

Court Decision on FDA Tobacco Rule

Department of Justice Summary

Today in Greensboro Judge Osteen denied the tobacco companies' motion for summary judgment that FDA could not legally assert jurisdiction over tobacco products. Judge Osteen expressly held: "tobacco products fit within the FDCA's definitions of 'drug' and 'device.'" The Court further agreed that FDA can regulate cigarettes and smokeless tobacco products under the combination product and restricted device provisions of the Food, Drug, and Cosmetic Act and upheld many of the restrictions imposed by FDA. However, on purely statutory grounds, Judge Osteen found that the restricted device authority does not allow FDA to regulate advertising and promotion of tobacco products.

In reaching his decision, Judge Osteen rejected the tobacco plaintiffs' contention that Congress had preempted the FDA from asserting jurisdiction. Judge Osteen stated, "This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products." The Court also refused to bind FDA to statements by prior Commissioners that the agency lacked jurisdiction to regulate tobacco products as customarily marketed or to find that Congress had ratified or acquiesced in those statements.

However, the district court held that FDA lacks authority under Section 360j to regulate promotion and advertising of tobacco products. The court found that the statutory provision giving FDA authority to set "such other conditions" on the sale, distribution, or use of restricted devices does not cover promotion and advertising restrictions.

In sum, FDA's regulations prohibiting the sale of tobacco products to children and adolescents, requiring retailers to check photo identification of purchasers under 27, banning self service and vending machine sales have been upheld, while the limits on advertising and promotion have not. Because of his statute-based ruling on advertising and promotion, Judge Osteen declined to reach the first Amendment challenge to those parts of the regulation.

Anderson, L

April 24, 1997

NOTE TO: Rahm Emanuel
Bruce Lindsey
Ron Klain
Bruce Reed
Ann Lewis
Michael Waldman
Mike McCurry

FROM: Elizabeth Drye 

SUBJECT: Q&A on Tobacco for Friday's Press Conference

Attached are the Qs&As on the tobacco settlement talks. We will have the Qs&As on the court's 11:00 am decision before noon.

cc: Elena Kagan
Toby Donenfeld
Julie Mason



Questions on Tobacco Settlement Talks

Q. How does the judge's decision affect the Administration's interest in a settlement?

A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling].

Q. Isn't the Administration deeply involved in settlement talks?

A. Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q. But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A. My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. But, I'll say this: everybody agrees that blanket immunity is out of the question. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

April 25, 1997

STATEMENT BY THE PRESIDENT

This is a historic and landmark day for the nation's health and children. With this ruling, we can regulate tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by the diseases that come with that addiction. This is a monumental first step in what we always knew would be a long, tough road, and we are ready to keep pushing on.

This is a fight for the health and lives of our children. Each day, 3,000 children and young people become regular smokers, and 1,000 of them will have their lives cut short as a result of smoking. This is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging. The Vice President and I are committed to protecting our children.

Our common sense approach is aimed at limiting the appeal of these products and making it harder for children to buy them. Retailers have the responsibility to make certain that they are not selling tobacco products to anyone under 18. Asking them for a photo ID is just plain common sense. Keeping tobacco billboards away from schools and playground is just plain common sense.

Senior attorneys from the Department of Justice, the Department of Health and Human Services and the Food and Drug Administration have carefully reviewed the District Court's opinion. On the basis of that review, the Solicitor General has informed me that an appeal would be appropriate for that part of the rule not upheld and I have directed that an appeal be filed.

We will continue to work to protect our children and our children's children. We will not stop until we succeed. Where our children's health and safety are concerned we cannot, and we will not, rest.

April 25, 1997

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

THE DECISION

The court ruled that FDA has jurisdiction and that the rule's access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

STATEMENT

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Background statement until POTUS statement:

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration have reviewed the opinion and a statement from the President on what the next legal steps the Administration will take will come shortly.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today, we won a historic victory in court, and we're going forward with the provisions the court upheld.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with the states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: The provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect and we are working with states to begin checking for compliance. And it means that FDA has the authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

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Questions on Tobacco Settlement Talks

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A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling].

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A: I'm not in any position to judge any settlement. But, I'll say this: everybody agrees that blanket immunity is out of the question. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

TEST FAX

FROM: Allison Sisk
Dept of Justice - Civil Division
202-616-1281

TO:

1. **Fax:** (202) 690-7998
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Recipient: Ken Zwick, (202) 514-4552

This is a test of the DOJ system for simultaneously transmitting a fax to multiple recipients. This is the system we will use to distribute the Greensboro tobacco decision when it is issued sometime after April 20.

Please have your office call me at 202-616-1281 to acknowledge that this test fax has been received. It consists of this cover page plus two additional pages.

Thanks,

Allison Sisk

[illegible]

[illegible]

Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

[Scenario C - No Jurisdiction, no restrictions]

Where our children's health and safety are concerned, we cannot rest. Today's ruling restricts our ability to protect our children from the deadly harms of tobacco, and that is why we will appeal it.

This is not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their new customers: cartoons like Joe Camel send a message that smoking is cool; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

That is why we took action last summer to make it harder for young people to buy cigarettes, and to stop the kind of marketing that tempts them to do so. We knew it would not be an easy fight, but we knew it was the right thing to do. And we will continue to do everything we can to protect our children from tobacco, and to help them lead healthy, productive lives. That is why we will appeal this ruling, and I am confident that we will prevail.

April 25, 1997

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From: HHS, FDA Public Affairs

BACKGROUND

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THE DECISION

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A: The bottom line is that we are going to protect our children. Today, we won a historic victory in court, and we're going forward with the provisions the court upheld. A statement on what next legal steps the Administration will take will come shortly.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with the states to ensure compliance.

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A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

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Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

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Follow-up

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Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

THE WHITE HOUSE
WASHINGTON

March 27, 1997

MEMORANDUM FOR: Rahm Emanuel
Ron Klain
Bruce Lindsey
Bruce Reed

FROM: Elizabeth Drye 

SUBJECT: Draft Response to Possible Court Rulings on FDA Tobacco Regulation

Judge William Osteen may announce his decision on industry's challenge to FDA's tobacco rule as early as Monday, March 31. HHS and DOJ have prepared Administration responses for three possible outcomes (attached). **Please provide any comments on these draft responses to me by COB today (EOB rm 222; 6-5573).** Elena Kagan and I are setting up a meeting with HHS and DOJ tomorrow afternoon to further refine our response strategy and will notify your office shortly of that meeting.

cc: Elena Kagan
Toby Donenfeld
Michelle Crisci

Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

[Scenario A - Jurisdiction Only]

Where our children's health and safety are concerned, we cannot rest; and today we have won a landmark victory in our fight to protect our children from the deadly harms of tobacco. The court has validated what we have known -- and tobacco companies have ignored -- for a long time: nicotine is a dangerous drug that we have the right to regulate, especially when our children's health is at stake. That is why we will appeal those parts of the ruling that let tobacco companies continue to reach our children with ads that lure them to smoke.

This is not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their new customers: cartoons like Joe Camel send a message that smoking is cool; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

That is why we took action last summer to make it harder for young people to buy cigarettes, and to stop the kind of marketing that tempts them to do so. We knew it would not be an easy fight, but we knew it was the right thing to do. And we will continue to do everything we can to protect our children from tobacco, and to help them lead healthy, productive lives.

