Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: list of invitees [partial] (1 page)	n.d.	P3/b(3)

COLLECTION:
Clinton Presidential Records
First Lady's Office
Melanne Verveer
OA/Box Number: 20055

FOLDER TITLE:
Teen Smoking [Folder 1]

2013-0534-S
rc1734

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Coalition on Smoking OR Health

AMERICAN CANCER SOCIETY®

American Heart Association

AMERICAN LUNG ASSOCIATION®

Coalition on Smoking OR Health

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 Facsimile: (202) 452-1417

News Conference Participants
National Press Club
August 3, 1995

JACQUELINE D. MCLEOD, M.P.H., M.Ed.
President, American Lung Association

SIDNEY C. SMITH, JR., M.D.
President, American Heart Association

GEORGE DESSART
Chairman-Elect, American Cancer Society

LONNIE R. BRISTOW, M.D.
President, American Medical Association

JEFREY POLLOCK AND ALEXANDER JUTKOWITZ
Pollsters, Global Strategy Group, Inc.

VICTOR CRAWFORD
Former Tobacco Industry Lobbyist

RICK APPLE
North Carolina Tobacco Grower

AMERICAN CANCER SOCIETY®

AMERICAN LUNG ASSOCIATION®

American Heart Association℠
Fighting Heart Disease and Stroke

Fran Du Melle
Deputy Managing Director

Washington Office
1726 M Street, N.W.
Suite 902
Washington, DC 20036-4502
Phone: (202) 785-3355
FAX: (202) 452-1805

National Headquarters:
1740 Broadway
New York, N.Y. 10019-4374

John R. Garrison
Managing Director

When You Can't Breathe, Nothing Else Matters®

AMERICAN LUNG ASSOCIATION®

Statement of Jacqueline D. McLeod, M.P.H., M.Ed.
President of the American Lung Association

President Clinton has at this moment an opportunity to combat the tobacco addiction and disease that afflicts our nation and ultimately prevent the horrific, untimely deaths of millions of Americans. It has been reported that Dr. David Kessler, head of the federal Food and Drug Administration, has determined that his agency can and should regulate tobacco as a drug. With that action, the FDA can make it more difficult for children to purchase tobacco products and for the tobacco industry to advertise and market to children.

The organizations represented here today -- the American Lung Association, the American Heart Association, the American Cancer Society and the American Medical Association -- plus 90 other health, medical, religious and children's advocacy organizations urge President Clinton to support Dr. Kessler. The tobacco industry and its allies in Congress are pressuring President Clinton to prevent Dr. Kessler and the FDA from acting. Instead, the industry is urging President Clinton to trust them to voluntarily solve the problem on their own.

We are here today to speak with one, strong, unified voice to urge President Clinton to stand up for our children and resist that pressure. The stakes are enormous. More than 400,000 Americans die each year from tobacco-related

diseases. Each day, 3,000 children in this country start to smoke -- almost 1,000 of those 3,000 will eventually die from smoking-related disease. Mr. President, don't bargain their lives away by cutting a deal with the tobacco industry. They can't be trusted.

In the early 1960s, they promised to tell the American people the truth about the health effects of their products. We now know they lied.

In 1964, they promised to restrict their advertising so it would not glamorize cigarettes for children. They lied.

In 1970, they promised not to sponsor sporting events that were to be broadcast on television. They did just the opposite. They lied.

In the 1980s, they promised to reduce youth access to tobacco by educating retailers and children. Instead, they created a program they knew would fail. Again, they lied.

Now, in 1995, they are again asking us to trust them to reduce tobacco use among children.

That would be foolish and unwise. The tobacco industry knows that nearly 90 percent of today's adult smokers began the habit by age 18. More than one-third of adults smokers began before they were old enough to purchase cigarettes legally. Tobacco profiteers know they must find new victims early and young.

Unfortunately, their tactics are working. Two recent studies, one by the University of Michigan and another by the Centers for Disease Control and Prevention, found a sharp increase in smoking among the young even while it has fallen among adults.

The sincerity of the tobacco industry's latest promise to do better should be measured against 40 years of dishonesty about the addictive nature of nicotine. This record is all the more onerous given the recent revelations about the manipulation of nicotine levels.

The tobacco industry's sincerity should be measured against the $6 billion it spends each year to promote the likes of the Marlboro Cowboy, Joe Camel and the Virginia Slims woman to our children!

The tobacco industry's sincerity should be measured against its opposition to every meaningful federal, state and local proposal to protect children from tobacco use.

Survey after survey, including polls conducted by *The New York Times*, CBS and the Robert Wood Johnson Foundation, show strong public support for federal action. This morning we are releasing the results of a new survey showing overwhelming public support for strong regulation of tobacco products. Nearly 83 percent of those polled, for example, believe the FDA should set standards to ensure the health and safety of tobacco products. Representatives of our polling agency will provide you with more details in a few minutes.

Another indicator of the depth of public support occurred recently when the Coalition on Smoking OR Health joined with 90 other organizations in collecting more than half a million signatures nationwide on petitions supporting FDA oversight of tobacco products. The petitions were delivered to President Clinton and Members of Congress with a request to move forward on the regulation of tobacco products.

We are not suggesting a ban on tobacco use by adults. Our goal is simple -- to stop children from smoking. Fewer young smokers today will mean fewer smoking-related illnesses and deaths tomorrow.

If ever there was a clear choice between right and wrong, this is it. In his heart and soul, President Clinton knows what is right. Our organizations and the majority of Americans stand behind him. He knows that his child and all of our nation's children should not smoke. He **KNOWS** what is right. We urge him to **DO** what is right.

# # #

American Heart Association℠
Fighting Heart Disease and Stroke

Office of Public Affairs
1150 Connecticut Avenue Northwest
Suite 810
Washington, D.C. 20036
Tel 202 822 9380
Fax 202 822 9883

Oral Statement of Sidney C. Smith, Jr., M.D.
President of the American Heart Association

Good Morning, I am Dr. Sidney Smith, President of the American Heart Association. I believe that the organizations represented here today share a common goal with President Clinton - we all want to stop the tobacco-disease epidemic that preys on our nation's youth.

To accomplish that goal, we are calling on the President of the United States and every member of the House and Senate to put aside special interest politics, ignore tobacco industry demands and commit to fair, equitable and common sense regulations for tobacco products.

Let's be clear on one thing: voluntary efforts by the tobacco industry do not work. We have learned an important lesson over the past 40 years: the best way to keep our children from becoming addicted to tobacco, is to keep the tobacco industry away from our children.

This commitment to helping children should take the form of a national policy on tobacco. Members of Congress and the President of the United States are receiving a letter today from more than 100 national health, medical, religious and children's organizations and from prominent individuals and political leaders asking them to sign the ***Contract for the Protection of America's Families and Children From Tobacco*** as part of a bipartisan effort to protect the health and welfare of American families and children. This strategy should include assisting American tobacco farmers who want to stop growing tobacco. We are asking the

President to work with Congress to identify a plan to accomplish that goal. For too long, the tobacco industry has profited at the expense of the public's health and at the expense of the American tobacco farmer.

The signatories on this **Contract** - individuals such as former Surgeon General C. Everett Koop and Pat Robertson, Chairman of the Christian Broadcasting Network, and organizations ranging from the Interreligious Coalition to the YMCA - demonstrates that this is not a Republican or a Democratic issue, nor is it a conservative or liberal issue. It's about protecting our children from addiction caused by smoking and promoting the health of the American family.

In the weeks and months ahead our organizations will ask all members of Congress to sign this **Contract**, and we will ask their constituents to demand action to stop the sale, advertising and promotion of tobacco to children.

We are asking President Clinton and Members of Congress to support a comprehensive, fair, common sense and *enforceable* policy on tobacco, to:

1. Ensure that tobacco products are not sold to children and teenagers;

2. Ensure that tobacco advertising and promotions are eliminated, as an interim step eliminate advertising and promotions that affect children;

3. Require that the public be given complete, accurate and truthful information about tobacco products, information which will allow the public to truly make an informed choice about whether they smoke;

4. Require that special and expanded efforts be made to warn and discourage tobacco product consumption by pregnant women who not only endanger their own life but also the life of their unborn; and

5. that Congress and the Administration work to find solutions to assisting the tobacco farmers and others who work in the tobacco industry to transition out of the tobacco business.

The goals set forth in this **Contract** can be accomplished and enforced by the Food and Drug Administration, the agency that Americans trust and rely on to protect public health. Tobacco is the product most deserving of FDA action. Tobacco products cause more deaths each year in this country than are caused by foods, drugs, medical devices and cosmetics combined, products that the public relies on the FDA to monitor. The public health benefit to be gained from common sense controls over tobacco products compared to all other legal products regulated by the FDA is immeasurable.

We hope that all members of Congress and the President will sign this **Contract** *and* support FDA action on tobacco to help end the cycle of disease, addiction and death that has plagued our nation. Now is the time to seize this historic opportunity for real solutions for the sake of public health and for the sake of our children's future.

-END-

1150 Connecticut Avenue Northwest Suite 810 Washington, D.C. 20036 202 822 9380 FAX: 202 822 9883

American Heart Association℠
Fighting Heart Disease and Stroke

Office of
Public Affairs

Statement of Sidney C. Smith, Jr., M.D.
President of the American Heart Association

Good Morning, I am Dr. Sidney Smith, President of the American Heart Association. Most of you in this room know full well that the present debate over whether tobacco should be fairly and equitably regulated by the Food and Drug Administration has little to do with health and almost everything to do with politics, money and corporate responsibility.

Today we are calling on the President of the United States and every member of the House and Senate to put politics aside and commit to working towards enactment of fair, equitable, common sense regulations for tobacco products. The days of voluntary efforts and waiting for the tobacco industry to demonstrate corporate ethics and responsibility must be declared over. We are also asking the President and the Congress to commit to working to identify economic solutions to the future of the tobacco farmer and other tobacco workers. The tobacco industry has profited at the expense of the public's health and they have profited at the expense of the American tobacco farmer for too long. Now is the time to seize this historic opportunity for change that seeks real solutions, not political posturing and stagnation.

Members of Congress and the President of the United States are today receiving a letter from prominent individuals, as well as over one hundred health, religious and youth organizations asking that they make a commitment to working towards protecting families and children of this country from the terrible toll caused by tobacco. These individuals and organizations who are joining together in this initiative are demanding change. They are demanding that our public health and the future of our children no longer be sacrificed for the profits of the tobacco industry. The letter accompanying the **Contract** clearly indicates that this is not a Republican versus a Democratic issue, that this is not a conservative versus liberal issue, but both a health and ethical issue.

All of these people and organizations representing the interests of millions and millions of Americans nationwide are asking Members of Congress and the President to sign a **Contract for the Protection of America's Families and Children from Tobacco Use,** to tell the American people where they stand on the tobacco and health issue. In the weeks and months ahead we will routinely go back to Members of Congress to ask for their commitment if they have not given it, and we will ask their constituents to raise this issue at town meetings and in the local press if necessary. It is time for Republicans and Democrats alike to stop playing politics with the lives of the American people. It is indeed time that we end what has been decades of a vicious cycle of disease, death and addiction.

The **Contract** calls on the President and the Congress to recognize and accept:

- that the tobacco companies have undermined the integrity of America's families and seduced its children into what is often a life long addiction leading to premature death;

- that the President and the Congress have an historic opportunity to restore accountability and integrity in our democratic processes which have been controlled by the tobacco manufacturers at the expense of the public's health; and

- that while Americans should take greater responsibility for their daily lives they can only do so if they are given the tools, assurances and opportunities that ensure that choices to smoke are based on truthful and accurate information, and that our children who do not have the sophistication to make responsible choices are not exploited or encouraged to use these addictive drugs.

The **Contract** has five primary areas where we are asking Members of Congress to make a commitment to support comprehensive, fair, common sense and *enforceable* laws and regulations. They are:

1. Ensure that children and teenagers do not have access to tobacco products;

2. Ensure that tobacco advertising and other promotional efforts be eliminated or significantly restricted particularly as they relate to the targeting of children;

3. Require that the public be given complete, accurate and truthful information about tobacco products, information which will allow the public to truly make an informed choice about whether they smoke;

4. Require that special and expanded efforts be made to warn and discourage tobacco product consumption by pregnant women who not only endanger their own life but also the life of their unborn; and

5. that Congress and the Administration work to find solutions to assisting the tobacco farmers and others who work in the tobacco industry to transition out of the tobacco business.

We believe that much of the work that must be accomplished under this **Contract** will and must come from the Food and Drug Administration, this nation's lead agency, in protecting the public's health from dangerous products. And we believe that in addition to the necessary federal role that the FDA must take, the Congress must return to the states the authorities to go further in their efforts if they so chose. In spite of what rhetoric you hear from the propaganda machines of the tobacco industry and its allies, let there be no mistake that if there is any product deserving of the intervention of the FDA from the standpoint of protecting the public's health it's tobacco. Tobacco products cause more deaths each year in this country than are caused by foods, drugs, medical devices and cosmetics combined, products that also fall under the purview of the FDA. The public health benefit to be gained from common sense controls over tobacco products compared to all other legal products regulated by the FDA are immeasurable. The American public should be outraged that many of our elected officials from both parties are still playing politics with our health and the future health of our children. When it comes to tobacco, politics and special interests, it seems it's business as usual.

We hope that all members of Congress and the President will sign this **Contract** and commit to ending the cycle of disease, addiction and death that has plagued this country because of the irresponsibility of the tobacco industry and the addiction to tobacco moneys that our policy makers have had. Let's not allow the tobacco industry to victimize our families, our children, or the tobacco farmers in this country anymore. Let's find meaningful solutions to real problems.

AMERICAN CANCER SOCIETY®

REMARKS BY GEORGE DESSART

AMERICAN CANCER SOCIETY

For Delivery at the
Coalition On Smoking OR Health Press Conference
Supporting FDA Regulation of Tobacco
National Press Club
Washington, D.C.
August 3, 1995

Good morning. I am George Dessart, Chairman-elect of the national board of directors of the American Cancer Society. I have been a volunteer for the American Cancer Society for many years and I am proud to be here today speaking on behalf of the Society's more than two million members. I have also chaired the Tobacco Control Committee which is a major effort of the American Cancer Society because tobacco use is the nation's single most preventable cause of death and disease. Nearly one in every five deaths in the U.S. is caused by tobacco.

From my background in the broadcast industry I have been especially disturbed by the sophisticated marketing of tobacco to our youth. About 3,000 kids start smoking every day, which is both a marketing windfall and a marketing necessity for the tobacco industry, since 90 percent of all smokers start as kids. Unfortunately, of this 3,000, some 1,000 will eventually die of tobacco use.

This die-off of customers is a major reason that the tobacco industry must continue to promote its product to attract more child smokers. These deadly numbers make another point clear: for the tobacco industry claims to be genuine about wanting to stop children from smoking -- and they are not genuine -- the industry would also have to be serious about significantly reducing its sales to youth, which is the wellspring of its future. Nothing in the industry's corporate culture indicates that is possible. In fact with its legendary profits, and $5 to $6 billion a year spent on promotions, it is clear that this industry puts profits ahead of human life.

There is no dignity to negotiating with an industry that knows that its product takes more than 400,000 lives a year in the United States alone. I hope the Administration is not politically pressured into indulging in that negotiating process. There are said to be two Federal Grand Juries currently investigating the veracity of the tobacco industry's public statements about their own research and knowledge of tobacco's addictive nature and health risks. Let the tobacco industry attorneys save their negotiating for the prosecutors.

As we know, the White House now has an historic opportunity. For the President to approve the proposed action of the FDA to assume regulatory control over tobacco would be a landmark decision. A major reason is that few Presidents can lay claim to taking such a courageous stand that will genuinely save so many lives over time. While the tobacco industry is held in low public regard, it has historically huge profits, and many investors who benefit. These funds will be used to attack the Administration using every available technique of lobbying, litigation, the coercion of financial interests, and political assault. When this fight is won, the bottom line is that every slash and stab at the President will go to validate the rightness of his decision.

