April 23, 1997

NOTE TO STEVE COHEN

FROM: Elizabeth Drye, DPC

SUBJECT: Tobacco Background and Q&A.

The First Lady may get questions from the press on tobacco tomorrow or Friday for two reasons. First, Judge Osteen, the North Carolina federal judge hearing industry's challenge to FDA's tobacco rule, will issue his decision Friday, April 25, at 11:00 a.m. Second, the press is covering negotiations among tobacco companies, state attorneys general, and trial attorneys seeking to reach a broad settlement of tobacco liability and regulatory issues. Attached are background materials and Qs&As on these issues.

Please let me know if you need any additional materials.

cc: Jennifer Klein
Brenda Costello

FDA TOBACCO RULE

Status of FDA Tobacco Rule

FDA issued its final tobacco rule in August, 1996. The rule restricts kids' access to tobacco and seeks to reduce the appeal of tobacco products to children. 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. A press release describing the rule is attached.

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.

Attachment

- Press release on FDA's rule.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
August 23, 1996

Contact: Jim O'Hara
(301) 443-1130

PRESIDENT CLINTON ANNOUNCES HISTORIC STEPS TO REDUCE CHILDREN'S USE OF TOBACCO

President Clinton today announced the nation's first comprehensive program to prevent children and adolescents from smoking cigarettes or using smokeless tobacco and beginning a lifetime of nicotine addiction. The President's announcement comes a little more than a year after the Food and Drug Administration (FDA) issued its proposed rule to reduce the access and appeal of tobacco products for children and adolescents.

The FDA rule-making on children and tobacco prompted the largest outpouring of public response in the Agency's history with more than 95,000 individual comments received, totaling more than 700,000 pieces of mail when form letters are counted. The final rule was put on display today at the Federal Register and will be published in the Federal Register next week.

Each day, almost 3,000 young people in the United States become regular smokers, and nearly 1,000 of them will die prematurely from diseases related to tobacco use. Each year, more than 400,000 Americans die from smoking-related diseases, more Americans than are killed each year by AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.

-More-

In the past four years, the United States has experienced dramatic increases in tobacco use by youngsters. Between 1991 and 1995, the percentage of eighth- and tenth-graders who smoke increased 34 percent. In 1995, more than a third of 12th-graders reported smoking in the past month, and daily smoking in that group was up to 21.6 percent. Among 10th-graders, current use was up to 27.9 percent, and daily use was up to 16.3 percent.

The President's goal is to cut in half tobacco use by children and adolescents over the next seven years.

"This is the most important public health initiative of our generation," said Health and Human Services Secretary Donna E. Shalala. "Our children's futures are at stake. President Clinton's action will ensure that children get their information about tobacco from their parents -- and not from Joe Camel."

The President's initiative to protect children is based on the final FDA rule that will make it harder for young people to buy cigarettes and smokeless tobacco and will reduce the appeal of tobacco products to children under 18. The rule is based on the Agency's finding that cigarettes and smokeless tobacco products are delivery devices for nicotine, an addictive drug. In addition to the rule, the FDA will propose to require tobacco companies to educate children and adolescents about the health risks of tobacco use as part of the President's initiative. This national mass media campaign would be monitored for its effectiveness.

- MORE -

Cigarettes and smokeless tobacco products remain legal products that can be marketed and sold to adults, 18 years and older.

"Nicotine addiction is a pediatric disease that often begins at 12, 13, and 14 only to manifest itself at 16 and 17 when these children find they cannot quit," said Commissioner of Food and Drugs David A. Kessler, M.D. "By then our children have lost their freedom and face the prospect of lives shortened by terrible diseases."

The President's initiative follows the recommendations of major medical and scientific organizations such as the American Medical Association and National Academy of Science's Institute of Medicine. It is a prevention strategy based on reducing children's access to tobacco products and limiting the appeal of these products to children. The tobacco industry spends more than $6 billion annually on advertising and promotion.

Besides the final rule, the FDA will propose to require tobacco companies to provide strong educational messages for children on the real dangers of smoking and using smokeless tobacco. This national multi-media campaign would include television spots, and it would be monitored for its effectiveness. FDA intends to begin consultations about this campaign with the nation's six tobacco companies with a significant share of sales to children. Under Section 518 of the Federal Food, Drug, and

Cosmetic Act, the FDA may require companies to inform consumers about the unreasonable health risks of their products.

"We have to tell our children the truth about the diseases caused by smoking," Kessler said. "For too long we have sent conflicting messages to our children and then have acted surprised when they begin to smoke."

