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FOR IMMEDIATE ATTENTION!

TRANSMISSION COVER SHEET

FROM: Walter C. Holton, Jr.
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Telephone # (910) 333-5351
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TO: Bruce Lindsey
The White House

ATTENTION: Jennifer Dudley

PHONE NO: 202/456-2328

FAX NO: 202/456-2983

RE: Attached is Judge Osteen's opinion in the lawsuit challenging FDA's regulation of tobacco products.

MESSAGE:

DATE: April 25, 1997

No. Pages (including cover sheet): _____

NOTE: IF YOU DO NOT RECEIVE THE TOTAL NUMBER OF PAGES INDICATED, OR IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE CALL THE SENDING INDIVIDUAL LISTED ABOVE IMMEDIATELY.

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."

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 informed the President that an appeal would be appropriate for that part of the rule not upheld. The President has directed that an appeal be filed.

"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 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 playgrounds is just plain common sense.

"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. We're going forward with the provisions the court upheld. A statement on what next legal steps the Administration will take will come shortly.

*Today is
an historic
Victory*

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?

April 24, 1997

NOTE TO: Rahm Emanuel
Bruce Lindsey
Ron Klain
Bruce Reed
Ann Lewis
Michael Waldman
Julie Mason

FROM: Elizabeth Dye *ED*

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

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: RLCR DATE: 12/11/13

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.

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Battle Over Federal Aid for Tobacco Heats Up as Lawmakers Debate Issue

By BRUCE INGERSOLL

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — Tobacco is as much a part of government programs for farmers, veterans and others as the tobacco-plant carvings that adorn marble columns in the Capitol. Cutting those programs will be a downright prickly task.

Antismoking lawmakers are intent on cutting off millions of dollars a year in government-subsidized crop insurance for the nation's tobacco growers. At the same time, the Department of Veterans Affairs is trying to persuade Congress to limit the government's potential liability for compensating and treating millions of veterans who began smoking in the service and later developed tobacco-related diseases.

The battle over tobacco was joined yesterday when Democratic Sen. Richard Durbin of Illinois and Rep. Diana DeGette, a Democrat from Colorado, declared that "the federal government has no business underwriting this deadly product." Tobacco-state lawmakers countered with vows to derail the crop-insurance measure, arguing that it would be unfair to discriminate against tobacco, which is a legal crop and a major U.S. export.

VA Proposal Is Assailed

Lobbyists for veterans groups, meanwhile, voiced great alarm yesterday over the VA's legislative proposal, which is designed to head off a potentially enormous wave of smoking-related compensation claims and medical bills for veterans. VA officials peg the potential cost at hundreds of millions of dollars a year. Currently, 32% of active-duty military personnel are smokers; 15 years ago, 51% smoked.

Under a little-known 1993 interpretation of current VA law, ailing veterans could qualify for compensation and medical care solely on the grounds that they began smoking during active duty. But now the VA is taking the position that the government should have to compensate only those veterans who developed smoking-related diseases before they were discharged from the military.

The politically potent veterans lobby vehemently disagrees with that stance, arguing that the military bears considerable responsibility for encouraging service men and women to smoke. Beginning in World War II, said William Russo, a

Vietnam Veterans of America official, soldiers, sailors and aviators in combat zones were given free cigarettes as part of their rations.

"My cigarette smoking is directly related to Vietnam," said Robert Piaro, a Vietnam veteran who now smokes at least a pack a day. "You were constantly under the gun; you smoked to relieve the stress."

Agencies at Odds

Just as the politics of tobacco are highly divisive, tobacco policies within government agencies are often oddly inconsistent. While the VA worries about liability, VA hospitals have so-called butt huts for patients who smoke. Military commissaries and exchanges continue to sell cartons of cigarettes at huge discounts to military personnel, while smoking is taboo at the Pentagon and other defense facilities. Two years ago, the military cleared \$850 million on tobacco sales while absorbing \$930 million in health-care and lost-productivity costs.

"We know there's a dichotomy," said Air Force Maj. Monica Aloisio, a Pentagon spokeswoman. "But you have to balance the need for a healthy fighting force and an individual's right to use tobacco."

In failing to get its act together on tobacco, the Clinton team is no different from preceding administrations. On one front, the White House pursues a high-profile regulatory campaign to stop underage smoking. On another, the Agriculture Department quietly advocates preserving crop-insurance subsidies for tobacco farmers. It also defends spending \$15 million a year to administer the tobacco price-support program.