I want to talk about the tobacco advertising constraints that are part of the FDA proposal, and their importance. Several recent studies show that kids are smoking in higher numbers than ever before, even though adult rates are declining. We also know that the increase in adolescent smoking rates coincides directly with the doubling of real expenditures for cigarette advertising and promotions. The increase in smoking initiation also coincides directly with the introduction of the Joe Camel campaign. Recalling the 3 to 1 ratio of new kid smokers to eventual fatalities, Joe Camel is no more than the Pied Piper of death for teenage America.

The tobacco problem among our youth was accurately labeled a "pediatric disease" by Dr. David Kessler, the FDA Commissioner. This has been supported by people representing a wide range of political and social beliefs. Former Senator Barry Goldwater is supporting the FDA and one of the nation's most eminent conservative thinkers, William F. Buckley, called Kessler's appraisal of the problem an "epiphany." Fifty self-identified conservative doctors and researchers sent a letter to House Speaker Newt Gingrich stating that "smoking is a physically addictive, life-shortening habit taken up primarily by kids." They warned him

of the political hazard of having the Republican Party be seen as the defender of the tobacco industry. Representative James Hansen of Utah called the increase in the number of children who smoke an "alarming trend."

Restrictions on the access of children to tobacco products will not achieve a sustained reduction in tobacco use unless these restrictions are accompanied by the end of advertising and marketing that attracts kids. The tobacco industry uses these devices to create demand among children. They use packaging to create positive associations. Wouldn't you want to be out there sailing? Wouldn't you want to be a race car driver? Wouldn't you want to be part of this young, physically attractive, happy crowd of people cavorting in the ads? I spent my career in broadcasting. I've watched the tobacco industry and I know that's what they are selling to our kids. The tragic irony is that the youth and vigor of their images is exactly the opposite of what use of their product delivers.

While the industry says it does not want kids to smoke, it markets to them incessantly. Joe Camel, the Marlboro cowboys, the massive increase in giveaways or coupon trade-ins for jackets, belts, t-shirts, hats, posters, back-packs and other youth-oriented paraphernalia are examples. These are multi-billion dollar promotional enterprises that have been refined, or in some cases invented by the U.S. tobacco industry to attract our kids and addict them to cigarettes. The sponsorships of pop music concerts or major sporting events like tennis or auto racing are equally insidious examples. This displays an industry best defined by profiteering and death trying to associate itself with the best of America's athletes and musicians.

We have long supported a general tobacco advertising ban, and in particular advertising intended to appeal to kids. We also support the elimination of marketing techniques for tobacco products and paraphernalia that attract the children's market. And the public supports us. Our most recent poll indicates that 67% of people favor an advertising ban. Eighty-one percent support a ban on advertising geared toward kids. These strong numbers should strengthen the resolve of any politician who the tobacco industry tries to intimidate.

William Buckley said youth advertising limits on tobacco are more than a legitimate enterprise of government. He made the point that government obliges children to go to

school, and not be allowed to drive, drink, or vote until certain ages. We would add that there are certain other health requirements such as childhood vaccinations before entering school. Limits on the advertising to children of tobacco products that will eventually kill a predictable percentage of its users is consistent with these other government responsibilities. Government review boards to set new youth advertising limits can be devised.

Trusting the tobacco industry to set and enforce the same limits voluntarily flies in the face of the industry's record and motives. Every time effective measures are proposed to protect children from tobacco, the tobacco industry launches a plan to avoid responsibility. The latest effort was Philip Morris' sudden announcement a few weeks ago that it was launching an "Action Against Access" campaign to allegedly reduce minors' access to cigarettes. This was an obvious effort to sidetrack what they knew the FDA would be recommending to the White House.

After 40 years of deception, the tobacco industry's promises to protect our kids are as believable as its claims that tobacco does not cause disease and nicotine is not addictive.

* * *

Remarks for Dr. Lonnie R. Bristow, M.D.

August 3, 1995

FDA Regulation of Nicotine

To para-phrase an old Virginia Slims advertisement -- "We've come a long way baby."

We are on the verge of an historic step that will be remembered as a courageous moment when nicotine in tobacco was put in its proper place as an powerful addictive drug under the control of the U.S. Food and Drug Administration.

But we are not there yet. Two weeks ago, the AMA published some of the most damning evidence to-date that the tobacco industry knew -- long ago -- of the addictive and deadly nature of tobacco.

Today, I speak for the physicians of the American Medical Association to urge President Clinton and Dr. Kessler to take bold and decisive steps to place all nicotine products under FDA control and implement a program to properly oversee the sale and advertising of all nicotine products.

Nicotine -- when in a patch or chewing gum -- is already under FDA oversight. Cigarettes are a drug delivery device -- a syringe for the delivery of the drug nicotine. As such, we see no other possible, logical or lawful step other than to place tobacco within the

purview of the FDA.

I have spoken directly to President Clinton and was impressed by his concern for the next generation -- our children. As I told Mr. Clinton, this should not be a political debate. It is a public health issue regardless of political party or ideological philosophy. It is a matter of life and death for 450,000 Americans each year.

Finally, I want to emphasize that we are not advocating a ban of tobacco products. We have great compassion for the millions of Americans -- our patients -- who are addicted to nicotine. Prohibition will not work and is not humane. We want to stop the cycle of addiction and manipulation that targets our youngest patients. Without the strong steps outlined in the editorial by the AMA just two weeks ago, a new generation of smokers grows by 3,000 kids every day.

Thank for your interest and the information you provide the American public.

#

For more information, please call:

James Stacey 202/789-7419
Brenda L. Craine 202/789-7447

The Brown and Williamson Documents

Where Do We Go From Here?

There is a massive body of evidence, derived from many scientific disciplines, that tobacco is addictive and kills smokers. Up to half of those who continue to smoke cigarettes will die prematurely from diseases caused by smoking, half of these deaths occurring in middle age.[1] Peto et al[2] have calculated that of the 1.25 billion people now living in developed countries, 250 million will, if present tobacco consumption patterns are maintained, die from tobacco. With 3 million deaths worldwide each year currently due to tobacco use, the consequences of tobacco to the public health have been, and will continue to be, staggering, and the importance of bringing this hazard under control is correspondingly great.

It is against this background that *JAMA* publishes several highly unusual articles this week.

The Documents

On May 12, 1994, Stanton A. Glantz, PhD, a professor of medicine in the Division of Cardiology at the University of California, San Francisco (UCSF), and a scholar interested in the field of tobacco and the public health, received from an unknown source, "Mr Butts," approximately 4000 pages of memoranda, reports, and letters, covering a 30-year period, from the Brown and Williamson Tobacco Corporation (B&W) and its parent company, the British American Tobacco Company (now BAT Industries).[3] In the subsequent months, Glantz received several thousand additional pages of documents from Congressman Henry Waxman's House Subcommittee on Health and the Environment and another few hundred pages of documents from the estate of the chief scientist of BAT. Glantz ultimately put all the documents into the library at UCSF.

This issue of THE JOURNAL is largely devoted to an analysis by Glantz and his colleagues of these three sets of documents.[4-8]

The documents show:

- that research conducted by tobacco companies into the deleterious health effects of tobacco was often more advanced and sophisticated than studies by the medical community.
- that executives at B&W knew early on that tobacco use was harmful and that nicotine was addictive and debated whether to make the research public.
- that the industry decided to conceal the truth from the public.
- that the industry hid their research from the courts by sending the data through their legal departments, their lawyers asserting that the results were immune to disclosure in litigation because they were the privileged product of the lawyer-client relationship.
- that despite their knowledge to the contrary, the industry's public position was (and continues to be) that the link between smoking and ill health was not proven, that they were dedicated to determining whether there was such a link and revealing this to the public, and that nicotine was not addictive.

We think that these documents and the analyses merit the careful attention of our readership because they provide massive, detailed, and damning evidence of the tactics of the tobacco industry. They show us how this industry has managed to spread confusion by suppressing, manipulating, and distorting the scientific record. They also make clear how the tobacco industry has been able to avoid paying a penny in damages and how it has managed to remain hugely profitable from the sale of a substance long known by scientists and physicians to be lethal. We hope that publication of the articles will encourage all our readers to become even more active in the campaign against tobacco.

The B&W documents Glantz first received are believed to be copies of documents themselves copied by a paralegal, Merrell Williams, who had once worked for one of B&W's outside counsel. Merrell Williams had, in 1993, turned the documents over to the attorney he had hired to make a claim for health damages against B&W. His ex-employers filed action against him in September 1993 to prohibit the use and dissemination of the B&W documents. In October 1993, B&W intervened as a plaintiff in the case, claiming that the documents were protected from disclosure to the public by the attorney-client privilege and the work product doctrine.[9]

The documents surfaced publicly on May 7, 1994, when

Dr Todd, Executive Vice President, AMA; Dr Rennie, Deputy Editor (West), *JAMA*; Dr McAfee, President, AMA; Dr Bristow, President-Elect, AMA; Dr Painter, Immediate Past President, AMA; Dr Reardon, Secretary-Treasurer, AMA; Dr Johnson, Speaker, AMA House of Delegates; Dr Corlin, Vice-Speaker, AMA House of Delegates; Dr Coble, AMA Trustee; Dr Dickey, Vice-Chair, AMA Board of Trustees; Dr Flaherty, AMA Trustee; Dr Formica, AMA Trustee; Dr Goldrich, AMA Resident Physician Trustee; Dr Jacott, AMA Trustee; Dr Lewers, AMA Trustee; Dr Nelson, AMA Trustee; Dr Seward, Chair, AMA Board of Trustees; Dr Smoak, AMA Trustee; Mr Suk, AMA Student Trustee; Dr Walker, AMA Trustee; Dr Wootton, AMA Trustee; and Dr Lundberg, Editor, *JAMA*.

Philip Hilts published the first of a series of articles in the *New York Times*,[10] and since then there have been reports in several national newspapers and on radio and television. In addition, Congressman Waxman made more documents public at hearings by the Subcommittee on Health and the Environment of the US House of Representatives in the summer of 1994. Since that time, in litigation in the District of Columbia, West Virginia, Massachusetts, Kentucky, and Mississippi, B&W has attempted to subpoena reporters and seal the documents. They have been unsuccessful. Judge Harold H. Greene of the US District Court for the District of Columbia quashed subpoenas directed at Congressmen Henry Waxman and Ron Wyden, concluding that B&W's course of conduct was "patently crafted to harass those who would reveal facts concerning B&W's knowledge of the health hazards of tobacco."[11]

In the case of the documents in the UCSF library, B&W has not only tried to remove the documents, but also sought to obtain the names of scholars who have used them, something the university has interpreted as a violation of the privacy rights of library patrons. In addition, the company hired private investigators to stake out the area in the UCSF library where the documents were kept, an action that had the effect of harassing and intimidating library personnel.[12] On May 25, 1995, Judge Stuart Pollak in the Superior Court of the State of California, without ruling on whether the documents were privileged, recognized that the documents were already in the public domain. The judge said that there was a strong public interest in permitting the information in the documents to remain available to the university and others. He noted that to grant B&W's application would have the effect of preventing the information from being used in the public dialogue bearing on public health, public law, and litigation. He denied B&W's application to take possession of all copies of the documents in the hands of the UCSF and its employees.[13] An appeal by B&W was unanimously rejected by the California Supreme Court on June 29, 1995. The documents, the authenticity of which is not in doubt, not least because of the actions B&W has taken to retrieve them, are therefore in the public domain because judges across the country say they should be.

Who Are the Authors?

The authors of the first five articles we publish in this issue of *JAMA* are people who have produced careful scholarship in the past, some of it published in *JAMA*.[14-16] They are academic researchers interested in national policy to reduce the toll from this devastating hazard to the nation's health.

The Articles

These five articles[4-8] provide a careful analysis of the documents. They detail the sharp disparities between the tobacco industry's private knowledge, developed by their own research during more than 30 years, and their public stance.

The articles show that the effect of tobacco company tactics, long suspected, has been to obfuscate the conclusions of scientists, to confuse the public, and to assist greatly the tobacco industry in its successful efforts to influence the political process in its favor. The surgeon general's report of 1964 would have been far more decisive in its conclusions and recommendations had the evidence available to the executives of B&W been available to the surgeon general's committee. We can only speculate how many lives would have been saved and how much suffering would have been averted.

JAMA hired Mr Tim Graham, a veteran editor with the Alameda Newspaper Group, which includes the *Oakland Tribune*. He, after reading the documents, has, according to usual journalistic practice, tried to contact executives of B&W and other interested parties to get their reactions. We publish Graham's article[17] together with the written questions he sent B&W and B&W's statement in response. We also publish an interview by Andrew Skolnick with Mr Victor Crawford, a lobbyist for the Tobacco Institute in Maryland, who is now dying of cancer of the oropharynx.[18]

Why Are We Publishing the Articles?

For many decades, the mission of the American Medical Association (AMA) has been to "promote the science and art of medicine and the betterment of public health." To remain silent about the B&W papers would be to deny our mission. Quite simply, we are publishing this research because it is the right thing to do.

Analysis of these papers suggests that we would have seen a very different picture of tobacco use today if the group knowing the most about the dangers of tobacco use, the industry, had been honest with its customers. The documents and the *JAMA* articles show us in a stark way that some of those who speak for the tobacco industry dissemble, distort, and deceive, despite the fact that the industry's own research is consistent with the scientific community's conclusion that continued use of their product will endanger the lives and health of the public at home and abroad. The industry continues to use the same tactics: even now, it is suing the government over the release of the Environmental Protection Agency report that has classified environmental tobacco smoke as a group A carcinogen.[19] It is spending vast amounts of money to overturn antismoking laws.[20]

These papers show us how little the tobacco industry is to be trusted when they speak on health issues and that the "evidence" they put before regulatory and legislative bodies at the national, state, and local level is highly suspect.

Where Do We Go From Here?

The AMA maintains an unequivocal stance against tobacco.[21] The AMA reminds physicians, the public, and politicians that the damning evidence against tobacco makes opposition to its use a pressing, nonpartisan public health issue. If the industry uses political weapons, so shall we. The AMA will not relent in its opposition to tobacco use.

To accomplish this goal, the AMA recommends and will pursue the following steps:

1. Further efforts should be made to educate physicians, the public, and policymakers about the consequences of tobacco use, the predatory nature of the tobacco industry, and ways individuals can break their addiction to tobacco.
2. Medical schools and research institutions, as well as individual researchers, should refuse any funding from the tobacco industry and its subsidiaries to avoid giving them an appearance of credibility. The B&W documents affirm our belief that such tobacco industry entities as the Council for Tobacco Research, the Smokeless Tobacco Research Council,

and the Center for Indoor Air Research are used by the tobacco industry to convince the public that there still is a controversy about whether tobacco has ill effects, to buy respectability, and to silence universities and researchers. We concur with the recommendation of a subcommittee of the National Cancer Advisory Board that federal funding be withdrawn from cancer research organizations that accept tobacco industry support.[22]

3. Politicians should not accept money from the tobacco industry but should direct their efforts to protection of the nonsmoking majority. Those who do accept money should be identified publicly.

4. The federal Occupational Safety and Health Administration should move forward with its proposal to require smoke-free workplaces nationwide.

5. Local communities should continue to control smoking in public.

6. State legislatures should assume responsibility for ensuring smoke-free areas. Any preemptive tobacco laws should be repealed by public demand.

7. Purchase of tobacco should be strictly limited to adults, with severe penalties for those who transgress. Underage use of tobacco should carry consequences for the user. All tobacco advertising should be eliminated, and a vigorous counteradvertising campaign should be instituted.