The Vice President and I

3/28/97

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: RLCR DATE: 12/05/13

FINAL DRAFT

CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL

FDA, HHS, DOJ reviewed

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling.

SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

SCENARIO TWO

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

STATEMENT

This is a landmark day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

OR

Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

A: The bottom line is that we are going to protect our children. We can appeal the ruling or we can redraft the rule. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and

published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we are prepared to work with Congress. We want action, and to date the only action has come from the President.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We believe we have good grounds to appeal. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

###

draft
4/9/97

April xx, 1997

Note to: WH Press Office, WH Domestic Policy Council
From: HHS/FDA Public Affairs

MEDIA PLAN FOR OPINION DAY AND FOLLOWING

- o White House, FDA press offices field (speaking on the record) initial inquiries using prepared talking points
- o POTUS statement after DOJ, HHS, FDA attorneys review opinion (if appropriate, will announce a decision to appeal)
- o VPOTUS made available for anchor interviews with ABC, CBS, NBC nightly news shows
- o DES made available for one of evening opinion shows (i.e., Lehrer NewsHour, Nightline, Larry King Live)
 - Other HHS/FDA officials (Thurm, Schultz, Zeller) used to fill in behind DES
- o FDA press office will arrange briefings of major editorial pages (NYTimes, WPost, USAToday, LATimes)

Note: Tobacco control activists, state attorneys generals, former FDA Commissioner DAK can also be expected to be interviewed by these media outlets on the day the opinion is issued

Opinion Day +1

- o If a decision to appeal has been made, HHS/FDA can announce filing of notice to appeal
 - HHS/FDA lawyers (Rabb, Schultz, Zeller, Witt) can do on-the-record interviews about legal strength of the rule
 - HHS radio actuality on decision made available nationwide
- o FDA press office will be prepared to answer follow-up questions about impact of opinion on rule (i.e., is FDA continuing to contract with states for enforcement, must retailers continue to check photo IDs for anyone under 27, etc.)
- o FDA press office will arrange briefings of regional editorial writers

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: RUR DATE: 12/05/13

4/11/97

FINAL DRAFT

~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

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Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

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Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have studied the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

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A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

SCENARIO THREE

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STATEMENT

We are very confident in the Agency's assertion of jurisdiction and the soundness of the rule. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

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A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We

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draft
potus statement IF appeal decision is made
4/11/97

The tobacco companies are formidable foes, have no doubt about that. They can pay \$500-an-hour lawyers for years on end. Their lobbyists and influence peddlers can spread millions of dollars around this town election year after election year. But, in the end, all of their money cannot hide the truth. Nicotine is hooking our children. Our children are their new customers. That has to stop.

Secretary Shalala and Solicitor General Delligner have informed me that the Administration will appeal this ruling. Attorneys from the Department of Justice, the Department of Health and Human Services and the Food and Drug Administration immediately reviewed the district court's opinion. They are convinced that we are on solid constitutional and legal ground.

It is also the right thing to do on public health and moral grounds. Let me remind you of why my Administration has taken on the tobacco industry. Each day, 3,000 young people will become regular smokers. Unless we and the states are allowed to protect our children with effective laws and rules, five million children alive today will have their lives cut short by the deadly diseases caused by tobacco use. We are fighting for the health and lives of our children. It is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging.

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We are not walking away from this fight with the tobacco companies. I had hoped they would work with us, but they have chosen a different course. They have made a mistake. We will protect our children and our children's children and the generations to come, and we will not stop until we succeed.

###

Tobacco Q&As

April 25, 1997

COURT DECISION

Background

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

The Decision

The court ruled that FDA has jurisdiction and that the access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

Statement

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today we won an historic victory in court, and we're going forward with the provisions the court upheld. A statement on what next legal steps the Administration will take will come shortly.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: It means that provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect, and we are working with states to begin checking for compliance. And it means that FDA has authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

SETTLEMENT TALKS

Q: How does the judge's decision affect the Administration's interest in a settlement?

A: I have no idea. Today, we should focus on this ruling. [Go to statement on ruling above].

Q: Isn't the Administration deeply involved in settlement talks?

A: Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q: But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A: My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

Out of date

STATEMENT OF THE PRESIDENT

Today the Department of Justice filed a notice in the Greensboro U.S. District Court appealing the part of Judge Osteen's order that invalidated the Food and Drug Administration's tobacco advertising restrictions. The Department is asking for an expedited appeal, because every day of delay matters to our children's health. Each day, 3,000 children and young people become regular smokers, and 1000 of them will have their lives cut short as a result of their smoking. And this problem of youth tobacco use is getting worse. The percentage of eighth and tenth graders who smoke has risen for four consecutive years. The FDA's common sense access and advertising restrictions would reverse this trend.

We will continue to work to protect our children from tobacco, and we will not stop until we succeed.

Talking Points on Tobacco Settlement Talks

- o The Administration is closely monitoring the settlement talks among the tobacco industry, state attorneys general, public health groups, and private lawyers. Any agreement would have to be passed by the Congress and signed by the President.
- o We will carefully review any settlement that emerges from the discussions, and we will seek the advice of the public health community. As the President has said, in reviewing any settlement proposal, our focus will stay squarely on protecting kids and the public health.

Q: Would you support a settlement that caps punitive damages? That seems to be the key stumbling block.

A: I'm not going to speculate on any particular aspects of a potential settlement. The Administration proposed the toughest measures ever to protect children from tobacco, and we are fighting in the courts to see that those restrictions take effect. Our focus in reviewing any settlement will stay on protecting kids and the public health. The President has made it clear he is not going to agree to anything with respect to tobacco that jeopardizes the public health.

Q: Senator Lott and others are urging quick closure to the talks. They say that the window of opportunity is closing. Is the Administration trying to help close the deal?

A: No. Because any settlement will have a profound and lasting impact on the public health, the Administration will have to consider a settlement in a careful and thorough manner. There will be no rush to judgment and no precipitous action. We are not going to take a position on a proposal until the Administration and the public health community have fully reviewed it.

\qaset2.tob

draft
4/9/97

April xx, 1997

Note to: WH Press Office, WH Domestic Policy Council
From: HHS/FDA Public Affairs

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- o White House, FDA press offices field (speaking on the record) initial inquiries using prepared talking points
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- o VPOTUS made available for anchor interviews with ABC, CBS, NBC nightly news shows
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4/11/97

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: PUC DATE: 12/05/13

FINAL DRAFT

~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

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SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

SCENARIO TWO

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

STATEMENT

This is a landmark day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have studied the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

OR

Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

A: The bottom line is that we are going to protect our children.

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Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We are very confident in the Agency's assertion of jurisdiction and the soundness of the rule. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

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Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

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draft

potus statement IF appeal decision is made

4/11/97

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4/9/97

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DETERMINED TO BE AN
ADMINISTRATIVE MARKINGINITIALS: wk DATE: 12/05/13

4/11/97

FINAL DRAFT

~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

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From: HHS, FDA Public Affairs

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Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

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draft
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4/11/97

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###

**Office of Public Affairs
15-05 Parklawn
HFI-1**

**301-594-6004 or 301-443-3819 (fax)
301-443-1130 (phone)**

TO:

FROM:

Elizabeth Dye 202-456-7028

JIM O'HARA

Mary Ellen Glynn 202-456-6210

Number of pages (includes cover) 4

Message:

~~CONFIDENTIAL~~

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: Rur DATE: 12/06/13

If this is not clear, please call and we will send
another fax. Thank you.

