary purpose --

QUESTION: Well, but then the --

QUESTION: -- primary purpose would serve the same thing. It's the primary purpose of the cigarette manufacturer to produce this satisfaction or tranquility or stimulation through an addictive mechanism. It is not the primary purpose of the drug manufacturer to produce the off-label use.

MR. COOPER: It may well be. In the case of --

QUESTION: Oh. Well, if it is, then why --

MR. COOPER: In the case --

QUESTION: -- shouldn't they go --

MR. COOPER: Well --

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QUESTION: -- through the process?

MR. COOPER: -- take a concrete example. Children's aspirin is -- is virtually -- has virtually no use for children these days because of Reye's syndrome, is widely used by adults on the advice of physicians.

QUESTION: And on your view, the FDA could not regulate the use of baby aspirin for adults.

MR. COOPER: Except if -- if FDA finds --

QUESTION: Under the way they now advertise it, they could not regulate it; isn't that right?

MR. COOPER: Well, they can. They can. FDA can always determine that overall it is an unsafe product, taking everything into account.

QUESTION: Even though there are no claims involved?

MR. COOPER: You -- you can take the adverse -- yes. You can take adverse effects --

QUESTION: Provided, though, it has to be intended for -- for use on the human body.

MR. COOPER: No, no. FDA's safety assessment is with respect to whether the benefits of the intended use outweigh the risks from -- from all uses of the product.

QUESTION: Yes, but --

QUESTION: Most -- most children's aspirin says on it, also for adult aspirin regime.

MR. COOPER: Yes, but without specifying what it's for.

QUESTION: Well, it's not the end of the world if they can regulate children's aspirin. I mean --

MR. COOPER: They do regulate it.

QUESTION: -- so they should. Right. So I thought the claim, of course, is always present with almost all drugs because drugs normally by their name don't explain themselves, but the unusual thing here is that we do have a product that everybody knows what it does, and that's why I ask whether claim isn't really indicative of intent rather than the other way around. Why do you need the word "claim" which isn't in the statute --

MR. COOPER: You need --

QUESTION: -- when in fact you have the product that the manufacturer wants it used for X and everybody knows it?

MR. COOPER: You need the word "claim" in order to make the statute workable. You need it for several reasons. You need it to avoid the -- making all drugs and devices with off-label uses unlawful and depriving the medical community of those products. Second, you need --

QUESTION: Why the -- the way around that -- the way around that was primary purpose.

MR. COOPER: But that -- that's got no textual basis either, with due respect.

QUESTION: Well, it would avoid the problem that you have. A lot of this --

QUESTION: Mr. Cooper, are you going to talk about your statutory argument? You say you have a whole separate basis that -- that exists separately. Frankly, my -- my whole concern with this thing is -- is that even assuming that originally the Food and Drug Act could have been interpreted to -- to apply to cigarettes, there's a lot of water over the dam since then, including representations
by -- by commissioners which have been the basis for other Federal legislation. Now, do you want --

MR. COOPER: Let me say --

QUESTION: -- to discuss what that other Federal legislation is --

MR. COOPER: I'd say two -- two things.

QUESTION: -- and why you think it's inconsistent with -- with the Food and Drug Act?

QUESTION: Just as a preface to this same subject, I -- I had the same concerns with the case, and they were addressed by Justice Souter when he asked about the global position of the case with reference to the statute, and I wasn't quite sure that the Solicitor

General was able to -- to focus in on it either.

As part of your discussion, perhaps you could tell me -- tell us, Section 1331, does this repeal the -- the original FDA in part and -- or -- or is it an indication that Congress is now taking away jurisdiction that once the FDA would have had?

MR. COOPER: Let me -- it's not a repeal, but I -- it's -- it's analogous methodologically to Estate of Romani and to U.S. v. Fausto. You have multiple statutes and you need to read them together to make sense.

What I would say 1331 shows, that there's more at stake here than health. Health problem is obviously critical, but Congress in 1331 made it clear that it's balancing and making tradeoffs among a number of interests in addition to health. Economic interests, interests in informed adult choice, those are beyond the ken of FDA.

As Commissioner Kessler said, the regulation of tobacco raises, in his words, societal issues of great complexity and magnitude. Those are not for FDA. Those are for Congress. Congress addressed them in the Federal Cigarette Labelling and Advertising Act, and it told how it was going to do it and how -- how these products are to be regulated in 1331.