8. The Justice Department should enforce the ban against indirect tobacco advertising such as televised sports events.

9. Tobacco itself should be considered a drug delivery vehicle and placed under the oversight of the Food and Drug Administration, with appropriate regulation as for other life-threatening drugs.[23]

10. State and federal excise taxes on tobacco products should be dramatically increased, both to help defray costs of tobacco-induced diseases and to deter young people from becoming addicted.

11. The federal government should prevent the export of tobacco to other countries.

12. The continued contribution to knowledge of the control of tobacco by the National Cancer Institute should be strongly supported.

13. Physicians and the public should support legal action against the tobacco industry to recover billions of dollars in excess medical costs from tobacco-related diseases borne by Medicare, Medicaid, and the Department of Veterans Affairs.

14. All avenues of individual and collective redress should be pursued through the judicial system.

In summary, the evidence is unequivocal—the US public has been duped by the tobacco industry. No right-thinking individual can ignore the evidence. We should all be outraged, and we should force the removal of this scourge from our nation and by so doing set an example for the world. We recognize the serious consequences of this ambition, but the health of our nation is more important than the profits of any single industry.

On behalf of the physicians of this country and the people they serve, the AMA pledges its best efforts to the eradication of tobacco-related disease. We solicit the support of the public and our government in this endeavor. It is a worthy cause.

James S. Todd, MD
Drummond Rennie, MD
Robert E. McAfee, MD
Lonnie R. Bristow, MD
Joseph T. Painter, MD
Thomas R. Reardon, MD
Daniel H. Johnson, Jr, MD
Richard F. Corlin, MD
Yank D. Coble, Jr, MD
Nancy W. Dickey, MD
Timothy T. Flaherty, MD
Palma E. Formica, MD
Michael S. Goldrich, MD
William E. Jacott, MD
Donald T. Lewers, MD
John C. Nelson, MD, MPH
P. John Seward, MD
Randolph D. Smoak, Jr, MD
Michael Suk, JD, MPH
Frank B. Walker, MD
Percy Wootton, MD
George D. Lundberg, MD

1. Doll R, Peto R, Wheatley K, Gray R, Sutherland I. Mortality in relation to smoking: 40 years' observations on male British doctors. *BMJ*. 1994;309:901-911.
2. Peto R, Lopez AD, Boreham J, Thun M, Heath C Jr. Mortality from tobacco in developed countries: indirect estimation from national statistics. *Lancet*. 1992;339:1268-1278.
3. Glantz SA. Declaration to the Superior Court of the State of California for the County of San Francisco in *Brown and Williamson Tobacco Corporation v Regents of the University of California*. May 15, 1995.
4. Glantz SA, Barnes DE, Bero L, Hanauer P, Slade J. Looking through a keyhole at the tobacco industry: the Brown and Williamson documents. *JAMA*. 1995;274:219-224.
5. Bero L, Barnes DE, Hanauer P, Slade J, Glantz SA. Lawyer control of the tobacco industry's external research program: the Brown and Williamson documents. *JAMA*. 1995;274:241-247.
6. Barnes DE, Hanauer P, Slade J, Bero L, Glantz SA. Environmental tobacco smoke: the Brown and Williamson documents. *JAMA*. 1995;274:248-253.
7. Hanauer P, Slade J, Barnes DE, Bero L, Glantz SA. Lawyer control of internal scientific research to protect against products liability lawsuits: the Brown and Williamson documents. *JAMA*. 1995;274:234-240.
8. Slade J, Bero L, Hanauer P, Barnes DE, Glantz SA. Nicotine and addiction: the Brown and Williamson documents. *JAMA*. 1995;274:225-233.
9. *Castano v The American Tobacco Company, et al*. US District Court Eastern District of Louisiana.
10. Hilts PJ. Tobacco company was silent on hazards. *New York Times*. May 7, 1994:A1.
11. Greene HH, in *Maddox v Williams*, June 6, 1994. DC District Court. 855 F Supp 406, pp 414-415.
12. Balderson AJ. UCSF library has tobacco firm's documents under lock and key. *UCFS Newsbreak*. March 11-24, 1995;10(5):1.
13. Pollack S. *Brown and Williamson v Regents of the University of California*. Superior Court of the State of California for the County of San Francisco. May 25, 1995.
14. Traynor M, Begay M, Glantz S. The tobacco industry strategy to prevent tobacco control. *JAMA*. 1993;270:479-488.
15. Glantz S, Begay M. Tobacco industry campaign contributions are affecting tobacco control policymaking in California. *JAMA*. 1994;272:1176-1182.
16. Glantz SA, Parmley WW. Passive smoking and heart disease: mechanisms and risk. *JAMA*. 1995;273:1047-1053.
17. Graham T. The Brown and Williamson documents: the company's response. *JAMA*. 1995;274:254-255.
18. Skolnick A. Cancer converts tobacco lobbyist: Victor L. Crawford goes on the record. *JAMA*. 1995;274:199.
19. *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*. Washington, DC: US Environmental Protection Agency; December 1992. EPA/600-90-006F.
20. Mallory M. Full-flavored, unfiltered statehouse shenanigans: Big Tobacco's big bucks can still turn antismoking laws around. *Business Week*. May 22, 1995:52.
21. Lundberg GD. In the AMA, policy follows science: a case history of tobacco. *JAMA*. 1985;253:3001-3003.
22. National Cancer Advisory Board, Subcommittee to Evaluate the National Cancer Program. *Cancer at a Crossroads: A Report to Congress for the Nation*. Washington, DC: National Cancer Institute; September 1994.
23. Lundberg GD. Tobacco: for consenting adults in private only. *JAMA*. 1986;255:1051-1053.

For more information call:

James Stacey 202-789-7419
Brenda L. Craine 202-789-7447

file kids (teen) smoking

Coalition on Smoking OR Health

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 Facsimile: (202) 452-1417

August 2, 1995

TO: Selected White House Personnel

FROM: Scott D. Ballin, J.D.
Vice President and Legislative Counsel, AHA
Chairman, Coalition on Smoking OR Health

Tomorrow, Thursday August 3, 1995, at 9:45 a.m. the American Heart Association, American Cancer Society and American Lung Association will hold a press conference at the National Press Club to discuss the FDA regulation of tobacco products. The American Medical Association and several other individuals, including a former tobacco lobbyist and a tobacco farmer from North Carolina, will participate.

During this time we will announce that a letter is being sent to the President and all members of Congress asking that they sign a ***Contract for the Protection of America's Families and Children From Tobacco Use***. The letter has been signed by former President Jimmy Carter, thirteen prominent health officials from past administrations, Pat Robertson of the Christian Broadcasting Network, as well as over 100 other health, religious and youth organizations.

Enclosed is a copy of the **Contract** for your information and advanced notice. Release or use of the document is embargoed until 9:45 a.m. tomorrow morning. If you have any questions, please feel free to contact my office.

AMERICAN CANCER SOCIETY®

AMERICAN LUNG ASSOCIATION®

American Heart Association℠
Fighting Heart Disease and Stroke

Organizations and Individuals in Support of Protecting Our Families and Children From Tobacco Use

August 1995

Response Requested

The Honorable William J. Clinton
Executive Office of the President
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

We the undersigned organizations and individuals, representing millions of Americans from all walks of life, write to ask that you add your signature to the ***Contract for the Protection of America's Families and Children from Tobacco Use.***

For too long Congress and past administration has shirked its constitutional responsibilities to ensure the proper protection of the American people from tobacco use, this nation's leading cause of preventable death and disability. For too long the tobacco industry has been able to irresponsibly manufacture and market its products, sacrificing public health for the sake of profit.

We believe that the enclosed ***Contract*** represents a fair, balanced and common sense approach to dealing with the tobacco epidemic in this country. We do not advocate a ban on tobacco products. We do advocate that our children, who do not have the ability to make responsible choices, be protected from the aggressive and irresponsible sale and marketing of this addictive killer. We do advocate that all Americans, smokers and non smokers, alike be given full, complete and truthful information about tobacco products so that they can make an informed choice about its use.

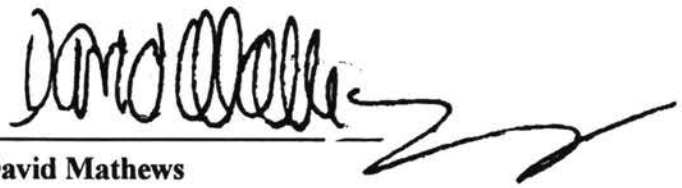
Let's work together to end the vicious cycle of addiction, disease and death that has killed more than 10 million Americans since the first Surgeon General's Report on Smoking and Health was issued more that thirty years ago. Let's work together to prevent this generation of children from becoming the next generation of victims who will die from cancer, heart disease, emphysema and stroke.

Please sign this Contract and return it to the Coalition on Smoking OR Health so that you can join others in a bipartisan effort to protect the health and welfare of American families and children.

Sincerely,

Jimmy Carter
President of the United States

Elliot L. Richardson
Secretary of HEW
Nixon Administration

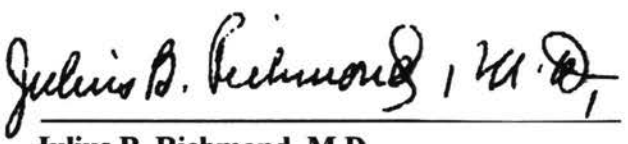


David Mathews
Secretary of HEW
Ford Administration

Otis R. Bowen, M.D.
Secretary of HHS
Reagan Administration

Louis Sullivan
Secretary of HHS
Bush Administration

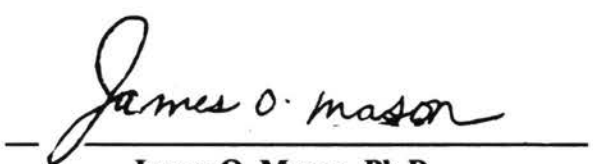
Merlin K. DuVal, M.D.
Assistant Secretary for Health
Nixon Administration



Julius B. Richmond, M.D.
Assistant Secretary and Surgeon General
Carter Administration

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health
Reagan Administration

Robert Windom, M.D.
Assistant Secretary for Health
Reagan Administration



James O. Mason, Ph.D.
Assistant Secretary for Health
Bush Administration

Jesse L. Steinfeld, M.D.
Surgeon General of the United States
Nixon Administration

S. Paul Ehrlich, Jr., M.D.
Surgeon General of the United States
Nixon/Ford Administration

C. Everett Koop, M.D.
Surgeon General of the United States
Reagan Administration

Antonia C. Novello, M.D.
Surgeon General of the United States
Bush Administration

Bob Whittaker
(R-KS Retired)

Mike Synar
(D-OK Retired)

Coalition on Smoking OR Health

Scott D. Ballin
Chairman, Coalition on Smoking OR Health
Vice President for Public Affairs
American Heart Association

Fran Du Melle
Deputy Managing Director
American Lung Association

Michael F. Heron
National Vice President for Public Affairs
American Cancer Society

Coalition's Public Policy Advisory Council

American Academy of Family Physicians
American Academy of Pediatrics
American Association for Respiratory Care
American College of Cardiology
American College of Physicians
American College of Chest Physicians
American Public Health Association
American Society of Internal Medicine
Association of State and Territorial Health Officials
National Coalition of Hispanic Health and Human Services Organizations (COSSMHO)

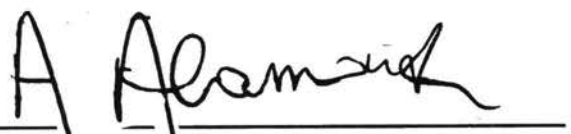
Religious Organizations

Interreligious Coalition on Smoking OR Health
Bryan Zervos, Roy Branson

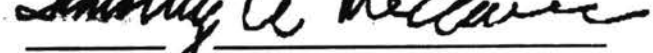
American Muslim Council
Catholic Charities USA
Church of the Brethren
Congress of National Black Churches
Friends Committee on National Legislation
National Association of Evangelicals
NETWORK: A National Catholic Social Justice Lobby
Presbyterian Church (U.S.A.)
Protestant Health Alliance
Seventh-day Adventist Church General Conference
United Church of Christ
Office for Church in Society
United Methodist Church
General Board of Church & Society
YMCA
YMCA U.S.A.
YWCA U.S.A.
Union of American Hebrew Congregations
Commission on Social Action

Washington Coalition
Bryan Zervos

The Christian Broadcasting Network
Pat Robertson, Chairman of the Board



American Muslim Council
Abdurahman Alamoudi



Church of the Brethren
Timothy A. McElwee

General Board of Church and Society
of the United Methodist Church
The Reverend Dr. Thom White Wolf Fassett

Shalom Foundation, Inc.
Eugene K. Souder, Director

Interfaith Center on Corporate Responsibility
Timothy H. Smith, Executive Director

Organizations

Advocates for Youth
American Association of Dental Schools
American College of Nurse-Midwives
American College of Preventive Medicine
American College of Surgeons Commission on Cancer
American Diabetes Association
American Institute for Biosocial Research
American Licensed Practical Nurses Association
American Nurses Association
American Society for Therapeutic Radiology and Oncology
American Society of Addiction Medicine
American Society of Clinical Oncology
American Society of Hematology
American Speech-Language-Hearing Association
American Veterans Committee
Americans for Nonsmokers' Rights
Associated Medical Schools of New York
Association for Nonsmokers - Minnesota
Association of American Cancer Institutes
Association of Pediatric Oncology Nurses
Association of Reproductive Health Professionals
Association of Schools of Public Health
Association of State and Territorial Chronic Diseases Program Directors

Association of State and Territorial Directors of Health Promotion and Public Health Education
Association of University Environmental Health Sciences Centers
AWHONN (Association of Women's Health, Obstetric & Neonatal Nurses)
Boston Women's Health Book Collective
Cancer Care Inc.
Cancer Research Foundation of America
Center for Science in the Public Interest (CSPI)
Citizens for Health
Citizens for Health Education
The Coalition Against Billboard Advertising of Alcohol and Tobacco
Coalition on Smoking or Health of Tennessee
Commission for a Healthy New York
Committee for Children
Doctors & Lawyers for a Drug Free Youth
FACT: Families Against Cancer
Foundation for Biosocial Research
Fox Chase Cancer Center
Fred Hutchinson Cancer Research Center
Houston GASP
GASP of Colorado
GASP - Georgians Against Smoking Pollution
Health Education Inc.
Illinois Caucus for Adolescent Health
INFACT
Joint Council of Allergy & Immunology
Missouri Department of Health - Assist Project
National Association of Community Action Agencies
National Association of Pediatric Nurse Associates and Nurse Practitioners
National Association for Medical Direction of Respiratory Care
National Coalition for Cancer Survivorship
National Parents' Resource Institute for Drug Education (PRIDE, INC.)
National Perinatal Association
National Women's Health Network
National 4-H Council
New Jersey Commission on Smoking OR Health
New Jersey Group Against Smoking Pollution (GASP)
Nonsmokers, Inc.
Oncology Nursing Society
Prospect Associates, Ltd.

Roswell Park Cancer Institute
Santa Fe Community Partnership
Smokefree Educational Services, Inc.
Smoke Free Pennsylvania
Society for Public Health Education Society of Cardiovascular & Interventional Radiology
S.T.A.T. (Stop Teenage Addiction to Tobacco)
Student Coalition Against Tobacco (SCAT)
Tobacco Control Resource Center
Tobacco-free Education & Action Coalition for Health (TEACH)
Tobacco-Free Las Cruces Coalition
Tobacco-Free Michigan Action Coalition
Tobacco Program, Interfaith Center on Corporate Responsibility
U.S. Public Interest Research Group (PIRG)
Washington DOC
YMCA of Metropolitan Washington
YMCA of the U.S.A.