3/28/97

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: BLR DATE: 12/05/13

FINAL DRAFT

CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL

FDA, HHS, DOJ reviewed

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Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we are prepared to work with Congress. We want action, and to date the only action has come from the President.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We believe we have good grounds to appeal. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

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A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

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~~CONFIDENTIAL~~

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: 242 DATE: 12/05/13

~~CONFIDENTIAL~~

CURRENT HHS TOBACCO-RELATED ACTIVITIES

Four HHS agencies engage in major tobacco-related activities.

A. NIH

According to ASMB, in FY 1997 NIH will spend approximately \$135 million a year on tobacco-related activities. Of this amount, about \$100 million will be invested in laboratory and epidemiologic studies. The remainder will be used by the NCI to fund intervention programs and research on tobacco prevention and control. These intervention activities are funded through two branches in NCI, the Public Health Applications Branch the Prevention and Control Extramural Branch, both of which are in the Cancer Control Science Program, which is a program within the Division of Cancer Prevention and Control.

The major tobacco control project which is located in the Public Health Applications branch is the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST), with a FY 1997 budget of about \$23 million. Begun in 1991, ASSIST is a collaborative project of the NCI and the American Cancer Society designed to implement and evaluate the effectiveness of comprehensive tobacco control programs in 17 states. During the intervention phase of the ASSIST program (1993-1998), NCI has been providing approximately \$20 million a year to be divided among the 17 states. The remaining money is used centrally for training, administration, and evaluation. Although the official evaluation of ASSIST will not be complete until 1999, interim data shows that by 1995, tobacco consumption was on average 10% lower in ASSIST states.

Kevin Thurm stated in a speech in October 1996 to an ASSIST conference that the Department will continue and expand the kinds of programs established by ASSIST.

B. FDA

Following the issuance of the final regulation in August, the FDA began working on its implementation plan. The key elements of the plan include outreach, enforcement, monitoring, and education. FDA is requesting \$63 million for FY 1998 to carry out its implementation plan.

C. SAMHSA

Most of SAMHSA's tobacco-related activities are focused on enforcing the Synar regulation. In FY 1997, SAMHSA will spend approximately \$1.35 million to track the states' compliance with the regulation and to provide technical assistance and other administrative services in support of the regulation.

D. CDC

The vast majority of the CDC's work on tobacco is performed by its Office of Smoking and Health (OSH), whose mission is to coordinate strategic efforts aimed at the prevention and cessation of tobacco use. Current efforts include conducting surveillance and epidemiological studies, conducting national health communication campaigns and assisting state health departments to do the same, and, since 1993, funding and administering the IMPACT program through which it assists 32 states and the District of Columbia (the non-ASSIST states) to build their capacity to sustain tobacco control programs.

OSH's FY 1997 budget is approximately \$21 million. Of that, nearly \$7 million is spent on the IMPACT program, \$5 million of which goes directly to the 32 states and the District of Columbia. In addition, OSH spends approximately \$2.25 million on its communications activities and \$1 million on surveillance and epidemiological studies.

Q. Are you pushing for a tobacco settlement?

A. We are pushing to implement the FDA rule so that we meet the goal I set to reduce tobacco use by our young people of 50 percent in 7 years. But I think it is amazing all those groups are at the table talking about a settlement. I have asked my staff to stay informed of the talks. And I wish all of the parties well. I think it would be good for the country is we could reach a settlement that all of the affected parties would support.

Q. Should the tobacco companies get immunity as part of a global settlement?

A. My job is to make sure that a settlement would be a good deal for the American people. You know it is hard to forget the image of the nation's tobacco CEOs swearing before Congress that their products are not addicting. And I was very troubled by the findings of the FDA investigation of tobacco companies. And we have yet to hear the findings of investigations by the Justice Department and the many state AGs. Immunity, under these circumstances, would be a very high price for the country to pay. But I think we need to wait and see what the parties are able to agree to. The two issues I care about most are: protecting our young people and putting the nation's public health first.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages **1**

To E. Drye	From Mande
Dept./Agency	Phone #
Fax #	Fax #

NSN 7540-01-317-7368

5099-101

GENERAL SERVICES ADMINISTRATION

3/28/97

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: RLR DATE: 12/05/13

FINAL DRAFT

CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL CONFIDENTIAL

FDA, HHS, DOJ reviewed

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling.

SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

SCENARIO TWO

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

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This is a landmark day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have had time to study the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

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Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

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Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and

published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we are prepared to work with Congress. We want action, and to date the only action has come from the President.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We believe we have good grounds to appeal. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

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W/Lindsey Edley

~~CONFIDENTIAL~~**DRAFT**

3/26/97

DRAFT~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

FDA, HHS, DOJ reviewed

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: DLR DATE: 12/05/13**BACKGROUND**

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling.

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~~CONFIDENTIAL~~**DRAFT**

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~~CONFIDENTIAL~~**DRAFT**

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if it accomplishes
our goal

Linda, Emma

~~CONFIDENTIAL~~**DRAFT**

3/26/97

DRAFT~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

FDA, HHS, DOJ reviewed

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: PLR DATE: 12/05/13**BACKGROUND**

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DRAFT

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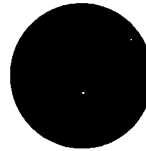
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if it ~~is~~ accomplishes
our goal of

THE WHITE HOUSE
WASHINGTON

March 27, 1997

MEMORANDUM FOR: Rahm Emanuel
Ron Klain
✓ Bruce Lindsey
Bruce Reed



FROM: Elizabeth Drye *ED*

SUBJECT: Draft Response to Possible Court Rulings on FDA Tobacco Regulation

Judge William Osteen may announce his decision on industry's challenge to FDA's tobacco rule as early as Monday, March 31. HHS and DOJ have prepared Administration responses for three possible outcomes (attached). **Please provide any comments on these draft responses to me by COB today (EOB rm 222; 6-5573).** Elena Kagan and I are setting up a meeting with HHS and DOJ tomorrow afternoon to further refine our response strategy and will notify your office shortly of that meeting.

cc: Elena Kagan
Toby Donenfeld
Michelle Crisci

0327.02

3/19/17

Lindsey
Demanteld
HHS/DOJ

No discussion before —
~ March 31st

Regimes stretched statute to avoid ban —
drug vs. combination device

Couldn't understand why parties didn't work it
out.

Overwhelming likelihood he would sway the rule.

- lengthy
- injunction not anticipated
- President has embarked on long term strategy.
- Total victory
 - Victory for kids
 - we're in this for the long haul.

Total Loss

- pre approval to see, we'll appeal

Bruce

- Gray Area — ^{Bruce} Decline victory —

Have to make certain we say — incredible
public health victory — court has said
present a public health risk.

What does it mean — take the rule back?