Last year, total tobacco outlays amounted to \$97 million, including \$69 million in crop-insurance subsidies. Sen. Durbin argued that it doesn't make any sense to subsidize producers of a potentially deadly crop when hundreds of other crops, such as squash and peaches, aren't subsidized at all.

The Agriculture Department, nonetheless, will oppose the Durbin-DeGette measure. "We're against underage smoking," said department spokesman Thomas Amontree. "We aren't against tobacco programs."

—Greg Hitt
contributed to this article.

THE WALL STREET JOURNAL
FRIDAY, APRIL 25, 1997

Senate Approves Chemical-Arms Pact, Setting Stage for Gains on Other Issues

By THOMAS E. RICKS

Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON — The Senate approved a controversial treaty on chemical weapons, giving the Clinton administration a major foreign-policy victory and possibly clearing the way for movement on other arms-control treaties and on federal budget negotiations.

The treaty, which bans the production of chemical weapons and requires the destruction of existing stocks, was passed by a vote of 74-26. Approval required two-thirds of the Senate, or 67 votes.

In a crucial move just hours before the vote, Majority Leader Trent Lott threw his support behind it. "I will vote for the [treaty] because I believe the U.S. is marginally better off with it than without it," the Mississippi Republican said.

Approval of the treaty could set the tone for a series of other political moves in the coming weeks. After declaring his support for the treaty, which exposes him to criticism from the right, Mr. Lott pointedly linked the move to the pending negotiations on a balanced budget. "Now we're going to see if the president is going to show similar courage" in taking a position that goes against his own political base, Mr. Lott told reporters. "Will he be prepared to do the same thing for the budget?"

Mr. Lott also called the extensive negotiations on the treaty between the White House and Congress a "model." The alternative, he said, is "trench warfare." He quickly added: "I don't want that."

In return for his support on the treaty, Mr. Lott clearly expects concessions from the White House on the budget. Securing a budget deal now, among other things, would enhance his status as a political leader, especially in the wake of the GOP's failure on the budget issue in the prior Congress.

Passage of the chemical-weapons treaty also might presage Senate approval of a series of other arms-control agreements in the coming months. Most notable is the controversial nuclear-test-ban treaty. In addition, the Senate will be

Chemical-Weapons Ban

Major provisions of the treaty approved by the Senate:

- **Requires** destruction of existing chemical weapons
- **Bans** the production, purchase, transfer or use of chemical weapons
- **Establishes** an international inspection system
- **Allows** nations to retain defenses against chemical weapons
- **Penalizes** nations that don't join the treaty

Source: The White House

considering agreements on conventional military forces in Europe, on land mines, on nuclear-free zones in the South Pacific and Africa and on revisions to the Anti-Ballistic Missile treaty designed to permit the deployment of some missile-defense systems.

Until the middle of this week, the vote on the treaty had been considered too close to call. But as soon as votes began on a series of amendments to the bill, it was clear that the administration had gained considerable support in recent days. Yesterday afternoon, in its first vote relating to the treaty, the Senate overwhelmingly rejected by a 71-29 tally a move by Senate Foreign Relations Committee Chairman Jesse Helms (R., N.C.), the leading foe of the treaty. The Helms proposal would have prevented the U.S. from ratifying the treaty until "rogue nations" such as North Korea and Iraq did so. A similar move concerning Russia lost by a 66-34 vote. In votes on amendments, only a simple majority was required to win.

The dwindling band of Senate hardliners continued to insist that no treaty at all would be better than the existing treaty. Talking about the "rogue states," Sen. James Inhofe (R., Okla.) said: "I wouldn't ratify this treaty unless they ratified it — and then I wouldn't trust them" to abide by it.

THE WALL STREET JOURNAL

FRIDAY, APRIL 25, 1997

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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. ~~We are monitoring the settlement talks that are going on to see if something results from those talks.~~

Q: What does this mean in everyday terms?

Self-Service
A: ~~The~~ *It means that* provisions that went into effect in February 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.~~ *already*

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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*Today was an historic victory.**already**will stay in effect. And it means that FDA**has authority**to take additional measures**to regulate nicotine and tobacco products*

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

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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.

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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.

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UP Comments.

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###

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.