CONTRACT FOR THE PROTECTION OF AMERICA'S FAMILIES AND CHILDREN FROM TOBACCO USE

As Republican and Democratic members of the House of Representatives, Senate and the Administration, we have an opportunity and a responsibility to work in a bipartisan manner to reduce tobacco use, the single most preventable cause of death and disability in the United States. We have an opportunity to restore accountability and integrity in Congress and the Executive Branch which has supported the tobacco manufacturers at the expense of the public's health. We recognize that the actions of the tobacco industry have undermined the integrity of our families and seduced our children into what is often a life long-addiction leading to premature death and disability. While science should be the driving force behind health policy determinations and actions, in the case of tobacco, politics has been allowed to dictate those policy decisions. This continues in spite of more than 60,000 scientific studies on smoking and health, 23 Surgeon General's reports and the call to action by the entire medical community, as well as by many in the religious community, and other representing youth organizations.

While Americans should take greater responsibility for their daily lives, they can only do so if they are given the tools, assurances and opportunities that ensure that their choices are made upon truthful, complete and accurate information. They can only do so if they are given assurances by their elected officials that their children, who do not have the sophistication or the ability to make responsible choices, are not exploited or encouraged to use these addictive dangerous drugs. It is time that appropriate action be taken to curtail the activities of tobacco companies that legitimize the use and promotion of a product that takes life, that undermines the values taught at home, and that undermine the family unit when a grandparent or a parent dies 10, 20, or 30 years prematurely due to their addiction to tobacco products.

While Congress and the Administration look forward to streamlining government and making it more effective and efficient, we cannot ignore the failure of Congress and the Executive Branch to give any federal agency oversight for tobacco products. Without change, 3,000 children each day will continue to try their first cigarette. Without change, each year 420,000 Americans will continue to die from cancer, heart disease, emphysema and stroke. Without change, pregnant women will continue to put their own lives at risk as well as the lives of their unborn children.

Tobacco manufacturers have failed to adhere to fundamental principles of ethics and responsibility, denying for more than 30 years that their products cause disease and are addictive. In spite of their continued assurances to do "what is right" they have failed in their corporate responsibility to accept fair, equitable and common sense health and safety standards for their products--standards that should be at the very least comparable to those for other legal products in our society. These standards should ensure adequate protection of the public's health, give assurances of the protection of our children, while at the same time allowing adults to make fully informed choices as to whether or not they use tobacco products. After more than 30 years of putting the interests of the tobacco industry first, it is time that Congress put the health interests of the American family first.

Therefore, ***we who believe in protecting the health and welfare of our citizens as required and guaranteed by the Constitution of the United States, commit to ending the cycle of disease, addiction and death caused by tobacco products by working towards enactment of fair, equitable and common sense standards that have as their goals the following principles and objectives:***

First: Ensure that children and teenagers do not have access to tobacco products. To that end we commit to ensuring enactment of common sense legislation and regulations that will:

- require that retailers ask for proof of age before selling any tobacco product to anyone who appears to be under the age of 21.

- require that retailers be licensed to sell tobacco products and that retailers who violate sales to minor laws are held accountable through fines or revocation of their licenses.

- prohibit the sale of tobacco products through vending machines.

- require that retailers post signs in their establishments indicating that they will not sell tobacco products to minors.

- prohibit the free distribution of tobacco products and coupons discounting tobacco products.

Second: Ensure (within parameters of the First Amendment to the Constitution) that tobacco advertising and other promotional efforts not be targeted at children. To that end we commit to ensuring enactment of common sense legislation or regulations which will:

- restrict or eliminate all advertising for tobacco products, consistent with the parameters of the First Amendment. Phase in such restrictions if necessary, on an interim basis, requiring text only advertising without pictures, human or animal images, or cartoon characters. The failure of the tobacco industry's code, which prohibits the use of images of sexual attraction, sophistication, success, athletic abilities and physical stamina - images which the tobacco industry more than 30 years ago said it would not use because they enticed children to use tobacco products--demonstrates the need for this action. The code has not been followed or adhered to by the industry in spite of public assurances to do so.

- prohibit the sponsorship of any sporting, cultural, or public event by a tobacco manufacturer who displays the name or logo of a brand of cigarettes or other tobacco product.

- eliminate the advertising and promotion of tobacco products through the use of promotional items such as T-shirts, hats, watches and other paraphernalia which have great appeal to

children and serve as effective marketing and advertising tools to encourage children to use tobacco products.

- return to the states and localities the authority to place additional restrictions on advertising and promotional practices as deemed appropriate by its citizens.

Third: Require that the public, parents, teachers and children be given complete information about tobacco products that will not only assist adults in making truly informed choices about whether or not they smoke but will also serve as an effective educational tool that discourages children from trying or using tobacco products. To that end we commit to ensuring enactment of common sense legislation and regulations which will:

- require that complete information about the dangers of tobacco products be made available to the public, including warnings and information on addiction, stroke, sudden infant death syndrome and environmental tobacco smoke.

- require that the public have access to full disclosure of the hundreds of chemicals used by the tobacco companies in their products, as well as assurances that these chemicals when used and burned in tobacco products do not present added health risks.

- require that information about the toxic substances found in tobacco smoke such as arsenic, benzene and formaldehyde be made available to the public.

- require, as promised by the tobacco industry in 1964 but never adhered to, that misleading and deceptive claims (direct or implied) that certain tobacco products are safer and less addictive be prohibited, unless such claims are based upon sound scientific evidence.

Fourth: Require that special and expanded efforts be made to warn and discourage tobacco product consumption by pregnant women who not only endanger their own life but also the life and well-being of their unborn. To that end we commit to ensuring enactment of common sense legislation, regulations and educational efforts which will:

- require that such information be included in or as part of a package insert on the tobacco product.

- require that expanded efforts be made with the private sector in counseling, advising and educating pregnant women about the dangers of smoking during pregnancy.

Fifth: Work to find solutions to assist tobacco farmers and others who work in the tobacco industry to transition out of the tobacco business, including assisting in building economic infrastructures for short term and long term economic development.

Name State Congressional District

Signature _____

RETURN TO: Coalition on Smoking OR Health
(American Cancer Society, American Heart Association and American Lung Association)
1150 Connecticut Avenue, N.W.
Suite 820
Washington, D.C. 20036

For Additional Information Call: (202) 452-1184

Coalition on Smoking OR Health

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 Facsimile: (202) 452-1417

For Release
9:45 a.m. Thursday, August 3, 1995

Contact: Joe Marx, AHA
202-822-9380
Diane Maple, ALA
202-785-3355
Tom Brandt, ACS
202-546-4011
Brenda Craine, AMA
202-789-7487

National Health and Medical Organizations Say Public Supports Strong Government Policy to Protect Children From Smoking Addiction

Washington, Aug. 3 -- The nation's leading health and medical organizations urged President Clinton today to give the Food and Drug Administration the green light to take authority over tobacco products to protect America's children from addiction and disease caused by tobacco use.

"President Clinton has the opportunity to do more to protect the health of future generations of Americans than any other single action he can take during his presidency," said Jacqueline McLeod, president of the American Lung Association.

The coalition of organizations, including the American Heart Association, the American Lung Association, the American Cancer Society and the American Medical Association, released the results of a nationwide survey of registered voters conducted by the New York-based Global Strategy Group, Inc. The survey, commissioned by the AHA, ALA and ACS, found that 83 percent of American adults (80 percent of tobacco state voters) believe that the FDA should ensure the health and safety of tobacco products as it currently does for foods, drugs and medical devices.

President Clinton is deciding whether to support FDA regulation of tobacco. The FDA does not currently regulate tobacco products.

"It's clear that the majority of Americans agree: the best way to keep our children from becoming addicted to tobacco is to keep the tobacco industry away from our children," said Sidney C. Smith Jr., M.D., president of the American Heart Association.

- MORE -

AMERICAN CANCER SOCIETY®

AMERICAN LUNG ASSOCIATION®

American Heart Association℠
Fighting Heart Disease and Stroke

The survey also found:

- 9 out of 10 adults, including 90 percent of smokers, believe that nicotine is addictive;
- 84 percent of American voters think that tobacco company executives lied to Congress when they testified that nicotine is not addictive;
- 75 percent of American voters believe that the federal government should play a larger role in reducing tobacco use among children; even three-fourths of voters in the largest tobacco-growing states want government to be more involved in lowering smoking among minors;
- More than 73 percent of adults voters favor more restrictions on the sale or promotion of cigarettes to minors under age 18;
- More than 67 percent of Americans would support a government-sponsored program to help tobacco farmers get out of the tobacco-growing business.
- 82 percent of adults believe that tobacco companies should be prohibited from using cartoons or other advertising that can be attractive to children.

"We want to stop the cycle of addiction and manipulation that targets children," said Lonnie R. Bristow, M.D., president of the American Medical Association.

"We urge President Clinton and Dr. Kessler to take bold and decisive steps to place all nicotine products under FDA control."

Recent evidence published in The Journal of the American Medical Association and information publicly released by Rep. Henry Waxman, D-Calif. indicates that tobacco companies have known for years about the harmful effects of tobacco but chose not to disclose the information. Instead the companies publicly questioned the validity of published reports on the hazards of tobacco.

"While the tobacco companies say they do not want children to smoke, they market to them incessantly. Their multi-billion dollar advertising and promotions, such as Joe Camel and The Marlboro Adventure Team, are designed to attract our children and addict them to cigarettes," said George Dessart, chairman-elect of the American Cancer Society.

- MORE -

At the news conference it was announced that more than 100 national health, medical, religious and children's organizations have sent a letter to President Clinton and all members of Congress urging them to sign a *Contract for the Protection of America's Families and Children From Tobacco* as part of a bipartisan effort to protect the health and welfare of American families and children.

The letter was signed by Former President Jimmy Carter as well as other prominent individuals, including Pat Robertson, chairman of the Christian Broadcasting Network and former U.S. Surgeon General C. Everett Koop. Prominent former government health officials and former U.S. Surgeons General from the Eisenhower through the Bush administrations and organizations, ranging from the American Association of Dental Schools to the YMCA, have also signed the contract which calls for the "enactment of fair, equitable and common sense standards" for preventing tobacco use. The contract has the following objectives:

- ensure that young people under age 18 do not have access to tobacco products;
- stop tobacco advertising and promotional campaigns targeted at children and teenagers;
- require tobacco companies to provide complete and truthful information about their products' hazards, such as warnings to women about the dangerous effects of smoking on the unborn;
- work with American tobacco farmers and farm leadership to find profitable alternatives to tobacco farming.

"Voluntary efforts by the tobacco industry don't work," said Smith.

" Keeping children from becoming addicted to tobacco must be accomplished by an enforceable national policy."

Added former tobacco lobbyist Victor L. Crawford, "The tobacco companies will do nothing voluntarily to hurt their profits. The only reason they are even close to the bargaining table is because states and now the federal government are willing to take the bit between their teeth and run with tobacco control laws and regulations."

"Voluntary controls by the tobacco industry will not be seen in your lifetime."

-End-

Global Strategy Group, Inc.
532 La Guardia Place, Suite 204
New York, NY 10012
Tel: 212.260.8813 Fax:212.260.9058

3 August, 1995

FOR IMMEDIATE RELEASE

Contrary to the national trend against government regulation, 75% of American voters feel that the federal government should play a larger role (including 58% who say "much" larger) in reducing tobacco use among children. *Even three fourths of voters from tobacco growing states (Kentucky, Virginia, North Carolina, South Carolina, Georgia, Tennessee, and Maryland) want more government involvement in lowering smoking among minors.*

This finding according to a survey conducted (July 29 to July 30, 1995) for the American Heart Association, American Lung Association, and American Cancer Society by Global Strategy Group, Inc., a New York based polling firm. The survey consisted of a nationwide random sample of 800 registered voters with a margin of error of +/- 3.5%.

The survey revealed several other major findings:

- 83% of registered voters think the Food and Drug Administration (FDA) should ensure health and safety standards for tobacco and cigarettes as they currently do for drugs, food, and medical devices. *(80% of tobacco state voters)*
- 91% (including 79% who strongly agree) of those interviewed agree that tobacco companies should be required to warn people about addiction and other medical problems which can be attributed to smoking. *(99% of women 18-34)*

American voters are overwhelmingly in favor of placing restrictions on tobacco advertising.

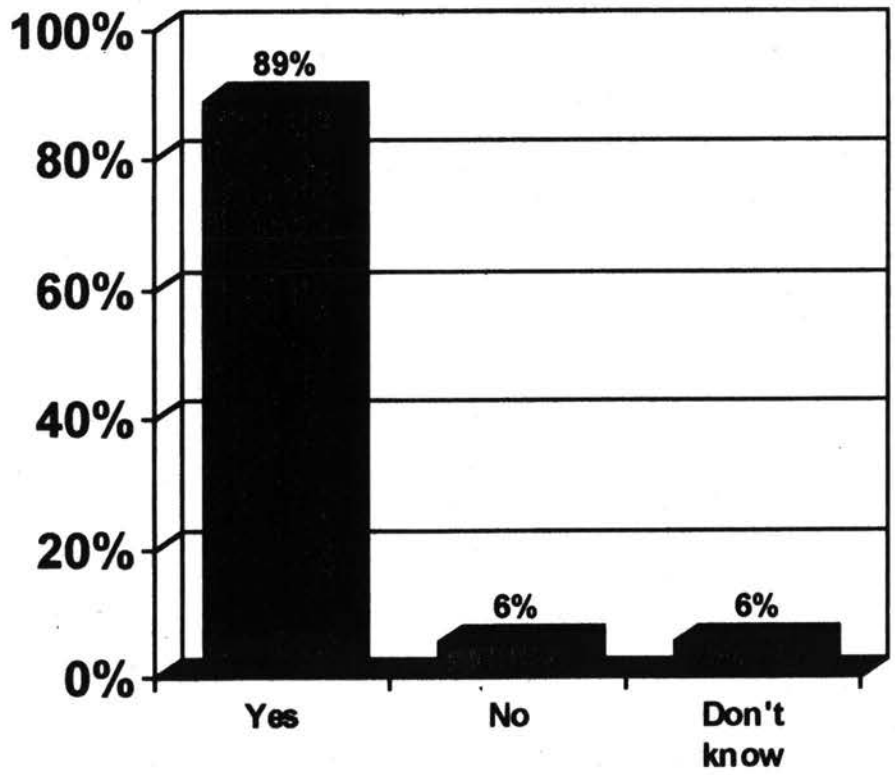
- 82% of registered voters believe that tobacco companies should be prohibited from using cartoons or other advertising which can be attractive to children. *(76% of smokers interviewed)*
- 67% of those surveyed support extending ban on cigarette advertisements in magazines, newspapers, and billboards. (*70% of Republicans, 67% of Democrats support extending restrictions)*

In regards to the Justice Department's investigations of tobacco executives testimonies before Congress, 84% of those surveyed felt that tobacco company executives were not telling the truth when they testified before Congress that tobacco is not addictive. *(9 out of 10 of those interviewed think that nicotine is addictive as do 90% of smokers)*

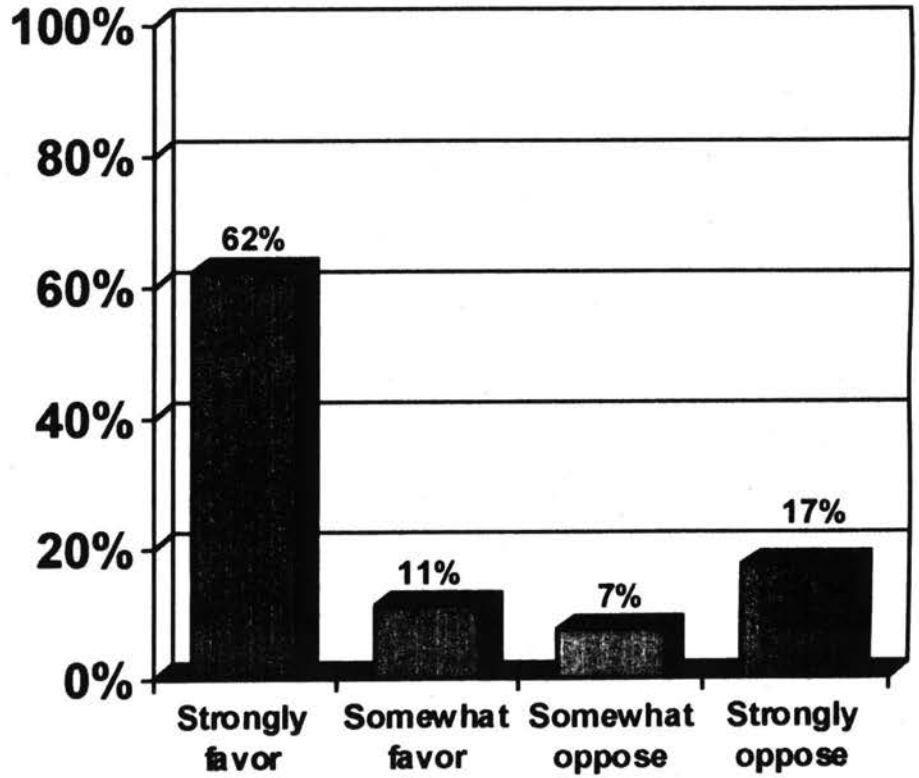
For more information please contact Jefrey Pollock or Alexander Jutkowitz at Global Strategy Group, Inc. 212.260.8813.