Bruce

- Jurisdiction is. No jurisdiction issue
 - reporters would have to know details

Schwartz / PMS Neergard / TP Singsal / Friedman

^{cleaned}
Two cases final legal hurdles
Mississippi case goes to trial early June
Florida case going to trial in August

^{Wilner} ^{won}
Woodie Cotticausen - plaintiff's case in Florida -
won by showing the jury

over 20 states filed for medicaid, but have
not been scheduled for trial.

Minnesota, Mississippi, Florida most
aggressive.

Federal courts decided they couldn't be nationwide
class action - state-based class actions.

**STATE OF MINNESOTA
OFFICE OF THE ATTORNEY GENERAL
LAW ENFORCEMENT SECTION**

Hubert H. Humphrey III
Attorney General

TRANSMISSION BY FACSIMILE

Suite 1400 NCL Tower
445 Minnesota Street
St. Paul, MN 55101
Tele No.: (612) 296-7575

DATE: 3/21/97

TO: See attached list

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TELEPHONE NO.: (612) 296-7575
FAX NO.: (612) 296-9663

NUMBER OF PAGES (including cover page): 5

***FOR TRANSMISSION PROBLEMS, please call Brenda Mammenga at
(612) 296-1799***

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AG:67038 v1

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Kenneth E. Warner, Ph.D.
FAX 313-764-4338

FOR IMMEDIATE RELEASE
Thursday, March 20, 1997

Contact: Joe Loveland (612) 296 -2069
Jennifer Freeman (612) 297-1321

SETTLEMENT CAUSES TOBACCO COMPANY TO MAKE HISTORIC ADMISSION
"One-time Deal Will Not Be Available to Tobacco Giants That Continue to Defraud"

Attorney General Hubert H. Humphrey III today announced a major agreement that would settle part of Minnesota's lawsuit against the cigarette industry. Under the agreement, Liggett Group would admit that cigarette smoking causes health problems, including lung cancer, emphysema, and heart disease. The company would also reveal documents that could be useful in lawsuits against the rest of the industry, cooperate in the prosecution of other tobacco companies, and make millions of dollars in payments to the states.

"Liggett is by far the smallest tobacco company, and its confession, concessions, payments, and continuing cooperation with the states will help us hold the rest of the industry accountable for breaking the laws that all other businesses must obey," Humphrey said. "This is a one-time deal that absolutely will not be available to the other tobacco companies."

Humphrey said the settlement announced today in Washington, D.C. follows weeks of negotiations with Liggett and other states. Liggett is the smallest of the tobacco manufacturers, with just two percent of the total domestic tobacco market. About a year ago (March 13, 1996), Liggett became the first tobacco company in history to agree to a settlement of a tobacco case. Minnesota was the only suing state that did not join that initial settlement. At the time, Humphrey objected to the initial settlement because Liggett was not required to disclose the truth or significantly change its ways, and because R.J. Reynolds Tobacco could also get the same financial considerations if certain merger scenarios played out. Those issues were addressed in this broader settlement with the sixteen states that have sued the tobacco industry since the first Liggett settlement was filed.

At today's Washington news conference, a statement by Liggett CEO Bennett LeBow was presented: "We at Liggett know and acknowledge that...cigarette smoking causes health problems, including lung cancer, heart and vascular disease and emphysema. We at Liggett also know and acknowledge that...nicotine is addictive."

Elements of the settlement include:

- **Document Disclosure.** Liggett will turn over all documents relating to the states' cases, most importantly documents which it has previously claimed as privileged.
- **Marketing To Kids.** Liggett will comply with certain FDA tobacco marketing restrictions, even if the regulations are ultimately overturned by the federal courts. The tobacco companies have challenged the FDA's legal authority to promulgate the regulations. As part of the agreement, Liggett will drop its opposition and concede that FDA regulation is appropriate.

- **Payments to States.** Liggett will pay 25% of its pretax income for 25 years to a fund that will be divided amongst the parties to the settlement. It has also agreed to pay an additional \$25 million if there is a merger or acquisition with a future affiliate.
- **Assist States In Prosecution.** In addition to turning over documents, Liggett will actively assist the states in prosecuting their cases against the remaining defendants, helping to locate former employees who might have relevant testimony.

Humphrey stressed that he opposed a second settlement proposed today between Liggett and class action lawyers. That settlement purported to resolve all other damage actions against Liggett. Humphrey and other attorneys general have in the past opposed private class action settlement where, among other things, the injured parties have no right to opt out of the class and litigate on their own. The states are not parties to the class action agreement.

"It is common practice for government lawyers to go easy on the first conspirator to admit guilt in order to better prosecute the others," Humphrey said. "By turning state's witness, this 'small fish' got a vastly better deal than the rest of the 'big fish' will get. As we have said from the beginning, we will insist that the tobacco industry be forced to stop marketing to kids, reform the way it does business, pay damages commensurate with the harm done, and disclose the whole truth."

In August 1994, Minnesota became the first state in the nation to sue the tobacco industry on consumer fraud and antitrust grounds. Facing a thousand-person tobacco litigation team, the State and its co-plaintiff Blue Cross and Blue Shield of Minnesota have won a series of important issues in court and amassed 28 million internal tobacco industry documents in depositories in Minneapolis and England. While many public documents that have been introduced in court prove Minnesota's claims, most of the documents obtained in the case are not publicly available due to a court order that the tobacco industry insisted on. The Minnesota case is set to go to trial in ten months.

**Office of Public Affairs
15-05 Parklawn
HFI-1
301-594-6004 or 301-443-3819 (fax)
301-443-1130 (phone)**

TO:

FROM:

Elizabeth Dyer

JIM O'HARA

202-456-5581

Number of pages (includes cover) _____

Message: _____

If this is not clear, please call and we will send
another fax. Thank you.

draft
4/9/97

April xx, 1997

Note to: WH Press Office, WH Domestic Policy Council
From: HHS/FDA Public Affairs

MEDIA PLAN FOR OPINION DAY AND FOLLOWING

- o White House, FDA press offices field (speaking on the record) initial inquiries using prepared talking points
- o POTUS statement after DOJ, HHS, FDA attorneys review opinion
- o VPOTUS made available for anchor interviews with ABC, CBS, NBC nightly news shows
- o DES made available for one of evening opinion shows (i.e., Lehrer NewsHour, Nightline, Larry King Live)
 - Other HHS/FDA officials (Thurm, Schultz, Zeller) used to fill in behind DES
- o FDA press office will arrange briefings of major editorial pages (NYTimes, WPost, USAToday, LATimes)

Note: Tobacco control activists, state attorneys generals, former FDA Commissioner DAK can also be expected to be interviewed by these media outlets on the day the opinion is issued

Opinion Day +1

- o If a decision to appeal has been made, HHS/FDA can announce filing of notice to appeal
 - HHS/FDA lawyers (Rabb, Schultz, Zeller, Witt) can do on-the-record interviews about legal strength of the rule
 - HHS radio actuality on decision made available nationwide
- o FDA press office will be prepared to answer follow-up questions about impact of opinion on rule (i.e., is FDA continuing to contract with states for enforcement, must retailers continue to check photo IDs for anyone under 27, etc.)
- o FDA press office will arrange briefings of regional editorial writers

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: RUE DATE: 12/05/13

4/11/97

FINAL DRAFT

~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina. A hearing on the industry's motion for summary judgement was held on February 10, 1997; the judge said he expected to rule on the motion within five to 10 weeks. To be prepared for that ruling, the following scenarios have been sketched out with proposed responses (a statement and back-up questions and answers) to be used by Administration officials. These are draft responses and will be finalized only after a court ruling. The statements and Q-and-A's are to be used by White House and FDA press offices for initial responses after the ruling. A statement by the POTUS will be expected later in the day on the day of the ruling.