In reviewing the public comments and developing a final rule, the FDA made a number of changes to more narrowly tailor provisions to children. For instance, there was little evidence presented that mail-order sales are used by children and adolescents, while they are used by adults in rural areas. Similarly, vending machines in facilities totally inaccessible to persons under 18 will accommodate adults while preventing easy access by young people.

The FDA rule reduces children's easy access to tobacco products by:

- Requiring age verification by photo ID for anyone under the age of 26 purchasing tobacco products;
- Banning vending machines and self-service displays except in "adult" facilities where children are not allowed, such as certain nightclubs totally inaccessible to anyone under 18; and
- Banning free samples, the sale of single cigarettes, and packages containing fewer than 20 cigarettes.

The FDA rule limits the appeal of tobacco products to children by:

- Prohibiting billboards within 1,000 feet of schools and playgrounds. Other advertising is restricted to black-and-white text only; this includes all billboards, signs inside and outside of buses, and all advertising in stores. Advertising inside "adult only" facilities like nightclubs can have color and imagery.
- Permitting black-and-white text-only advertising in publications with significant youth readership (under 18). Significant youth readership means more than 15 percent or more than 2 million readers under 18; there are no restrictions on print advertising below these thresholds.
- Prohibiting sale or giveaways of products like caps or gym bags that carry cigarette or smokeless tobacco product brand names or logos.
- Prohibiting brand-name sponsorship of sporting or entertainment events (including teams and entries), **but** permitting it in the corporate name.

These provisions will be phased in between six months and two years from the date of publication in the <u>Federal Register</u> to give businesses adequate time to comply.

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TOBACCO SETTLEMENT TALKS

Status (see attached articles).

Question and Answer on Settlement Talks

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

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, 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.

follow-up

Q. But I read in the paper that Bruce Lindsey is intimately involved in the settlement talks.

A. The Administration is not a participant in the talks. We do get regular and frequent updates about the discussions. But we are focused right now on defending our rule in court and moving forward to implement it.

Attachments

- Intitial *New York Times* story on the negotiations.
- Today's *New York Times* article on Hugh Rodham Jr.'s participation.

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The New York Times

THURSDAY, APRIL 17, 1997

2 Top Cigarette Makers Seek Settlement

By JOHN M. BRODER

WASHINGTON, April 16 — Seeking to resolve its mounting legal and political difficulties, the tobacco industry has initiated negotiations that could lead to tighter Government regulation, restrictions on advertising and the creation of a huge fund to cover the costs of smoking-related illnesses in exchange for immunity from most lawsuits.

In clandestine talks, which have taken place over the last three weeks in Washington, Chicago and northern Virginia, the nation's two largest tobacco companies have offered sweeping concessions, including submission to Food and Drug Administration regulation and payments of more than $250 billion over the next 25 years to compensate states and individuals for tobacco's toll on health and the expenses related to the treatment of tobacco-related illnesses.

The talks, with the companies' legal opponents, have for the first time included the top executives of the nation's two largest tobacco companies, Steven F. Goldstone of the RJR Nabisco Holdings Corporation and Geoffrey C. Bible of the Philip Morris Companies.

The discussions are the most dramatic evidence to date that the tobacco industry's once-impregnable resistance to compromise is crumbling.

The existence of the talks was first disclosed by the Wall Street Journal today.

But the proposed deal is still in its embryonic stages and faces daunting hurdles, including disputes over the size of the damage fund, and opposition by members of Congress as well as a wide array of anti-tobacco forces.

And the price the industry and its lawyers are demanding for a settlement is high: near-total immunity from lawsuits from states seeking compensation for the Medicaid costs of treating smokers, as well as from individual and class-action lawsuits filed by smokers and their families.

The tobacco industry has been driven to the negotiating table by the accelerating momentum of legal, political and financial pressure.

President Clinton is pressing for broad oversight of the industry's sales practices by the F.D.A.; plaintiffs' attorneys are starting to win damage cases, and one cigarette maker settled a case last month with 22 states, agreeing to turn over potentially explosive internal documents detailing industry knowledge of tobacco's harmful health effects.

In addition, the fraud division of the Justice Department is conducting a wide-ranging investigation into tobacco industry marketing and the conduct of its executives and lawyers, including the truthfulness of sworn testimony in courts and before Congress. One person familiar with the talks described the Federal investigation as "a hidden club motivating the industry to settle."

Scott Harshbarger, the Attorney General of Massachusetts and one of the participants in the recent talks, said that the tobacco industry for the first time "has come to the table to

Continued on Page A24, Column 1

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sue for peace."