General Opinions of Cigarettes and Tobacco

Do you think that nicotine is addictive?

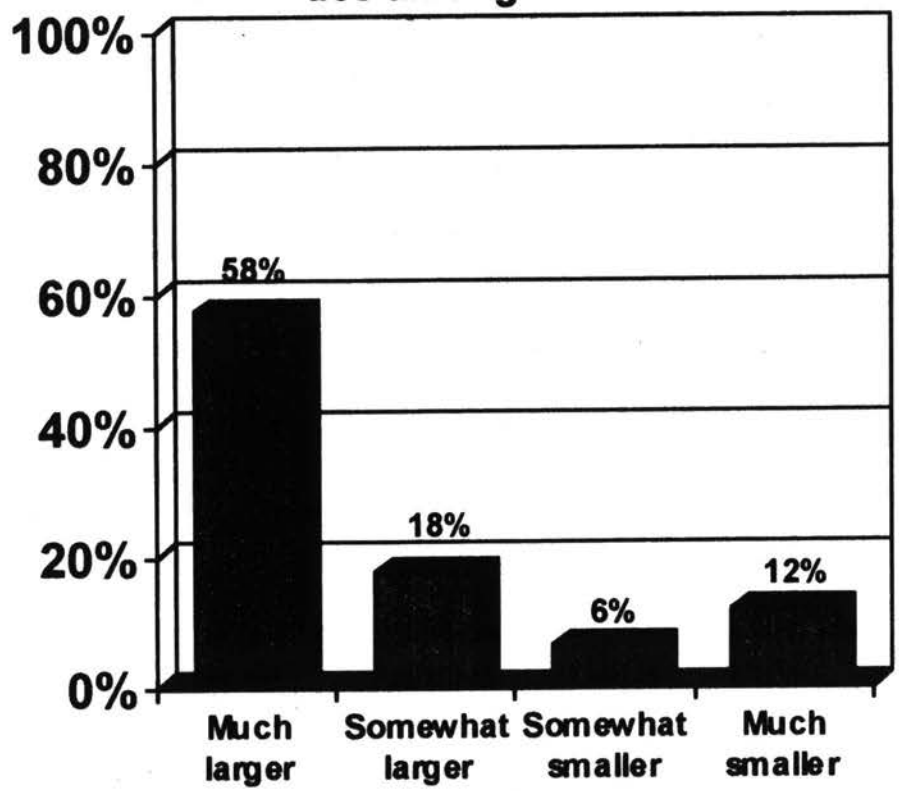


Support of restrictions on the sale and promotion of cigarettes and tobacco to minors...

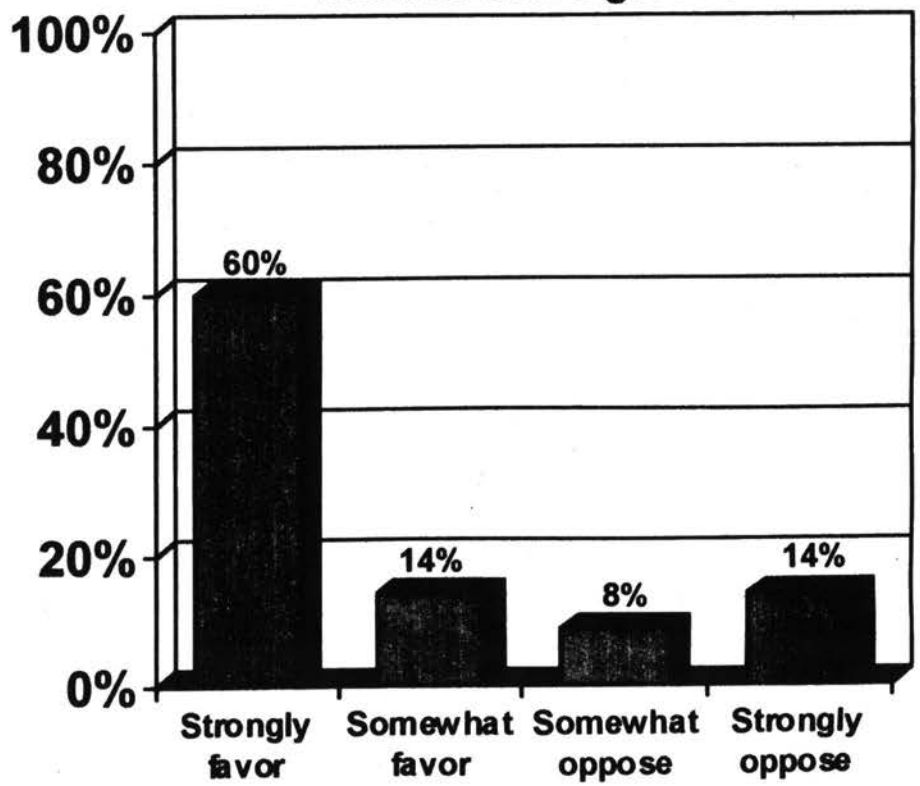


[redacted] The Government's Role in Tobacco Regulation

How much of a role should the federal government play in reducing tobacco use among children?



Support of more government regulation of promotion and marketing to minors of tobacco and cigarette...

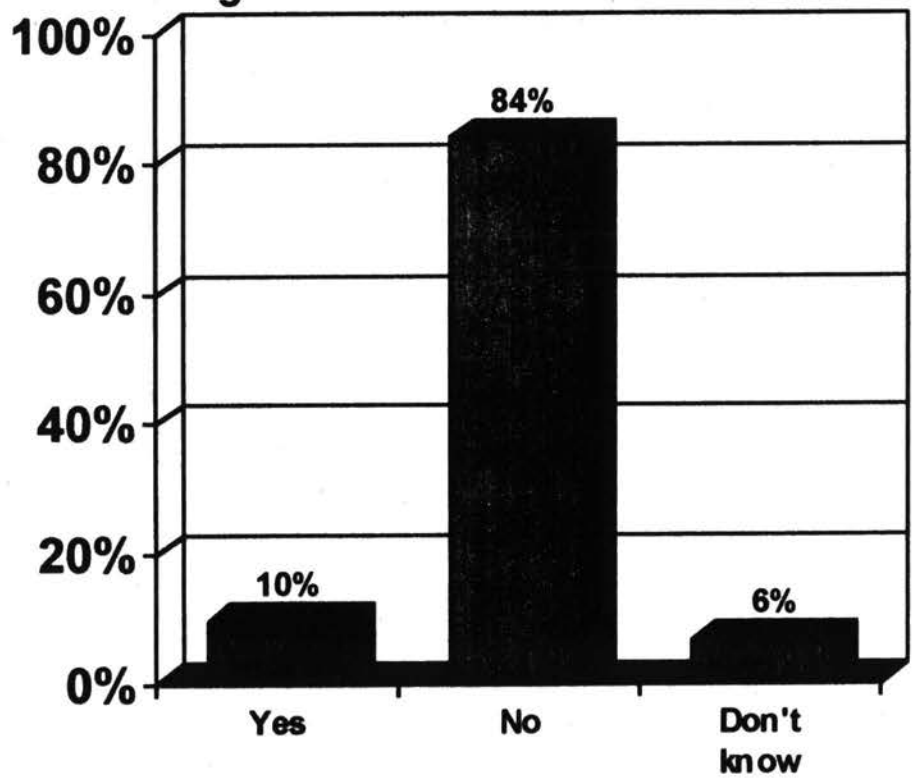


GSG
Global Strategy Group

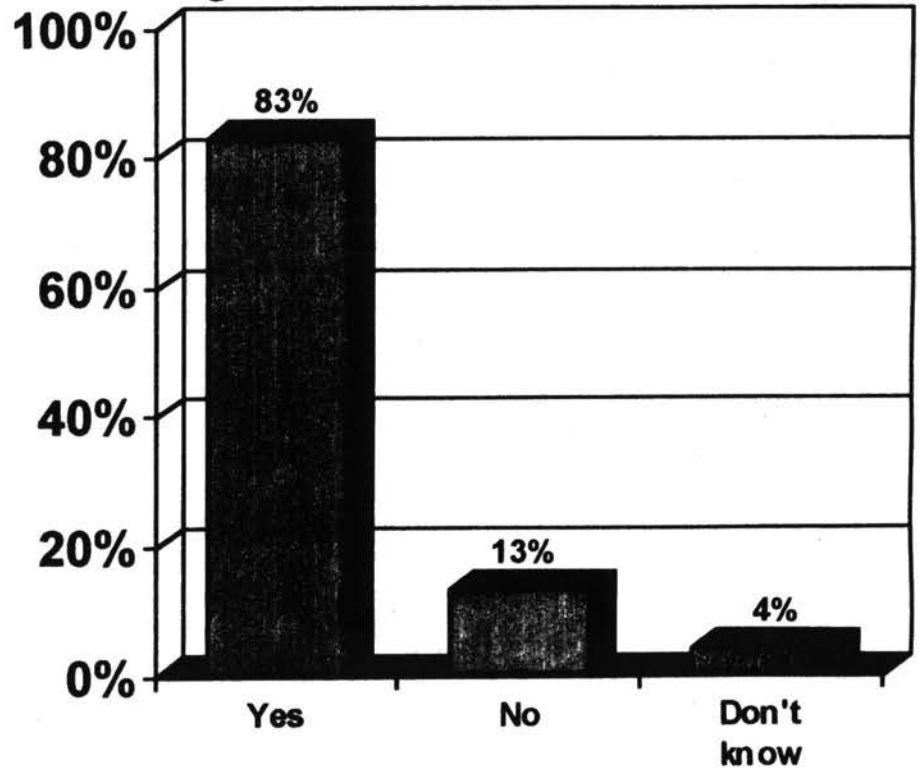
3 August, 1995

[redacted] Congressional Hearings and FDA Regulation

Do you believe that tobacco company executives were telling the truth when they testified before Congress that tobacco is not addictive?

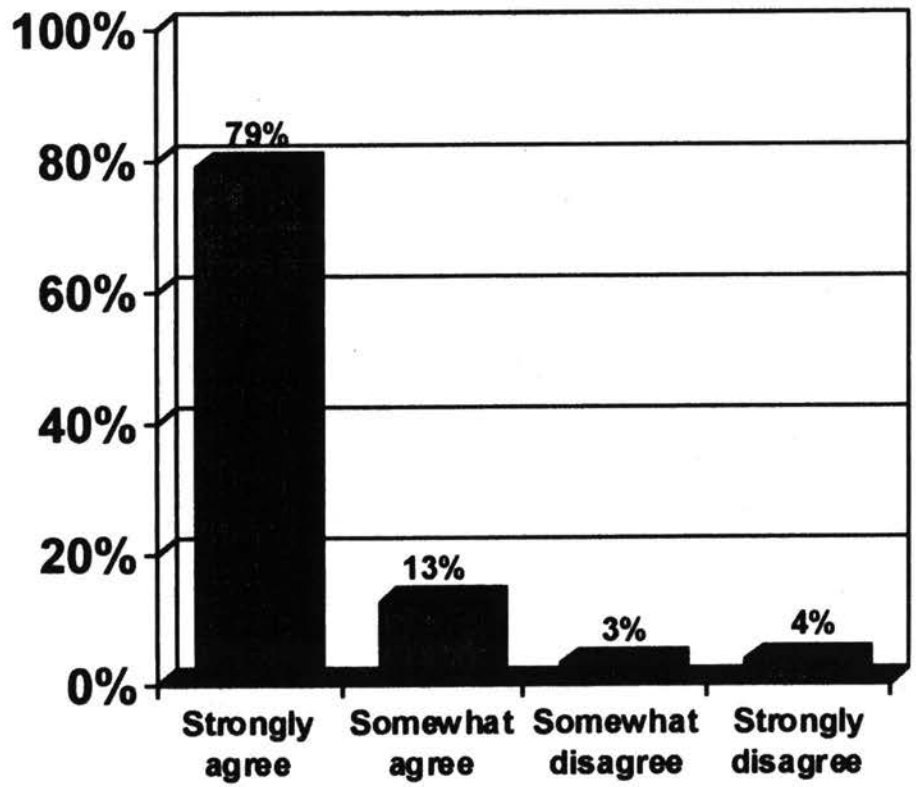


Do you think the FDA should ensure health and safety standards for tobacco and cigarettes as they do for new drugs?

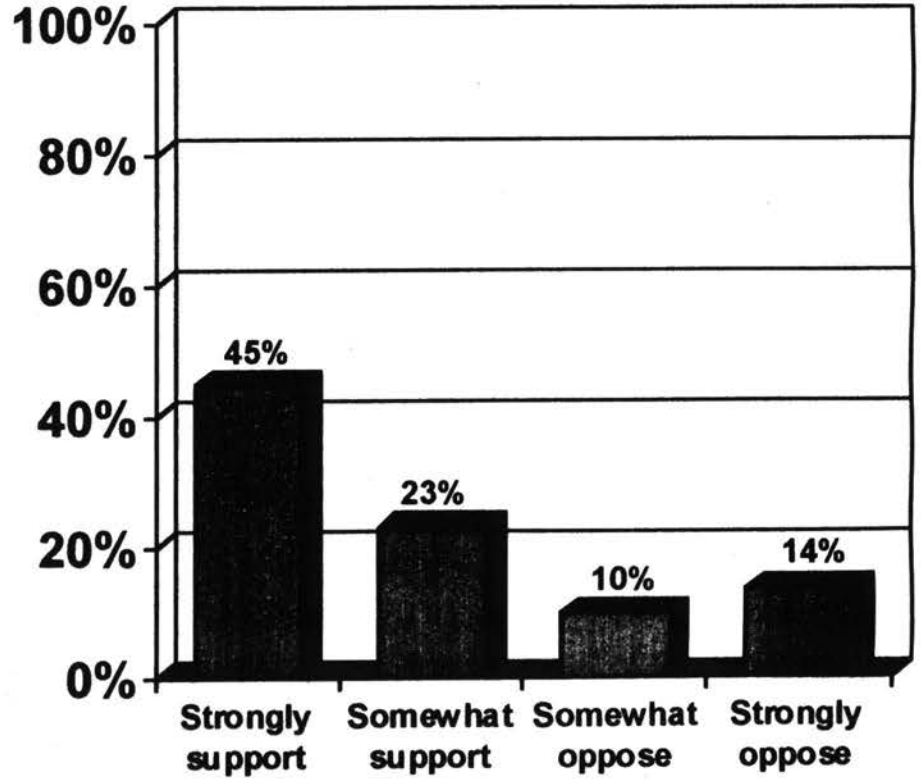


[redacted] Tobacco Warning and Farming Alternatives

Tobacco companies should be required to warn people about addiction and other medical problems which can be attributed to smoking...