SCENARIO ONE

The court rules that FDA has jurisdiction over nicotine-containing tobacco products and rejects the industry's challenge to the final rule.

STATEMENT

The children of the United States won a great victory today. The court upheld the Administration's efforts to kick Joe Camel and the Marlboro Man out of our kids' lives. (Use second sentence only if court upholds advertising restrictions.) Our children will live healthier and longer lives because of today's ruling.

Q: What does this mean in everyday terms?

A: Several of the provisions making it harder for children to buy cigarettes and smokeless tobacco products are already in effect and we are working with states to begin checking for compliance. The provisions to limit the appeal of these products go into effect in August; like we did for the access provisions, we will conduct extensive outreach efforts to educate businesses and the public and will begin working to ensure that these provisions are also enforced.

Q: What about the education campaign that was also announced last August?

A: The FDA is working on contacting the affected companies and will begin consulting with them.

Q: Won't the companies appeal this ruling and/or seek an injunction -- and doesn't that mean delay?

A: You'll have to ask the companies what they intend to do, but our position remains the same as it has been: We are going forward with protecting our children by implementing the rule unless the courts tell us otherwise. We would hope the companies would start working with us to protect our children instead of fighting us every step of the way.

SCENARIO TWO

The court rules that FDA has jurisdiction, but that portions (or all) of the rule are invalid.

STATEMENT

This is a landmark day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. Obviously, we will review the Judge's decision where he questioned the rule, but the bottom line is historic: the federal government can regulate tobacco products to protect our children's health.

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

Q: What are you going to do about the provisions of the rule the court struck down?

A: The bottom line is that we are going to protect our children. We're going forward with the provisions the court upheld. We can appeal the ruling or we can redraft the rule with regard to the provisions the court struck down. We will make that decision after we have studied the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

OR

Q: What are you going to do now that the court has said all the provisions of the rule are invalid?

A: The bottom line is that we are going to protect our children.

We can appeal the ruling or we can redraft the rule. We will make that decision after we have studied the ruling. (Only HHS and FDA officials should use "we" in speaking about rule-making; White House officials should say "the Agency.")

Q: Doesn't this mean more delay?

A: Since the FDA began its inquiry into tobacco in 1994, it has shown repeatedly that it will move quickly to protect our children. The Agency reviewed 700,000-plus comments and published a final rule in a year's time. The Administration will continue to move on other fronts: enforcement of the Synar Amendment, enforcement of existing laws such as the ban on television advertising.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

SCENARIO THREE

The court rules against FDA jurisdiction and rule.

STATEMENT

We are very confident in the Agency's assertion of jurisdiction and the soundness of the rule. We knew from the beginning it would be a long and hard road against the entrenched and powerful interests opposing us, and today's ruling is just the first step. We have to act to protect our children. We are committed to continuing this fight to protect our children and believe we will ultimately succeed. We have to. Each day almost 3,000 young people become regular smokers and nearly 1,000 of them will have their lives shortened from the death and diseases of tobacco use.

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration are already reviewing the opinion, and we expect to announce later today what legal steps we will be taking.

Q: Do you think an appeal will be successful?

A: We believe we have a very strong case and we will ultimately prevail.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We

are still open to a legislative solution if it accomplishes
our goal of protecting our children.

###

draft
potus statement IF appeal decision is made
4/11/97

The tobacco companies are formidable foes, have no doubt about that. They can pay \$500-an-hour lawyers for years on end. Their lobbyists and influence peddlers can spread millions of dollars around this town election year after election year. But, in the end, all of their money cannot hide the truth. Nicotine is hooking our children. Our children are their new customers. That has to stop.

Secretary Shalala and Solicitor General Delligner have informed me that the Administration will appeal this ruling. Attorneys from the Department of Justice, the Department of Health and Human Services and the Food and Drug Administration immediately reviewed the district court's opinion. They are convinced that we are on solid constitutional and legal ground.

It is also the right thing to do on public health and moral grounds. Let me remind you of why my Administration has taken on the tobacco industry. Each day, 3,000 young people will become regular smokers. Unless we and the states are allowed to protect our children with effective laws and rules, five million children alive today will have their lives cut short by the deadly diseases caused by tobacco use. We are fighting for the health and lives of our children. It is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging.

Our children have the odds stacked against them. The industry spends more than \$5 billion a year promoting and marketing its products. Joe Camel tells our children smoking is cool. The Marlboro Man tells them smoking will make them independent. Virginia Slims and Merit promise them glamour.

Our common sense approach is aimed at limiting the appeal of these products and making it harder for children to buy them. Store clerks have a responsibility to make certain they are not selling tobacco products to anyone under 18. Asking for a photo ID is just plain common sense. Keeping tobacco billboards away from schools and playgrounds is just plain common sense.

We are not walking away from this fight with the tobacco companies. I had hoped they would work with us, but they have chosen a different course. They have made a mistake. We will protect our children and our children's children and the generations to come, and we will not stop until we succeed.

###

F (6) Tobacco

- **Hijacking Terrorist Conviction:** On October 7, in DC, Omar Mohammed Ali Rezaq was sentenced to life in prison on one count of air piracy, and ordered to pay restitution to the victims. Rezaq was convicted on July 19, in connection with his role in the November 1985 hijacking of Egyptair Flight 648.
- **OK Public Housing:** On September 25, federal, state, and local law enforcement authorities in the Tulsa, OK, area arrested 98 individuals for drug and firearms violations. The three-month investigation and subsequent arrests were part of a nationwide HUD effort called Operation Safe Home to reduce crime in public housing communities.
- **NY Crime Family:** Last week, James Galione, a soldier in the La Cosa Nostra Luchese Organized Crime Family, and Luchese Family associates Mario Gallo and Vincent Nastase were indicted for racketeering, racketeering conspiracy, murder, murder conspiracy, and harboring a fugitive.
- **Citizenship Hearing:** On October 22, the Senate Subcommittee on Immigration Reform chaired by Senator Simpson will hold a hearing on changes in naturalization law, dual citizenship, and differences in rights and privileges of Legal Permanent Residents and citizens. INS General Counsel David Martin will testify.
- **Media Inquiries:** The *Washington Post* is working on a piece regarding campaign finances of the Clinton/Gore campaign.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

- **Medicare HMO Initiative:** On October 21, HHS will announce the release of a Medicare Beneficiary Advisory Bulletin titled, "What Medicare Beneficiaries Need to Know About Health Maintenance Organization Arrangements: Know Your Rights." The bulletin will provide information about HMO obligations and beneficiary rights regarding HMO enrollment, provision of services and disenrollment.
- **Tobacco:** On October 15, the plaintiffs filed summary judgment briefs in the NC lawsuits challenging FDA's regulations restricting the sale and distribution of tobacco products to protect children and adolescents. The plaintiffs motions are based on the following legal grounds: First, Congress has withheld from FDA the authority to regulate these products in favor of tobacco-specific legislation. Second, the Food, Drug, and Cosmetic Act does not authorize FDA to regulate these products or to impose the particular restriction it adopted. Third, the First Amendment's free speech protections prohibit those restrictions. The government's responsive briefs are due on December 2.