"Our position is that if Big Tobacco is willing to accept terms and conditions that include financial relief, protections for kids and changes in their business practices, it would be a major public health breakthrough. We have an opportunity to get more through a settlement now than we could through years of protracted litigation," Mr. Harshbarger said.

The tobacco companies and the lawyers representing them referred all inquires to the Washington public relations firm of the Bozell Sawyer Miller Group, owned by Bozell, Jacobs, Kenyon & Eckhardt. Scott Williams, an official of the firm, said that he had been instructed not to comment on the talks.

The first phase of settlement talks concluded today and there was no date set for their resumption, a person involved in the talks said. The negotiations could fall apart at any time, people familiar with the negotiations cautioned, and any accord would face tremendous hurdles even if the 40 participants reach an agreement in the next several months.

Philip Morris announced strong first-quarter earnings yesterday, following news of the talks, and tobacco stocks rose sharply.

The companies expressed willingness to accept regulation by the F.D.A., to be renamed the Food, Drug and Tobacco Administration and be given broad powers to regulate tobacco advertising and force disclosure of cigarette ingredients.

Advertising restrictions under discussion include the elimination of billboard advertising, an end to cigarette company sponsorship of sports events and a ban on the use of human characters in cigarette ads. Britain has outlawed the Marlboro man and images of healthy, youthful smokers because they mislead young people about the adverse effects of smoking.

The companies would also be required to create a fund of as much as $500 million to educate consumers, particularly young people, about the risks of smoking.

The industry's willingness to submit to Federal regulation is seen by many observers as perhaps the most meaningful concession in the talks.

"The significance of the F.D.A. cave-in cannot be underestimated," said one person close to the talks. "There are those who do not want this to work, who will say it is a matter of money. It is not. It is an attempt to save lives now."

But the nascent deal still faces numerous obstacles.

Many state attorneys general expressed reservations about the emerging shape of the settlement and several members of Congress said that there was no guarantee that any such "global" agreement could win Congressional approval.

"This industry has earned a significant amount of distrust, so naturally I'm skeptical," said Senator Frank R. Lautenberg, a New Jersey Democrat. "I want to make sure that the citizens are collecting appropriate damages for the plague that smoking has visited upon them."

The participants in the talks are the highest-powered group ever to engage in peace talks during the long-running war against tobacco.

In addition to the two tobacco company chief executives, Mr. Goldstone and Mr. Bible, the industry has been represented by former Senate Majority Leader George Mitchell, now affiliated with the law firm Verner, Liipfert, Bernhard, McPherson & Hand; Herbert Wachtell of Wachtell, Lipton, Rosen & Katz; and Arthur Golden of Davis Polk & Wardwell. Also representing the industry was Phil Carlton, a politically well-connected former Justice of the North Carolina Supreme Court.

Opposite the industry supporters were al state attorneys general, including Michael C. Moore of Mississippi, who in July is scheduled to bring to trial the first state lawsuit against the industry. Mr. Moore was instrumental in the negotiations that led the Liggett Group, a unit of Brooke Group Ltd., last month to break ranks with its bigger tobacco industry peers and admit the harmful effects of tobacco in exchange for release from civil liabilities.

Also among the anti-tobacco forces at the table were Matthew Myers of the Campaign for Tobacco-Free Kids and Hugh Rodham, a plaintiffs' attorney and former public defender representing smokers, who is the brother of First Lady Hillary Rodham Clinton. Plaintiffs' attorneys John P. Coale of Washington and Russ M. Herman of the New Orleans firm Herman, Herman, Katz & Cotlar, are also participating.

The White House has monitored the talks almost hourly, a person close to the negotiations said.

Mr. Moore said that the two tobacco giant leaders were invited to the talks on April 3, to test the industry's sincerity. He said the focus of much of the last three weeks was on ending marketing to children by the industry and a demand for a high level of Government scrutiny and regulation of the industry.

"I'm very optimistic about what we've accomplished on the public health issues and the children's arena," Mr. Moore said. "I would say we've progressed further than anybody contemplated."

The proposed fund to be created by the tobacco companies would be modeled on similar pools created for victims of black lung disease and asbestos poisoning, which affected far fewer people than smoking. Although $250 billion sounds like an enormous sum, industry critics and public health advocates said that it does not begin to cover the costs of smoking-related health problems.

Richard A. Daynard, director of the Tobacco Products Liability Project at the Northeastern University Law School, estimated the health care costs of smoking at $50 billion a year and indirect costs, such as lost productivity, at an additional $50 billion to $100 billion annually.