Support of a government program to aid tobacco farmers in switching over to a different crop or get out of tobacco growing...



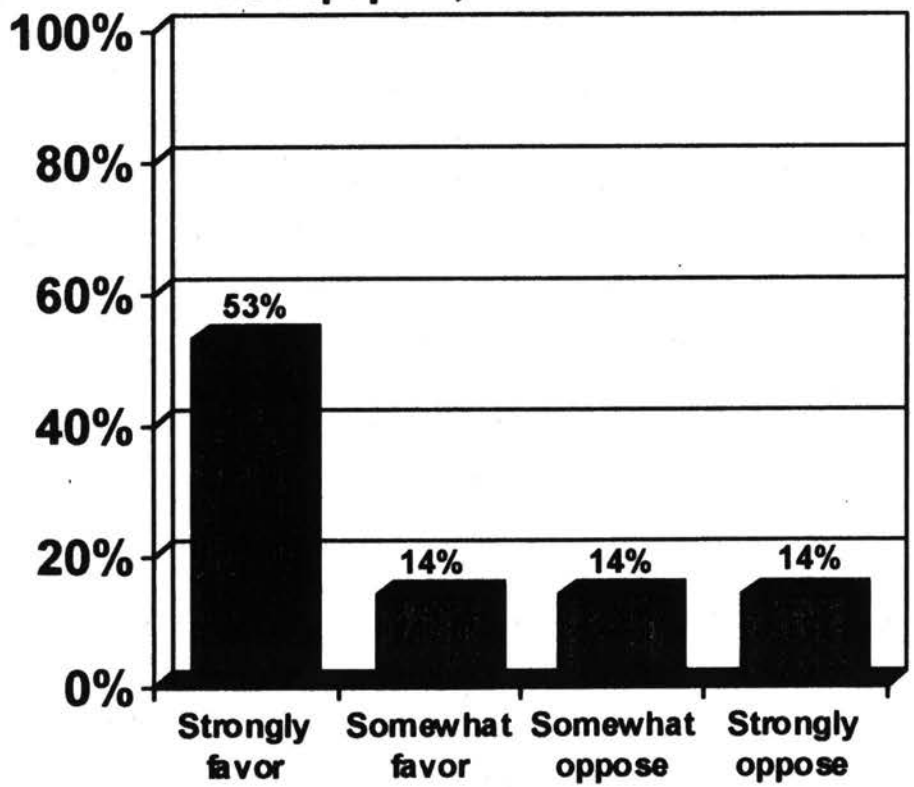
GSG

Global Strategy Group

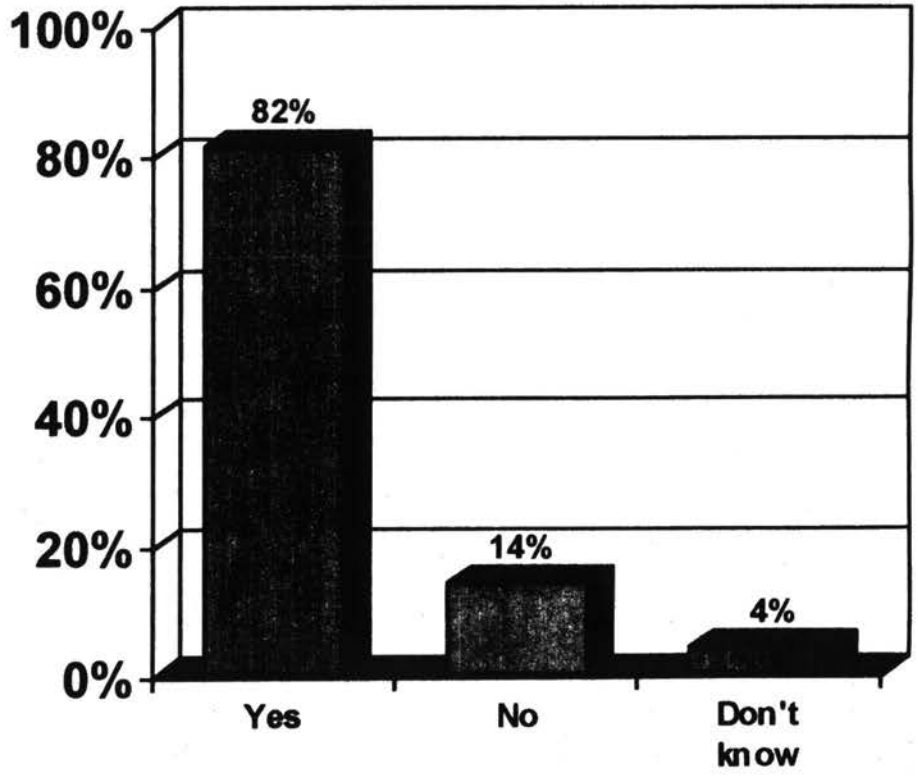
3 August, 1995

[redacted] Restrictions on Tobacco Advertising

Support of extending ban on cigarette advertisements in magazines, newspapers, and billboards...



Should tobacco companies be prohibited from using cartoons or other advertising which can be attractive to children?



GSG

Global Strategy Group

3 August, 1995

Organizations and Individuals in Support of Protecting Our Families and Children From Tobacco Use

August 1995

Response Requested

Dear Member of Congress:

We the undersigned organizations and individuals, representing millions of Americans from all walks of life, write to ask that you add your signature to the ***Contract for the Protection of America's Families and Children from Tobacco Use.***

For too long Congress has shirked its constitutional responsibilities to ensure the proper protection of the American people from tobacco use, this nation's leading cause of preventable death and disability. For too long the tobacco industry has been able to irresponsibly manufacture and market its products, sacrificing public health for the sake of profit.

We believe that the enclosed ***Contract*** represents a fair, balanced and common sense approach to dealing with the tobacco epidemic in this country. We do not advocate a ban on tobacco products. We do advocate that our children, who do not have the ability to make responsible choices, be protected from the aggressive and irresponsible sale and marketing of this addictive killer. We do advocate that all Americans, smokers and non smokers, alike be given full, complete and truthful information about tobacco products so that they can make an informed choice about its use.

Let's work together to end the vicious cycle of addiction, disease and death that has killed more than 10 million Americans since the first Surgeon General's Report on Smoking and Health was issued more that thirty years ago. Let's work together to prevent this generation of children from becoming the next generation of victims who will die from cancer, heart disease, emphysema and stroke.

Please sign this Contract and return it to the Coalition on Smoking OR Health so that you can join others in a bipartisan effort to protect the health and welfare of American families and children.

Sincerely,

Note: Also sent to the President of the United States

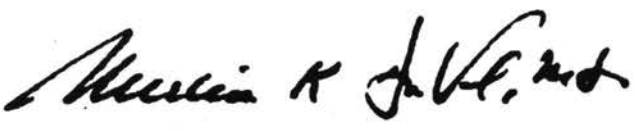
Jimmy Carter
President of the United States

Elliot L. Richardson
Secretary of HEW
Nixon Administration

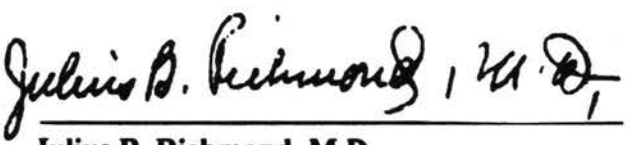
David Mathews
Secretary of HEW
Ford Administration

Otis R. Bowen, M.D.
Secretary of HHS
Reagan Administration

Louis Sullivan
Secretary of HHS
Bush Administration



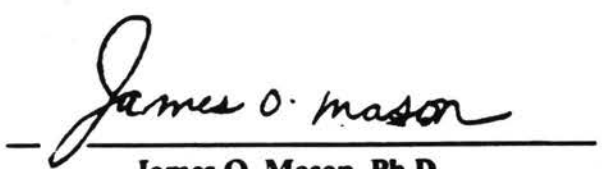
Merlin K. DuVal, M.D.
Assistant Secretary for Health
Nixon Administration



Julius B. Richmond, M.D.
Assistant Secretary and Surgeon General
Carter Administration

Edward N. Brandt, Jr., M.D.
Assistant Secretary for Health
Reagan Administration

Robert Windom, M.D.
Assistant Secretary for Health
Reagan Administration



James O. Mason, Ph.D.
Assistant Secretary for Health
Bush Administration

Jesse L. Steinfeld, M.D.
Surgeon General of the United States
Nixon Administration

S. Paul Ehrlich, Jr., M.D.
Surgeon General of the United States
Nixon/Ford Administration

C. Everett Koop, M.D.
Surgeon General of the United States
Reagan Administration

Antonia C. Novello, M.D.
Surgeon General of the United States
Bush Administration

Bob Whittaker
(R-KS Retired)

Mike Synar
(D-OK Retired)

Coalition on Smoking OR Health

Scott D. Ballin
Chairman, Coalition on Smoking OR Health
Vice President for Public Affairs
American Heart Association

Fran Du Melle
Deputy Managing Director
American Lung Association

Michael F. Heron
National Vice President for Public Affairs
American Cancer Society

Coalition's Public Policy Advisory Council

American Academy of Family Physicians
American Academy of Pediatrics
American Association for Respiratory Care
American College of Cardiology
American College of Physicians
American College of Chest Physicians
American Public Health Association
American Society of Internal Medicine
Association of State and Territorial Health Officials
National Coalition of Hispanic Health and Human Services Organizations (COSSMHO)

Religious Organizations

Interreligious Coalition on Smoking OR Health
Bryan Zervos, Roy Branson

American Muslim Council
Catholic Charities USA
Church of the Brethren
Congress of National Black Churches
Friends Committee on National Legislation
National Association of Evangelicals
NETWORK: A National Catholic Social Justice Lobby
Presbyterian Church (U.S.A.)
Protestant Health Alliance
Seventh-day Adventist Church General Conference
United Church of Christ
Office for Church in Society
United Methodist Church
General Board of Church & Society
YMCA
YMCA U.S.A.
YWCA U.S.A.
Union of American Hebrew Congregations
Commission on Social Action

Washington Institute
Bryan Zervos

The Christian Broadcasting Network
Pat Robertson, Chairman of the Board

American Muslim Council
Abdurahman Alamoudi

Church of the Brethren
Timothy A. McElwee

General Board of Church and Society
of the United Methodist Church
The Reverend Dr. Thom White Wolf Fassett

Shalo... Foundation, Inc.
Eugene K. Souder, Director

Interfaith Center on Corporate Responsibility
Timothy H. Smith, Executive Director

Organizations

Advocates for Youth
American Association of Dental Schools
American College of Nurse-Midwives
American College of Preventive Medicine
American College of Surgeons Commission on Cancer
American Diabetes Association
American Institute for Biosocial Research
American Licensed Practical Nurses Association
American Nurses Association
American Society for Therapeutic Radiology and Oncology
American Society of Addiction Medicine
American Society of Clinical Oncology
American Society of Hematology
American Speech-Language-Hearing Association
American Veterans Committee
Americans for Nonsmokers' Rights
Associated Medical Schools of New York
Association for Nonsmokers - Minnesota
Association of American Cancer Institutes
Association of Pediatric Oncology Nurses
Association of Reproductive Health Professionals
Association of Schools of Public Health
Association of State and Territorial Chronic Diseases Program Directors

Association of State and Territorial Directors of Health Promotion and Public Health Education
Association of University Environmental Health Sciences Centers
AWHONN (Association of Women's Health, Obstetric & Neonatal Nurses)
Boston Women's Health Book Collective
Cancer Care Inc.
Cancer Research Foundation of America
Center for Science in the Public Interest (CSPI)
Citizens for Health
Citizens for Health Education
The Coalition Against Billboard Advertising of Alcohol and Tobacco
Coalition on Smoking or Health of Tennessee
Commission for a Healthy New York
Committee for Children
Doctors & Lawyers for a Drug Free Youth
FACT: Families Against Cancer
Foundation for Biosocial Research
Fox Chase Cancer Center
Fred Hutchinson Cancer Research Center
Houston GASP
GASP of Colorado
GASP - Georgians Against Smoking Pollution
Health Education Inc.
Illinois Caucus for Adolescent Health
INFACT
Joint Council of Allergy & Immunology
Missouri Department of Health - Assist Project
National Association of Community Action Agencies
National Association of Pediatric Nurse Associates and Nurse Practitioners
National Association for Medical Direction of Respiratory Care
National Coalition for Cancer Survivorship
National Parents' Resource Institute for Drug Education (PRIDE, INC.)
National Perinatal Association
National Women's Health Network
National 4-H Council
New Jersey Commission on Smoking OR Health
New Jersey Group Against Smoking Pollution (GASP)
Nonsmokers, Inc.
Oncology Nursing Society
Prospect Associates, Ltd.

Roswell Park Cancer Institute
Santa Fe Community Partnership
Smokefree Educational Services, Inc.
Smoke Free Pennsylvania
Society for Public Health Education Society of Cardiovascular & Interventional Radiology
S.T.A.T. (Stop Teenage Addiction to Tobacco)
Student Coalition Against Tobacco (SCAT)
Tobacco Control Resource Center
Tobacco-free Education & Action Coalition for Health (TEACH)
Tobacco-Free Las Cruces Coalition
Tobacco-Free Michigan Action Coalition
Tobacco Program, Interfaith Center on Corporate Responsibility
U.S. Public Interest Research Group (PIRG)
Washington DOC
YMCA of Metropolitan Washington
YMCA of the U.S.A.

CONTRACT FOR THE PROTECTION OF AMERICA'S FAMILIES AND CHILDREN FROM TOBACCO USE

As Republican and Democratic members of the House of Representatives, Senate and the Administration, we have an opportunity and a responsibility to work in a bipartisan manner to reduce tobacco use, the single most preventable cause of death and disability in the United States. We have an opportunity to restore accountability and integrity in Congress and the Executive Branch which has supported the tobacco manufacturers at the expense of the public's health. We recognize that the actions of the tobacco industry have undermined the integrity of our families and seduced our children into what is often a life long-addiction leading to premature death and disability. While science should be the driving force behind health policy determinations and actions, in the case of tobacco, politics has been allowed to dictate those policy decisions. This continues in spite of more than 60,000 scientific studies on smoking and health, 23 Surgeon General's reports and the call to action by the entire medical community, as well as by many in the religious community, and other representing youth organizations.

While Americans should take greater responsibility for their daily lives, they can only do so if they are given the tools, assurances and opportunities that ensure that their choices are made upon truthful, complete and accurate information. They can only do so if they are given assurances by their elected officials that their children, who do not have the sophistication or the ability to make responsible choices, are not exploited or encouraged to use these addictive dangerous drugs. It is time that appropriate action be taken to curtail the activities of tobacco companies that legitimize the use and promotion of a product that takes life, that undermines the values taught at home, and that undermine the family unit when a grandparent or a parent dies 10, 20, or 30 years prematurely due to their addiction to tobacco products.

While Congress and the Administration look forward to streamlining government and making it more effective and efficient, we cannot ignore the failure of Congress and the Executive Branch to give any federal agency oversight for tobacco products. Without change, 3,000 children each day will continue to try their first cigarette. Without change, each year 420,000 Americans will continue to die from cancer, heart disease, emphysema and stroke. Without change, pregnant women will continue to put their own lives at risk as well as the lives of their unborn children.