Cathy R. Mays 04/24/97 09:36:59 AM

Record Type: Record

To: See the distribution list at the bottom of this message
cc: Lori L. Anderson/WHO/EOP, Michelle Crisci/WHO/EOP, Laura Emmett/WHO/EOP, Jennifer D. Dudley/WHO/EOP
Subject: Conference Call

There will be a short conference call TODAY at 3:45 p.m. to review tobacco press strategy for tomorrow. Others on the call will be Melissa Skolfield, Jim O'Hara, and George Phillips.

Due to the amount of traffic today on the conference lines, I'm still working with the switchboard to work out the conference lines/codes. I'll be sending you another e-mail message to notify you of the code/number you will use.

Thanks.

Message Sent To:

- Rahm I. Emanuel/WHO/EOP
- ✓ Bruce R. Lindsey/WHO/EOP
- Donald H. Gips/OVP @ OVP
- ✓ Toby Donenfeld/OVP @ OVP
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6-6766 WH

Kagan

6-5584

McBurt 6-2572

Code 9910

Rahm

6-2531

Emily/Marcia

Toliv

6-2580

TSCA

Consumer Product Safety Act

Controlled Substance Act



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INITIALS: RUR DATE: 12/05/13

MASTER
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April 21, 1997

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April 21, 1997

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April 21, 1997

Tobacco Q&As

April 25, 1997

COURT DECISION

Background

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

The Decision

The court ruled that FDA has jurisdiction and that the access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

Statement

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today we won an historic victory in court, and we're going forward with the provisions the court upheld. A statement on what next legal steps the Administration will take will come shortly.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: It means that provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect, and we are working with states to begin checking for compliance. And it means that FDA has authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

SETTLEMENT TALKS

Q: How does the judge's decision affect the Administration's interest in a settlement?

A: I have no idea. Today, we should focus on this ruling. [Go to statement on ruling above].

Q: Isn't the Administration deeply involved in settlement talks?

A: Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q: But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A: My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

Q&A on FDA Tobacco Rule

Status of FDA's Tobacco Rule

The President announced FDA's final tobacco rule in August, 1996. The first two provisions of the rule -- effective February 28th, 1997 -- require retailers to check the ID of anyone under age 27 and prohibit the sale of cigarettes or smokeless tobacco to anyone under age 18. A North Carolina federal judge will issue his decision on the industry's challenge to the FDA rule on Friday, April 25th, at 11:00 a.m.

Question and Answer on Pending Court Decision

- Q. Do you expect the judge in Greensboro to rule in favor of the government; tobacco analysts are saying the judge is going to rule in favor of the industry?
- A. I am not going to speculate about the court's decision. We continue to have every confidence in our legal position.

Question and Answer on Settlement Talks Among Tobacco Companies, State Attorneys General, and Plaintiffs' Lawyers

- Q. Is the White House pushing for a tobacco settlement?
- A. Like other parties interested in this issue, we have been monitoring the talks. But as you know, the Administration's focus has been on the FDA regulations: reducing our kids access to tobacco and its appeal to kids caused by advertising, and ultimately achieving a decline in youth tobacco use. We have 3,000 children and young people becoming regular smokers each day, and nearly 1,000 of them will have their lives cut short. We simply have to reduce the number of children who start smoking.

**Office of Public Affairs
15-05 Parklawn
HFI-1
301-594-6004 or 301-443-3819 (fax)
301-443-1130 (phone)**

TO:**FROM:**Victor Zonana**JIM O'HARA**Mary Ellen Lynn 456-6210Elizabeth Dye 456-7028**Number of pages (includes cover)**2**Message:**

If this is not clear, please call and we will send another fax. Thank you.

April 23, 1997

Note to: HHS Press
White House Press

From:  Jim O'Hara, FDA Public Affairs (301-443-1130)

Q: Do you expect the judge in Greensboro to rule in favor of the government; tobacco analysts are saying the judge is going to rule in favor of the industry?

A: We are not going to speculate about the court's decision. We continue to have every confidence in our legal position.

▶ **Jordan Tamagni**
04/22/97 05:29:59 PM
.....

Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc:

Subject: Re: TOBACCO COURT DECISION WILL BE RELEASED FRIDAY, APRIL 25, 11:00 am 

Play ball! Here is what I just promised.

Today I am announcing that we will appeal this morning's Federal District Court decision to block our efforts to protect children from the deadly harms of tobacco.

This not a matter of choice; it is a question of survival: every year, 3000 of our young people will start smoking, and a third of them will die from it. But tobacco companies' more than \$5 billion-a year marketing schemes lure our children with a message that smoking is cool: cigarette packets are emblazoned with cartoons like Joe Camel; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke.

We cannot afford to stand idly by while our children's lives are at stake. So last summer, we took action to stop the kind of tobacco marketing that tempts our young people to smoke, and we made it harder for children to buy cigarettes. We knew it would not be an easy fight, but we knew it was the right thing to do. And we will continue to do everything we must to protect our children from tobacco, and to help them lead healthy, productive lives. That is why we will appeal this ruling, and I am confident that we will prevail.

Q&A on FDA Tobacco Rule

Status of FDA's Tobacco Rule

The President announced FDA's final tobacco rule in August, 1996. The first two provisions of the rule -- effective February 28th, 1997 -- require retailers to check the ID of anyone under age 27 and prohibit the sale of cigarettes or smokeless tobacco to anyone under age 18. A North Carolina federal judge will issue his decision on the industry's challenge to the FDA rule on Friday, April 25th, at 11:00 a.m.

Question and Answer on Pending Court Decision

- Q. Do you expect the judge in Greensboro to rule in favor of the government; tobacco analysts are saying the judge is going to rule in favor of the industry?
- A. I am not going to speculate about the court's decision. We continue to have every confidence in our legal position.

Question and Answer on Settlement Talks Among Tobacco Companies, State Attorneys General, and Plaintiffs' Lawyers

- Q. Is the White House pushing for a tobacco settlement?
- A. Like other parties interested in this issue, we have been monitoring the talks. But as you know, the Administration's focus has been on the FDA regulations: reducing our kids access to tobacco and its appeal to kids caused by advertising, and ultimately achieving a decline in youth tobacco use. We have 3,000 children and young people becoming regular smokers each day, and nearly 1,000 of them will have their lives cut short. We simply have to reduce the number of children who start smoking.

▶ Jordan Tamagni

04/24/97 06:29:46 PM

.....

Record Type: Record

To: Laura Emmett/WHO/EOP

cc:

Subject: Draft Language for Statement

Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

[Scenario A - Jurisdiction Only]

Where our children's health and safety are concerned, we cannot rest; and today we have won a landmark victory in our fight to protect our children from the deadly harms of tobacco. The court has validated what we have known -- and tobacco companies have ignored -- for a long time: nicotine is a dangerous drug that we have the right to regulate, especially when our children's health is at stake. That is why we will appeal those parts of the ruling that let tobacco companies continue to reach our children with ads that lure them to smoke.