He said that the tobacco companies could recoup the $12 billion to $15 billion annual cost of the settlement by raising cigarette prices by 50 cents a pack, which would have at most a marginal impact on sales.

"The industry is desperate about the cases coming up. Their potential liability is in the billions of dollars and they think they're going to lose so they have every interest in trying to get bailed out," Mr. Daynard said.

Public health advocates may be even more difficult to persuade. The companies have fought them so hard and so long that they are dubious about any industry proposal.

Dr. David A. Kessler, the former head of the F.D.A. and a longtime industry critic, said that no one can put a price tag on the health of millions of Americans.

"Every time we've hailed a significant milestone in the fight against tobacco — whether it was the 1964 Surgeon General warning or the ban on television advertising — the industry has always turned it to their advantage," Dr. Kessler said.

First Brother-in-Law Has Tobacco Talks Role

By BARRY MEIER

At a recent round of the landmark tobacco settlement talks, Richard Blumenthal, the Connecticut Attorney General, met a member of President Clinton's family whom he had not encountered as a classmate of Bill and Hillary Clinton at Yale Law School: Hugh E. Rodham Jr.

"I had never met Hugh before, so I was immediately curious about him and why he was there," Mr. Blumenthal said.

Other participants in the negotiations have been curious, too, because the First Lady's brother has seemed a bit out of place among the high-powered lawyers, corporate executives and state regulators gathered around the negotiating table.

His involvement in tobacco litigation has been relatively brief, about 18 months, while other lawyers have spent decades fighting cigarette companies. Other lawyers maintain that Mr. Rodham, a Miami lawyer, has apparently never negotiated a major settlement of a product liability lawsuit.

Many participants in the talks are puzzled over whether other plaintiffs' lawyers brought Mr. Rodham into the talks as an equal, as a back channel into the White House or as a piece of potentially useful political window-dressing. Mr. Rodham, 46, did not return numerous telephone calls seeking comment.

Mrs. Clinton's brother became involved in discussions about possibly resolving the tobacco litigation well before the current round of negotiations this month. Since the beginning of the year, he has occasionally been among a small group of tobacco plaintiffs' lawyers who have met four or five times with Bruce Lindsey, the deputy White House counsel, said a person familiar with the talks. As negotiations have intensified this

Some lawyers are puzzled over a political presence.

month with the participation of top cigarette company executives, Mr. Rodham has stayed in touch with the Clinton Administration, a White House official said.

Mr. Rodham's involvement in the talks over one of the nation's most important public health issues has come swiftly. Until 1993, he worked for more than a decade in the Dade County public defender's office in Florida, largely handling drug cases. In 1994 he was soundly defeated in a bid to unseat Senator Connie Mack, Republican of Florida. Since then, Mr. Rodham has made only a faint mark on tobacco litigation.

"I know virtually everyone involved in tobacco litigation, and I had never heard of his name before," said Stanley Rosenblatt, a plaintiffs' lawyer in Miami who is handling two class-action cases in Florida against cigarette manufacturers.

Mr. Rodham's role in the lawsuits against cigarette companies began about 18 months ago, when he joined a nationwide coalition of plaintiffs' lawyers in what is known as the Castano case, said Russ Herman, a plaintiffs' lawyer in New Orleans who is a member of the coalition.

The coalition, consisting of some 65 law firms, was formed in 1994, with each firm contributing an initial $100,000 to finance the case of Peter Castano, a lawyer who died of lung cancer. The lawyers' group sought to fashion a nationwide class-action lawsuit against the cigarette industry on the issue of addiction.

John Coale, a member of the Castano group who joined Mr. Rodham for talks at the White House, declined to comment on meetings there involving the First Lady's brother.

Mr. Lindsey declined to answer questions about Mr. Rodham's role in the tobacco talks.

Mr. Herman said: "Hugh Rodham stands on his own two feet, and the meetings at the White House would have taken place without him. He has been helpful to us because Hugh has credibility on the issue, and he is well known. But there are other people involved with significant profiles."

Mr. Coale said the White House had shown no preference toward the plaintiffs' group because of Mr. Rodham's presence at the bargaining table.

If a settlement is approved, Mr. Rodham could emerge a winner because of probable provisions for compensating plaintiffs' lawyers in general. And for tobacco plaintiffs' lawyers, such a payoff may come quicker in a settlement than through court battles. The Federal class action filed by the Castano group in New Orleans was dismissed last year, and the group is now pursuing lawsuits in more than a dozen states against cigarette producers.

The New York Times

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