Tobacco manufacturers have failed to adhere to fundamental principles of ethics and responsibility, denying for more than 30 years that their products cause disease and are addictive. In spite of their continued assurances to do "what is right" they have failed in their corporate responsibility to accept fair, equitable and common sense health and safety standards for their products--standards that should be at the very least comparable to those for other legal products in our society. These standards should ensure adequate protection of the public's health, give assurances of the protection of our children, while at the same time allowing adults to make fully informed choices as to whether or not they use tobacco products. After more than 30 years of putting the interests of the tobacco industry first, it is time that Congress put the health interests of the American family first.

Therefore, *we who believe in protecting the health and welfare of our citizens as required and guaranteed by the Constitution of the United States, commit to ending the cycle of disease, addiction and death caused by tobacco products by working towards enactment of fair, equitable and common sense standards that have as their goals the following principles and objectives:*

First: Ensure that children and teenagers do not have access to tobacco products. To that end we commit to ensuring enactment of common sense legislation and regulations that will:

- require that retailers ask for proof of age before selling any tobacco product to anyone who appears to be under the age of 21.
- require that retailers be licensed to sell tobacco products and that retailers who violate sales to minor laws are held accountable through fines or revocation of their licenses.
- prohibit the sale of tobacco products through vending machines.
- require that retailers post signs in their establishments indicating that they will not sell tobacco products to minors.
- prohibit the free distribution of tobacco products and coupons discounting tobacco products.

Second: Ensure (within parameters of the First Amendment to the Constitution) that tobacco advertising and other promotional efforts not be targeted at children. To that end we commit to ensuring enactment of common sense legislation or regulations which will:

- restrict or eliminate all advertising for tobacco products, consistent with the parameters of the First Amendment. Phase in such restrictions if necessary, on an interim basis, requiring text only advertising without pictures, human or animal images, or cartoon characters. The failure of the tobacco industry's code, which prohibits the use of images of sexual attraction, sophistication, success, athletic abilities and physical stamina - images which the tobacco industry more than 30 years ago said it would not use because they enticed children to use tobacco products--demonstrates the need for this action. The code has not been followed or adhered to by the industry in spite of public assurances to do so.
- prohibit the sponsorship of any sporting, cultural, or public event by a tobacco manufacturer who displays the name or logo of a brand of cigarettes or other tobacco product.
- eliminate the advertising and promotion of tobacco products through the use of promotional items such as T-shirts, hats, watches and other paraphernalia which have great appeal to

children and serve as effective marketing and advertising tools to encourage children to use tobacco products.

- return to the states and localities the authority to place additional restrictions on advertising and promotional practices as deemed appropriate by its citizens.

Third: Require that the public, parents, teachers and children be given complete information about tobacco products that will not only assist adults in making truly informed choices about whether or not they smoke but will also serve as an effective educational tool that discourages children from trying or using tobacco products. To that end we commit to ensuring enactment of common sense legislation and regulations which will:

- require that complete information about the dangers of tobacco products be made available to the public, including warnings and information on addiction, stroke, sudden infant death syndrome and environmental tobacco smoke.

- require that the public have access to full disclosure of the hundreds of chemicals used by the tobacco companies in their products, as well as assurances that these chemicals when used and burned in tobacco products do not present added health risks.

- require that information about the toxic substances found in tobacco smoke such as arsenic, benzene and formaldehyde be made available to the public.

- require, as promised by the tobacco industry in 1964 but never adhered to, that misleading and deceptive claims (direct or implied) that certain tobacco products are safer and less addictive be prohibited, unless such claims are based upon sound scientific evidence.

Fourth: Require that special and expanded efforts be made to warn and discourage tobacco product consumption by pregnant women who not only endanger their own life but also the life and well-being of their unborn. To that end we commit to ensuring enactment of common sense legislation, regulations and educational efforts which will:

- require that such information be included in or as part of a package insert on the tobacco product.

- require that expanded efforts be made with the private sector in counseling, advising and educating pregnant women about the dangers of smoking during pregnancy.

Fifth: Work to find solutions to assist tobacco farmers and others who work in the tobacco industry to transition out of the tobacco business, including assisting in building economic infrastructures for short term and long term economic development.

Name State Congressional District

Signature _____

RETURN TO: Coalition on Smoking OR Health
(American Cancer Society, American Heart Association and American Lung Association)
1150 Connecticut Avenue, N.W.
Suite 820
Washington, D.C. 20036

For Additional Information Call: (202) 452-1184

Coalition on Smoking OR Health
Activities Supporting Fair Regulation of
Tobacco Products by the FDA

✣ September 16, 1987
The Coalition on Smoking OR Health supported legislation introduced by Congressman Bob Whittaker (R-KS), HR 3294, to amend the Federal Food, Drug and Cosmetic Act to regulate the sale and distribution of tobacco products containing tar, nicotine, additives, carbon monoxide, and other potentially harmful constituents.

✣ April 25, 1988
The Coalition on Smoking OR Health filed a petition to request that the FDA classify low tar and low nicotine cigarettes as drugs under section 201 of the Food, Drug and Cosmetic Act.

✣ April 25, 1988
The Coalition on Smoking OR Health filed a petition to request that the FDA declare R.J. Reynolds new alternative nicotine delivery product (Premier) as a drug under section 201 of the Food, Drug and Cosmetic Act.

✣ March 20, 1989
The Coalition on Smoking OR Health supported legislation introduced by Congressman Whittaker (R-KS), HR 1494, to amend the Food, Drug and Cosmetic act to regulate the manufacture, sale, promotion, distribution of tobacco products.

✣ September 15, 1989
The Coalition on Smoking OR Health filed supplemental information with the FDA to support both the low tar and low nicotine petition and the Premier cigarette petition filed in 1988.

✣ July 12, 1990
The Coalition on Smoking OR Health provided testimony advocating fair and equitable regulation of tobacco by the FDA at a hearing held by Congressman Henry Waxman (D-CA). The hearing focused on Waxman's bill, "Tobacco Control and Health Protection Act." The legislation was to restrict and regulate the advertising and promotional efforts of the tobacco industry. The Coalition supported the bill.

✣ April 8, 1991
The Coalition on Smoking OR Health filed a petition with the FDA urging the agency to declare the Philip Morris "de-nicotined" cigarette "Next" and other similar de-nicotined tobacco products (Benson and Hedges "De-Nic") drugs under the Food, Drug and Cosmetic Act.

✣ May 16, 1991
The Coalition on Smoking OR Health supported legislation introduced by Senator Edward Kennedy (D-MA), S 1088, "The Tobacco Product Education and Health Protection Act of 1991," to mandate a provision to regulate tobacco products under the Food, Drug and Cosmetic Act. The bill would require the tobacco industry to disclose additives and levels of tar and nicotine in cigarettes, and would give state and local governments the authority to place their own restrictions on tobacco advertising.

✣ February 27, 1992
The Coalition on Smoking OR Health petitioned the FDA and the FTC to use their existing authority to regulate as drugs tobacco products that make health claims and use adverting and promotional campaigns to mislead consumers that some cigarettes are safer, healthier, or less addictive than others. Three petitions were filed with each agency:

Merit Ultima, manufactured by the Philip Morris Company,
Jazz cigarettes, imported from Argentina by Bensen International, and
all cigarettes which make implied or direct weight loss claims.

✣ February 27, 1992
The Coalition on Smoking OR Health called on the Bush Administration and Congress to take immediate steps to include tobacco control policy measures and specifically FDA regulation of tobacco products as part of national health care reform.

✣ February 27, 1992
The Coalition on Smoking OR Health fully supported Congressman Mike Synar's (D-OK) legislation, HR. 4350, to amend the Food, Drug and Cosmetic act to regulate the manufacture, sale, promotion and distribution of tobacco products.

✣ March 20, 1992
The Coalition on Smoking OR Health filed a petition with the FDA to provide additional information responding to the Tobacco Institute's comments on the Coalition's original petition classifying low-tar, low-nicotine cigarettes as drugs.

✣ July 14, 1992
The Coalition on Smoking OR Health presented comments before the Drug Abuse Advisory Committee of the FDA on nicotine patches and nicotine in general.

✣ September 29, 1992
The Coalition on Smoking OR Health petitioned regulatory agencies in five states to classify low-tar, low-nicotine cigarettes as drugs under existing laws and to act to ensure proper labeling and to prohibit misleading advertising of those products.

✣ December 2, 1992
The Coalition on Smoking OR Health sent a letter to President-elect Clinton urging him to put strong tobacco control policies at the top of his national health care agenda, including supporting authority for the FDA to regulate the manufacture, sale, labeling, and marketing of tobacco products.

✣ January 6, 1993
The Coalition on Smoking OR Health held a press conference to recommend specific action steps that Congress and President-elect Clinton should take to reduce tobacco deaths. One of the steps included the passing of legislation to require the FDA to regulate tobacco products.

✣ February 2, 1993
The Coalition on Smoking OR Health submitted to the FDA supplemental materials to its previous petitions. The Coalition requested the Chairman of the Energy and Commerce Committee, John Dingell (D-MI), to conduct a thorough investigation of the tobacco industry's deceptions and practice of withholding information on critical health and safety issues related to their products.

✣ February 24, 1993
The Coalition on Smoking OR Health filed a statement with the FDA in support of its pending petitions which seek to classify all low tar and low nicotine products as drugs.

✣ May 17, 1993
The Coalition on Smoking OR Health released a Gallup survey revealing that a majority of Americans believe that the FDA should regulate tobacco products in a manner similar to the way drugs are regulated. Congressmen Mike Synar (D-OK) and Richard Durbin (D-IL) introduced legislation to provide the FDA with the authority to regulate tobacco products.

✣ January 11, 1994
The Coalition on Smoking OR Health held a press conference on the 30th anniversary of the first Surgeon General's report on smoking and health. The

Coalition issued "A 30-Year Report Card For The Federal Government On Tobacco Control." The report card noted government's failure to adequately deal with this nation's single most preventable cause of death and disability. The FDA, White House, and Congress received low marks for 30 years of inaction on this central public health issue.

✣ February 25, 1994
In a letter addressed to Scott Ballin, Chairman of the Coalition on Smoking OR Health, FDA Commissioner David Kessler stated that evidence has been accumulating that indicates that tobacco companies are deliberately manipulating the nicotine in cigarettes for the purpose of keeping smokers addicted. The FDA also said that tobacco products can be regulated as drugs under the Federal Food, Drug and Cosmetic Act.

✣ March 7, 1994
The Coalition on Smoking OR Health filed a petition with the FDA requesting that all cigarette products be classified as drugs under the section 201 of the Food, Drug and Cosmetic Act. The petition provided information not included in previous petitions.

✣ March 25, 1994
The Coalition on Smoking OR Health presented testimony on the FDA regulation of tobacco products before the House Energy and Commerce Subcommittee on Health and the Environment.

✣ March 31, 1994
The Coalition on Smoking OR Health released a statement at a House Energy and Commerce Subcommittee on Health and the Environment press conference which supported making public the tobacco industry's knowledge of nicotine addiction.

✣ April 14, 1994
The Coalition on Smoking OR Health issued a background press release in conjunction with the tobacco hearings held by the House Energy and Commerce Subcommittee on Health and the Environment at which the seven tobacco company CEO's testified.

✣ June 13, 1994
The Coalition on Smoking OR Health issued a press release in support of the amendment to the House Agriculture Appropriations bill introduced by Congressmen Synar (D-OK), Durbin(D-IL), and Ron Wyden (D-OR). The amendment would clarify the FDA's authority to regulate tobacco products under the agency's existing drug laws.

✣ June 23. 1994
The Coalition on Smoking OR Health issued a statement on the need for government oversight and comprehensive regulation of tobacco products by the FDA at a hearing of the House Energy and Commerce Subcommittee on Health and Environment.

✣ July 26. 1994
At the request of the Coalition on Smoking OR Health, thirteen former Secretaries of the Department of Health, Education, and Welfare and the Department of Health and Human Services, as well as, former Assistant Secretaries of Health and Surgeons General of the United States sent a letter to all members of Congress calling for the FDA regulation of tobacco products.

✣ August 8. 1994
The Coalition on Smoking OR Health provided testimony and written comments to the FDA, Drug Abuse Advisory Committee concerning nicotine addiction and the need to regulate tobacco products.

✣ October 4, 1994
The Coalition on Smoking OR Health, including more than 75 health, medical, consumer, and religious organizations, launched a national petition drive and public awareness campaign, *Citizens to Protect Our Children From Tobacco*, to bring tobacco products under the jurisdiction of the FDA.

✣ November 16, 1994
The Smoke-Free Class of 2000 presented thousands of signed petitions to Former President Jimmy Carter at a ceremony at the Carter Center in Atlanta, Georgia. The petitions urge the FDA to protect our children from tobacco, by taking authority over tobacco products. President Carter served as honorary chairman along with Surgeon General C. Everett Koop for the petition drive that eventually garnered approximately 500,000 signatures.

✣ January 5, 1995
The Coalition on Smoking OR Health sent a letter to all members of the House Commerce Committee requesting that they make tobacco control a high priority for the 104th Congress.

✣ January 11, 1995
The Coalition on Smoking OR Health sent a letter to all members of Congress to announce that 270,000 signatures were delivered to the House and Senate leadership that called on the Congress, Administration, and FDA to take action to regulate tobacco products.

✣ January 11, 1995
Representatives from the Smoke-Free Class of 2000 delivered petitions to the FDA and to congressional leaders urging the FDA to protect children and all Americans from tobacco, by taking authority over tobacco products.

✣ January 23, 1995
The Coalition on Smoking OR Health sent a letter to Abner Mikva, Counsel to the President, requesting the Administration provide leadership on regulating tobacco products.

✣ May 25, 1995
The Coalition on Smoking OR Health submitted a statement to the House Subcommittee on Oversight and Investigations concerning FDA standards for tobacco products.

✣ May 30, 1995
The Coalition on Smoking OR Health sent a letter to Commissioner Kessler stating that the recall of Philip Morris cigarettes underscored the need for the FDA to assert jurisdiction over tobacco products.

✣ July 13, 1995
The Coalition on Smoking OR Health issued a press release in support of Commissioner Kessler's proposal to regulate tobacco products.

7/27/95

file

THE WHITE HOUSE

WASHINGTON

December 22, 1995

Students of Mr. Clark's
Fifth Grade Class
Snowden Elementary School
Aurora, North Carolina 27806

Dear Students:

Your puzzle got my attention, and I hope it got the attention of all the readers of USA Today.

You asked a very important question: "Each year, what kills more people than AIDS, alcohol abuse, car accidents, murders, suicides, illegal drugs, and fires combined?"

The answer, of course, is tobacco use. Mr. Clark and your other teachers and your parents, all of them have probably taught you that more than 400,000 Americans die each year from smoking-related diseases. They may have taught you another important fact: each day, 3,000 young people become regular smokers in the United States, and nearly 1,000 of them will die prematurely because of this.

That's why my Administration -- especially the Food and Drug Administration -- is working very hard to make it more difficult for children under 18 to buy cigarettes and chewing tobacco and to make these products less appealing to children.

I can't tell you how proud I am of what you have done to make people aware of the disease and death that comes from cigarettes and chewing tobacco. Thank you for your creativity, your commitment, and your concern.

You've taught us all an important lesson.

Sincerely,

Bill Clinton

THE WHITE HOUSE

WASHINGTON

December 22, 1995

Students of Mr. Clark's
Fifth Grade Class
Snowden Elementary School
Aurora, North Carolina 27806

Dear Students:

Your puzzle got my attention, and I hope it got the attention of all the readers of USA Today.

You asked a very important question: "Each year, what kills more people than AIDS, alcohol abuse, car accidents, murders, suicides, illegal drugs, and fires combined?"

The answer, of course, is tobacco use. Mr. Clark and your other teachers and your parents, all of them have probably taught you that more than 400,000 Americans die each year from smoking-related diseases. They may have taught you another important fact: each day, 3,000 young people become regular smokers in the United States, and nearly 1,000 of them will die prematurely because of this.