↗
This not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their newest customers: ~~cigarette packets are emblazoned with~~ cartoons like Joe Camel; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

↗ cool
That is why we took action last summer to make it harder for young people to buy cigarettes, and to stop the kind of marketing that tempts them to do so. We knew it would not be an easy fight, but we knew it was the right thing to do. And we will continue to do everything we can to protect our children from tobacco, and to help them lead healthy, productive lives.

parallel changes each version

~ Shell for
easy POTOS statement
FROM Jordan
7:00 pm
Waltman has not
reviewed yet

Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

[Scenario B - Jurisdiction, Restrictions OK]

Where our children's health and safety are concerned, we cannot rest; and today we have won a landmark victory in our fight to protect our children from the deadly harms of tobacco. The court has validated what we have known -- and the tobacco companies have ignored -- for a long time: nicotine is a dangerous drug that we have the right to regulate, especially when our children's health is at stake.

This not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their newest customers: cigarette packets are emblazoned with cartoons like Joe Camel; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

That is why we took action last summer to make it harder for young people to buy cigarettes, and to stop the kind of marketing that tempts them to do so. We knew it would not be an easy fight, but we knew it was the right thing to do. And we will continue to do everything we can to protect our children from tobacco, and to help them lead healthy, productive lives.

Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

[Scenario C - No Jurisdiction, no restrictions]

Where our children's health and safety are concerned, we cannot rest. Today's ruling restricts our ability to protect our children from the deadly harms of tobacco, and that is why we will appeal it.

This not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their newest customers: cigarette packets are emblazoned with cartoons like Joe Camel; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

That is why we took action last summer to make it harder for young people to buy cigarettes, and to stop the kind of marketing that tempts them to do so. We knew it would not be an easy fight, but we knew it was the right thing to do. And we will continue to do everything we can to protect our children from tobacco, and to help them lead healthy, productive lives. That is why we will appeal this ruling, and I am confident that we will prevail.

Draft 4/24/97 5:00pm

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TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

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This is not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their new customers: cartoons like Joe Camel send a message that smoking is cool; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

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Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

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Draft 4/24/97 5:00pm

**PRESIDENT WILLIAM J. CLINTON
TOBACCO RULING STATEMENT
THE WHITE HOUSE
APRIL 23, 1997**

[Scenario C - No Jurisdiction, no restrictions]

Where our children's health and safety are concerned, we cannot rest. Today's ruling restricts our ability to protect our children from the deadly harms of tobacco, and that is why we will appeal it.

This is not a matter of choice; it is a question of survival: every year, 3000 of our young people start smoking, and a third of them will die from it. But tobacco companies spend more than \$5 billion dollars a year on marketing, and our children are their new customers: cartoons like Joe Camel send a message that smoking is cool; t-shirts and baseball caps bear the logos of cigarette brands; and billboards near our children's schools and playgrounds picture a world of adventure for people who smoke. In the end, all the money in the world cannot hide the truth: nicotine is hooking our children and cutting short their lives.

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

April 25, 1997

STATEMENT BY THE PRESIDENT

This is a historic and landmark day for the nation's health and children. With this ruling, we can regulate tobacco products and protect our children from a lifetime of addiction and the prospect of having their lives cut short by the diseases that come with that addiction. This is a monumental first step in what we always knew would be a long, tough road, and we are ready to keep pushing on.

This is a fight for the health and lives of our children. Each day, 3,000 children and young people become regular smokers, and 1,000 of them will have their lives cut short as a result of smoking. This is a fight we cannot afford to lose. It is a fight we cannot afford to stop waging. The Vice President and I are committed to protecting our children.

Our common sense approach is aimed at limiting the appeal of these products and making it harder for children to buy them. Retailers have the responsibility to make certain that they are not selling tobacco products to anyone under 18. Asking them for a photo ID is just plain common sense. Keeping tobacco billboards away from schools and playground is just plain common sense.

Senior attorneys from the Department of Justice, the Department of Health and Human Services and the Food and Drug Administration have carefully reviewed the District Court's opinion. On the basis of that review, the Solicitor General has informed me that an appeal would be appropriate for that part of the rule not upheld and I have directed that an appeal be filed.

We will continue to work to protect our children and our children's children. We will not stop until we succeed. Where our children's health and safety are concerned we cannot, and we will not, rest.

April 25, 1997

Note to: WH Press Office, Domestic Policy Council

From: HHS, FDA Public Affairs

BACKGROUND

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

THE DECISION

The court ruled that FDA has jurisdiction and that the rule's access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

STATEMENT

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Background statement until POTUS statement:

Attorneys from the Justice Department, the Department of Health and Human Services and the Food and Drug Administration have reviewed the opinion and a statement from the President on what the next legal steps the Administration will take will come shortly.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today, we won a historic victory in court, and we're going forward with the provisions the court upheld.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with the states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: The provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect and we are working with states to begin checking for compliance. And it means that FDA has the authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Questions on Tobacco Settlement Talks

Q. How does the judge's decision affect the Administration's interest in a settlement?

A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling].

Q. Isn't the Administration deeply involved in settlement talks?

A. Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q. But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A. My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. But, I'll say this: everybody agrees that blanket immunity is out of the question. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

###

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

April 25, 1997

STATEMENT BY THE PRESIDENT

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Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

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Q: Why not seek a legislative settlement?

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Q: What does this mean in everyday terms?

A: The provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect and we are working with states to begin checking for compliance. And it means that FDA has the authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

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Toby Donenfeld @ OVP

04/28/97 01:46:55 PM



Record Type: Record

To: Donald H. Gips/OVP @ OVP, Elizabeth Drye/OPD/EOP, Virginia M. Terzano/OVP @ OVP, Heidi Kukis/OVP @ OVP

cc:

Subject: Good News!

Scotus-Billboards,550

Ban on cigarette, liquor billboards upheld

WASHINGTON (AP) The Supreme Court, in an apparent victory for President Clinton's proposed crackdown on tobacco advertising, today left intact Baltimore's bans on billboard ads for cigarettes and alcoholic beverages.

The justices, without comment, turned away arguments that the city's twin bans on such ads violate free-speech rights.

A federal judge in North Carolina left that constitutional question unanswered last week when he ruled that existing federal law doesn't allow the Food and Drug Administration to restrict cigarette advertising and promotion.

But the judge also handed tobacco companies a big setback in ruling that the FDA can regulate tobacco as a drug.

President Clinton said that part of the judge's ruling on advertising and promoting would be appealed.

The president has proposed forbidding cigarette brand advertising at sports events, on T-shirts and billboards within 1,000 feet of schools and playgrounds, and in magazines likely to be read by teen-agers.

Opponents of the proposal contend it runs afoul of a constitutionality test created by a 1980 Supreme Court ruling.

In it, the court said commercial speech that is truthful and not misleading may be limited only if government has a substantial interest, the limitation directly advances that interest and is no more extensive than necessary.