QUESTION: What you're saying basically, there's kind of a legal stenosis going on here; that because of

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everything that has happened, the original grant to the -- to the FDA has been somewhat narrowed?

MR. COOPER: I -- I would say there was no original grant to FDA. The possibility of an original grant, the theoretical possibility has been eliminated -- was eliminated in 1965.

Give you one other example. FDA acknowledges that the cigarette and smokeless statutes prevented from requiring health information on packages of tobacco products. These are products sold over the counter. Health information on drugs and devices sold over the counter is the predominant way that FDA ensures that these products are safe and effective. If you take that away from FDA, as Congress did with respect to tobacco products, there's no way to ensure as a practical matter that these products be safe and effective. It would make no sense for Congress to delegate to FDA authority to regulate tobacco products as over-the-counter drugs and devices, but disable FDA from using the primary tool to ensure the safety of these products.

You go into a drug store. You pick up a drug or a device. It will tell you in great detail how to use it safely and effectively, and FDA is disabled from using that core power with respect to these products.

QUESTION: Do you read 1331 as saying -- as

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being a congressional determination that tobacco is a lawful product?

MR. COOPER: Yes, I do, and -- and -- and that determination existed even in 1938. In the Agricultural Adjustment Act of 1938, which is cited on page 10 of the Philip Morris Lorillard brief, Congress in Section 311, which today is 7 United States Code 1311, found that the marketing of tobacco is one of the greatest basic industries of the United States, and further found that stable conditions therein are necessary to the general welfare. That finding is absolutely incompatible not only with a ban, but with a delegation to an agency of authority to ban.

QUESTION: Which is conceivable. I guess downhill skiing is not good for your health either, and -- and we do allow that, don't we?

MR. COOPER: We permit adults --

QUESTION: Yeah.

MR. COOPER: -- and others to do that.

I would submit that FDA's assertion of jurisdiction here is lawless, and however admirable its intentions, its motive, it is setting aside established principles of law. It is doing real harm to the Food, Drug and Cosmetic Act, potentially expanding the agency's jurisdiction beyond limit, and severely weakening the

consumer protection provisions of the Act in the interest of enhancing the Agency's discretion. That Congress provided for the way these products are to be regulated, and if there are new facts, the precedent of 1964 should be followed when the Surgeon General made his report to Congress and went and testified and Congress enacted a new statute. That's what should happen here, and FDA's assertion of authority should not stand.

Thank you.

QUESTION: Thank you, Mr. Cooper.

General Waxman, you have 2 minutes remaining.

REBUTTAL ARGUMENT OF GEN. SETH P. WAXMAN

ON BEHALF OF THE PETITIONERS

GEN. WAXMAN: Lawless. The agency has made a reasoned determination about a statute that this Court has always given it great deference to, and this -- which this Court has uniformly said must be given a broad reading to effectuate its purposes. It has found without dispute that pharmacological effects are produced, they are intended, and that the manufacturers secretly for years have engineered their products to sustain those particular uses.

The -- the notion that this somehow exceeds the bounds of the law, I suppose, depends on either a notion that although this statute is careful in different

sections to talk about intended use versus claims -- and we've cited many of the instances in our -- in our brief -- nonetheless, intended use has to be meant to read -- to read claim.

That -- if this Court were to construe the FDCA to have intended use mean market claims would revolutionalize the way this agency has done business for more than 60 years, and it would create the largest regulatory hole in existence by allowing anyone, no matter how dangerous or benign their product, to market it simply by saying that it provides satisfaction, or it's ibuprofen, we're not going to tell you what it -- what it regulates.

QUESTION: What do you do about -- about the doctors using -- using medicines for non-prescribed uses? What -- how do you explain that?

GEN. WAXMAN: As we've explained in our brief at page 5 and with specific reference to the aspirin example, which is the only example that they've given, the FDA does not regulate off-label use by -- may I finish my answer? -- does not regulate off-label use by physicians, but it provides -- and there is a 1972 notice that was published in the Federal Register that when it determines that an off-label use becomes widespread or common, it will inquire, ask the manufacturer to come in and may require it to label it, which it has done with respect to baby

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aspirin itself.

CHIEF JUSTICE REHNQUIST: Thank you, General Waxman.

GEN. WAXMAN: Thank you very much.

CHIEF JUSTICE REHNQUIST: The case is submitted.

(Whereupon, at 10:59 a.m., the case in the above-entitled matter was submitted.)

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