The Baltimore dispute dates back to a pair of 1994 ordinances that forced the removal of cigarette and alcoholic beverage ads from most city billboards.

The ordinances were aimed at reducing illegal underage drinking and smoking.

The 4th U.S. Circuit Court of Appeals upheld the bans last year, but was ordered by the Supreme Court to restudy its rulings in light of the justices' decision last May giving advertisers significantly greater protection from government regulation.

The trend of rulings by the nation's highest court in recent years is to give commercial speech enhanced protections from government regulation.

But after reconsidering each of Baltimore's bans, the 4th Circuit court again upheld both in August.

The appeals court said the bans withstood the scrutiny required under the Supreme Court's 1980 ruling, and that the May ruling did not apply to the billboard dispute.

The lower court added that measures to protect children deserve "special solicitude" by courts.

"Baltimore's interest is to protect children who are not yet independently able to assess the value of the message presented," the appeals court said. "This decision thus conforms to the Supreme Court's repeated recognition that children deserve special solicitude in the First Amendment balance."

The amendment guarantees freedom of speech.

The alcoholic-beverage ad ban was challenged by Anheuser-Busch, brewer of such popular beers as Budweiser and Michelob, and Penn Advertising of Baltimore, a billboard-leasing company.

Penn Advertising challenged the city's cigarette ad ban.

Alcoholic beverages still can be advertised in Baltimore on city buses, taxicabs, delivery trucks and stores licensed to sell such drinks. The city's ban also did not affect television, radio, newspaper and magazine advertisements.

The city's cigarette-advertising ban also permits ads on buses and taxis, stores licensed to sell cigarettes and at professional sports stadiums.

The cases are Anheuser-Busch vs. Schmoke, 96-1428, and Penn-Advertising vs. Schmoke, 96-1429.
APNP-04-28-97 1013EDT

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Received by NewsEDGE/LAN: 4/28/97 10:02 AM

If Judge Osteen issues a "split decision" on FDA's tobacco rule, it will be an historic victory for the Clinton Administration. The judge is ruling on three questions: 1) Has Congress preempted FDA jurisdiction over tobacco? 2) Has FDA properly applied its drug and device authority? 3) Does the FDA rule violate the 1st Amendment? The worst we can do under a split decision is for the judge to uphold FDA's jurisdiction under the Food, Drug, and Cosmetic Act, but strike down some or all of the rule's provisions (e.g., rule that nicotine is a drug, but that cigarettes are not a drug delivery device, and remand the rule to FDA).

A decision by this judge that affirms FDA jurisdiction over tobacco is without question an historic change of the tobacco landscape for at least three reasons.

First, the tobacco industry has fought hard and succeeded for thirty years to maintain absolute control of how it does business. As a result, today, no government agency oversees tobacco products, and thus the industry is able to maintain a marketplace where the overwhelming majority of its customers become addicted as children and cannot quit. A split decision would give FDA oversight. For the first time the government would have significant control over tobacco products.

Second, regardless of the judge's decision, two new, meaningful federal restrictions on youth access are in place and will likely remain in place. The judge has already indicated privately that when he rules he will also take steps to maintain the status quo. In other words, provisions of the FDA rule that took effect on February 28th requiring retailers to check the ID of anyone under 27 and prohibiting the sale of cigarettes or smokeless tobacco to anyone under 18 will remain in effect.

Third, the government's position will probably improve throughout the appeals process. The industry hand picked the court. Now the process moves first to the Fourth Circuit and then to the Supreme Court. Both courts are likely to uphold more of the FDA rule. In particular, based on recent precedent-setting opinions, they are likely to uphold some of the advertising restrictions. While the Administration will not make this point, many others will.

Tobacco Q&As

April 25, 1997

COURT DECISION

Background

The President announced the FDA rule to protect children from tobacco in August 1996; the rule was immediately challenged by the industry in U.S. District Court in North Carolina.

The Decision

The court ruled that FDA has jurisdiction and that the access and labeling provisions are still in effect, but that the advertising and promotion portions of the rule are invalid.

Statement

This is a landmark and historic day for the nation's public health and our children. With this ruling, we can regulate nicotine-containing tobacco products and take important steps to protect our children from a lifetime of addiction and the prospect of having their lives cut short by tobacco-related diseases. We have taken a monumental first step down the long, hard road we knew we had to go to protect our children.

Q: What are you going to do about the provision of the rule the court struck down?

A: The bottom line is that we are going to protect our children. Today we won an historic victory in court, and we're going forward with the provisions the court upheld. A statement on what next legal steps the Administration will take will come shortly.

Q: Doesn't this mean the FDA will have to do something more drastic in terms of access to protect children -- like make these prescription products?

A: We have taken a common sense approach to protect our children by restricting access and we have proposed a common sense approach to limiting appeal. We still believe that is the right way to approach this terrible public health crisis threatening our children.

Q: Doesn't this mean more delay?

A: The access provisions that went into effect in February have been upheld, remain in place and we are working with states to ensure compliance.

Q: Why not seek a legislative settlement?

A: From the beginning, we have said that if Congress wants to put forth a legislative package as strong as our FDA rule with appropriate oversight and enforcement, we remain prepared to work with Congress.

Q: What does this mean in everyday terms?

A: It means that provisions that went into effect in February making it harder for children to buy cigarettes and smokeless tobacco products will stay in effect, and we are working with states to begin checking for compliance. And it means that FDA has authority to regulate nicotine-containing tobacco products.

Q: If you appeal, do you think an appeal will be successful?

A: This is an historic decision by the court on the Agency's authority over tobacco products. We believe we have a very strong case and we will ultimately prevail on all parts of the rule to protect our children.

Q: Isn't it time to seek legislation?

A: We have been open to a legislative solution that is as strong as the FDA rule with appropriate oversight and enforcement since the President announced the proposal in August 1995. We are still open to a legislative solution if it accomplishes our goal of protecting our children.

SETTLEMENT TALKS

Q. How does the judge's decision affect the Administration's interest in a settlement?

A. I have no idea. Today, we should focus on this ruling. [Go to statement on ruling above].

Q. Isn't the Administration deeply involved in settlement talks?

A. Like other parties interested in this issue, we have been monitoring the talks. We have a deep interest in protecting kids and the public health.

Follow-up

Q. But papers have reported that Bruce Lindsey is intimately involved in the settlement talks.

A. My staff are staying informed of the talks, but we are not a party in the talks. My only interest is in protecting kids and the public health.

Q: Would you support a settlement that gives tobacco companies immunity?

A: I'm not in any position to judge any settlement. As I've said, my only interest is in protecting kids and the public's health. We have to do right by them.

Follow-up

Q: Then, what form of immunity would you support?

A: I'm not going to speculate on what the participants in the negotiations might agree to. My Administration proposed the toughest measures ever to protect children from tobacco, and I am going to fight to see that those restrictions take effect. I'm not going to agree to anything with respect to tobacco that jeopardizes the public health. Our focus will stay on protecting kids and the public health.

Follow-up

Q: Anti-tobacco advocates -- including former FDA Commissioner David Kessler -- held a press conference yesterday saying immunity should be off the table altogether. Do you disagree?

A: I have tremendous respect for Dr. Kessler on this issue. Again, I'm not going to support anything that jeopardizes the public health.