That's why my Administration -- especially the Food and Drug Administration -- is working very hard to make it more difficult for children under 18 to buy cigarettes and chewing tobacco and to make these products less appealing to children.

I can't tell you how proud I am of what you have done to make people aware of the disease and death that comes from cigarettes and chewing tobacco. Thank you for your creativity, your commitment, and your concern.

You've taught us all an important lesson.

Sincerely,

Bill Clinton

file

ROUTING AND TRANSMITTAL SLIP

Date: July 7, 95

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. GC Health Committee U.S.-side		
2. Area Leads		
3.		
4.		
5.		

x	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

Attached is a memo from Linda calling a general interagency meeting for the large ENRG group, on Thursday July 27. This will be followed by a more action-oriented meeting of just the Area leads on August 2. For both we are working on getting N-vision so that CDC can participate fully.

Attached are background documents from the recent GC Health Committee and 5th Commission Meetings. Please distribute to all those concerned with your own cover notes/explanation as appropriate. (E.G., your team participants and concerned non-government players).

Please contact my office for details. I'll be out until July 24. Thanks,

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
Peter H. Henry, Ph.D., Director Office for Europe & the NIS/OIH	18-90 PKLN Phone No. 301-443-9426

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

☆ U. S. Government Printing Office: 1979—281-184/8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date July 6, 1995

From Director
Office of International Health

Subject Outcome of Second US-Russia Health Committee Meeting in Moscow, June 28, - Interagency Briefing and Discussion of Next Steps

To Health Committee Executive Network Resource Group (ENRG)

Meeting:

A briefing and strategy session for the U.S.-Russia Health Committee Executive Network Resource Group (ENRG) will be held **on Thursday, July 27th from 1:00-2:30pm** in Room 729G of the Hubert Humphrey Building. We have made arrangements to provide a remote video hook-up to CDC in Atlanta through N-vision. Please notify OIH/OASH (Loretta Ellison (301) 443-9426) concerning your attendance at this meeting or desire to send an alternate.

Agenda:

This meeting will be chaired by Dr. Jo Ivey Boufford, Principal Deputy Assistant Secretary for Health and Point of Contact for the G-C Health Committee.

Agenda:

This meeting will give us an opportunity to brief you on what transpired during the second meeting of the G-C Health Committee, June 28, in Moscow, and the following two days of Gore-Chernomyrdin Commission meetings (GC-5). We will also discuss and seek your advice on how best to move forward with the approved action plans, especially in regard to increased emphasis on the potential for inter-agency cooperation.

Documents and Highlights from the Moscow Meeting:

Attached is a set of documentation from the Health Committee meeting. Highlights follow:

- Action plans for the 8 priority areas were endorsed.
- Agreement was reached to develop a procedural annex to the FDA-Russian memorandum of agreement on registration in Russia by U.S. producers of FDA-approved pharmaceutical products. Standard forms for registration will be developed and there will be a joint Russian-U.S. training program.

- A new time-limited, ad hoc work group to address the issue of supply in Russia of high-quality pharmaceuticals, medical supplies, and products will be established that includes the U.S. Departments of Commerce and Defense, the Overseas Private Investment Corporation, and USAID in addition to the Department of Health and Human Services. On the Russian side, the Ministry of Health and Medical Industry and other appropriate organizations will be involved. The new group will address specific opportunities and obstacles to the availability of these drugs and medical supplies in the priority health areas of diabetes, family planning, and vaccines and sera.

- Other trade issues related to health (eg. period of registration, licensure, 10 percent tariff on pharmaceuticals) were discussed for the first time during the Health Committee and concern about the 10 percent tariff on pharmaceuticals was expressed to the Commission.

- An agreement was reached to hold an exhibition (Russian proposal) on health education and promotion and related areas in Russia, probably in St. Petersburg, in 1996.

- The Secretary and the Minister released a joint statement regarding issuance of Vital and Health Statistics: Russian Federation and United States, Selected Years 1980-93.

Our work over the next six months will be critical to the Health Committee's success in realizing its action plans.

Linda A. Vogel

Attachments:

Tab A Press release on Health Committee Meeting
Tab B Health Committee Report
Tab C Statement on NCHS-Russian Vital and Health Statistics...
Tab D Priority area action plans
Tab E Secretary's remarks to Commission
Tab F News article

List of Invitees:

Robert Baldwin
Associate Director for International Liaison
CDC

Susan Levine
Senior Vice President
Overseas Private Investment Corporation

Phil Budashewitz
Associate Director for Special Programs
Food and Drug Administration

Carol Carnahan
Program Assistant
Department of State

Gary Christopherson
Assistant Secretary of Defense for Health Affairs
Department of Defense

Joe Davis
Associate Director for International Health and Dir.
CDC

Mary Jo Deering
Director of Health Communication Staff
Office of Disease Prevention and Health Promotion
DHHS

George Dines
Associate Administrator for International Health Affairs
Health Resources and Services Administration
DHHS

Matt Edwards
International Trade Specialist, Medical Equipment
Department of Commerce

Elaine Esber
Associate Director for Medical and International Affairs
Food and Drug Administration

Michael Feldstein
Special Assistant to the Deputy Administrator
USAID

Jeff Gren
Director, Office of Micro Electronic
Medical Equipment and Instruments
Department of Commerce

Steven Hadler
Director of Epidemiology and Surveillance Division
CDC

James Harrell
Acting Director
Office of Disease Prevention and Health Promotion
DHHS

Peter Henry
Director, Office for Europe and the NIS
Office of International Health
DHHS

David Hohman
Director
Office of International Affairs
DHHS

Ruth Hegyeli
Associate Director for International Programs
Heart, Lung, and Blood Institute
NIH

Alan Hinman
Assistant Surgeon General and Senior Advisor to the Director
CDC

Allen Holt
Program Officer for Europe
Fogerty International Center
NIH

Bud Jacobs
Deputy Director, Office of East European and NIS Affairs
USIA

Jeanne Jehl
Director of the Working Group on Comprehensive Services
Department of Education

Eric Katz
Senior Policy Analyst
Agency for Health Care Policy and Research
DHHS

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: list of invitees [partial] (1 page)	n.d.	P3/b(3)

COLLECTION:
Clinton Presidential Records
First Lady's Office
Melanne Verveer
OA/Box Number: 20055

FOLDER TITLE:
Teen Smoking [Folder 1]

2013-0534-S
rc1734

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Eileen Kennedy
Executive Director, Center for Nutrition, Policy & Promotion
U.S. Department of Agriculture

Mike Kerr
Diabetes Translation Division
CDC

(b)(3) [redacted] [0013]

Tom Macklin
Executive Assistant to the Coordinator
for Assistance to the NIS
Department of State

Joseph MacManus
Desk Officer for Russia
United States Information Agency

Don Miller
Acting Chief, International Policy Program Officer
NASA

Mary Pendergast
Deputy Commissioner/Senior Advisor to the Commissioner
Food and Drug Administration

Marilyn Pifer
Science Program Officer
Department of State

Nicole Rabner
Assistant to the Deputy Chief of Staff
Office of the First Lady

Petra Reyes
Health and Population Program for Europe and the NIS
USAID

Marc Rivo
Director, Division of Medicine
Health Resources and Service Administration
DHHS

Anthony Rock
Director, Technical Competitiveness and Health
Department of State

Christopher Sempos
National Center for Health Statistics
DHHS

Anne Sigmund
Director, Office of Eastern European and NIS Affairs
USIA

Kathryn Sullivan
Special Advisor to the Vice President
for International Affairs
Office of the Vice President

Frank Vinicor
Director, Diabetes Translation Division
CDC

Linda Vogel
Director
Office of International Health
DHHS

Edward Washburn
Staff Scientist
Department of Energy

Gary Waxmonsky
Office of International Activities
Environmental Protection Agency

The White House
Office of the Vice President

For Immediate Release

June 30, 1995

U.S. Russian Joint Commission
on Economic and Technological Cooperation

RUSSIA AND U.S. APPROVE ACTION PLANS FOR COOPERATION IN EIGHT PRIORITY HEALTH AREAS

The Health Committee of the Gore-Chernomyrdin Commission held its second meeting on 28 June, in Moscow. Vice President Albert Gore and Russian Prime Minister Viktor Chernomyrdin had added the Health Committee to the G-C Commission in late 1994. At its first meeting on 14 December 1994, the Committee established its structure and functions and identified eight priority areas--diabetes, health education and promotion, prevention and control of infectious diseases, primary care practice, tuberculosis treatment and control, maternal and child health, health reform and policy, and environmental health.

In their joint report to the Commission on 30 June, U.S. Secretary of Health and Human Services Donna E. Shalala and Russian Minister of Health and Medical Industry Dr. Edward Nechayev cited the extraordinary progress that had been made in just six months. During this period nearly 100 Russians and Americans from many different government agencies and the private sector had contributed their time and expertise to create action plans in the identified priority areas, establishing a collegial and firm foundation for future efforts. Secretary Shalala said, "We are all neighbors when it comes to public health. Disease and poor health care in one part of the world eventually threaten us all. The Gore-Chernomyrdin Commission shows the type of cooperative spirit we need for the 21st century."

The action plans for health promotion, maternal and child health and environmental health will give special consideration to the health of children. All of the plans focus on both short-term and long-term objectives. They emphasize making a difference for people's health by sharing health-related data and experience between Russia and American experts and implementing demonstration projects, training, and joint research. The plans will strengthen public health infrastructure, enhance scientific programs, and improve health care delivery and health status. Many of the action plans are designed to build partnerships among our agencies, academic institutions as well as non-governmental organizations and, as appropriate, business enterprise of both countries.

Focusing on protecting and promoting the reproductive health of Russian women in their child-bearing years, the Russian Ministry of Health and Medical Industry (MOHMI) and the U.S. Agency for International Development (USAID) will continued in 1996 highly effective seminars for health professionals across Russia, which have already trained over 800 health professionals. Topics will include developments in the fields of contraceptive technology and professional training. These seminars will complement and reinforce activities already under way which are designed to decrease reliance on abortion as a primary means for family planning.

The Health Committee approved a plan to collaborate in the conduct of pilot projects for diphtheria control in two oblasts in order to further efforts to end the diphtheria epidemic. Cooperation between the State Committee for Sanitary and Epidemiological Surveillance and the U.S. Centers for Disease Control and Prevention to strengthen epidemiological capacity is being continued and expanded.

Tuberculosis has increased in both countries. Projects to assess the effectiveness in Russia of short-course ambulatory treatment will be initiated. A project is planned in Ivanovo oblast with participation by the World Health Organization, the Russian Central Tuberculosis Research Institute, the U.S. Centers for Disease Control and Prevention and Operation Know-How, based in the United Kingdom, joining in the effort. Marion Merrell Dow Inc. a research-based global pharmaceutical organization, will donate two of its leading prescription products for use in the program, and will work with the cooperating institutions to improve the TB cure rate.

Russian and U.S. participants in the area of health care policy and reform announced the publication of *Vital and Health Statistics: Russian Federation and United States, Selected Years 1980-1993*, featuring health status and health services data for both countries. This document provides standardized data, using internationally recognized definitions that can guide health planners and policy makers at all levels to improve public health.

Diabetes currently affects a combined total of over 20 million people in both countries and is a major cause of death and disability. The G-C Health Committee approved a plan directed toward facilitating establishment of a national diabetes register in Russia, improved training for health professionals to promote a team approach to diabetes case management stressing enhanced education of diabetic patients and their families to improve their care and the quality of their lives. There will be a number of partners in both countries including, for example, from the U.S., private organizations in Minneapolis, Minnesota, and LaCrosse, Wisconsin; the American Diabetes Association and other professional bodies; as well as industry, including Eli Lilly, Inc., which has already donated significant supplies of insulin to projects in Russia.

The Committee addressed a number of inter-related trade issues, including initial steps to sharpen the current Memorandum of Understanding between the U.S. Food and Drug Administration and the Russian Ministry of Health and Medical Industry, which is designed to facilitate registration of pharmaceutical products of U.S. firms which are FDA-approved.

To complement key areas of technical cooperation between the two countries in the health field, USAID will support short-term training and Study tours in the U.S. for 22 Russians. The training will focus on health education and promotion, strengthening primary care practice, diabetes treatment and epidemiology.

###

TAB B

UNCLASSIFIED

OUTGOING
TELEGRAM

Copies *Department of State*

OIA DISTRIBUTION SHC2818

SSA _____ ADAMHA _____
HDS
HCFA _____ FDA _____
ORR _____ HRSA _____
W/W _____ NIH _____
NCHS _____ NIOSH _____
OIH _____ Init _____
AHCPR _____

ORIGIN EUR-00

INFO LOG-00 AID-00 CIAE-00 SMEC-00 COME-00 OASY-00 DODE-00
FBIE-00 HHS-01 TEDE-00 INR-00 ABS-00 NSAE-00 CIAE-00
OES-09 OPIC-01 DRL-09 /021R

DRAFTED BY: EUR/RUS: KEDDINS
APPROVED BY: EUR/RUS: TLYNCH

DS196F 010028Z /38

O 010025Z JUL 95
FM SECSTATE WASHDC
INFO USMISSION USNATO IMMEDIATE

UNCLAS STATE 158654

FOLLOWING MOSCOW 20614 DATED 30 JUN 95 SENT ACTION SECSTATE, INFO WHITE HOUSE WASHDC, HHS PHS WASHDC, HQ EPA WASHDC, USIA, USDOC WASHDC, ST PETERSBURG BEING REPEATED FOR YOUR INFO QUOTE

UNCLAS MOSCOW 020614

STATE FOR EUR/RUS (CARNARHAN), OES/STH (ROCK) AND S/NIS/C (MACKLIN)
STATE PASS TO HHS FOR OIA (HOHMAN)
STATE PASS TO DOC FOR MOTTUN
STATE PASS TO EPA FOR WITZE
STATE PASS TO USIA FOR SIGMOND
STATE PASS TO AID FOR AID/NIS (TURNER)
STATE PASS TO EPA FOR OIA (WAXMONSKY)

STATE PASS TO FDA (PENDERGAST/BUDASHEWITZ)
OPIC FOR BORPOE
WHITE HOUSE FOR OSTP (WALES/BORIGHT/SCHWEITZER)

E.O. 12356: N/A
TAGS: KGCC, TBIO, SOCI, PGOV, RS
SUBJECT: GORE-CHERNOMYRDIN COMMISSION -- REPORT OF THE HEALTH COMMITTEE TO THE FULL COMMISSION

1. SUMMARY: ON JUNE 30TH, THE HEALTH COMMITTEE OF THE GORE CHERNOMYRDIN COMMISSION REPORTED TO THE FULL COMMISSION ON PROGRESS MADE IN ACHIEVING THE COMMITTEE'S OBJECTIVES SINCE THE COMMITTEE'S INAUGURAL MEETING IN DECEMBER 1994. SECRETARY FOR HEALTH AND HUMAN SERVICES DONNA SHALALA AND RUSSIAN HEALTH MINISTER EDWARD NECHAYEV REPORTED THAT THE COMMITTEE HAD MADE SUBSTANTIAL PROGRESS IN INITIATING ACTIVITIES IN EACH OF ITS EIGHT PRIORITY AREAS. BOTH SIDES NOTED THE IMPORTANCE OF LOOKING FOR OPPORTUNITIES IN THE COMMERCIAL SECTOR WHERE U.S.-RUSSIAN COOPERATION COULD LEAD TO THE INCREASED AVAILABILITY OF KEY PHARMACEUTICAL AND MEDICAL PRODUCTS. NECHAYEV URGED THAT BOTH U.S. AND RUSSIAN INVESTORS ACT "BOLDLY" IN THIS REGARD. SHALALA HIGHLIGHTED THE COMMITTEE'S AGREEMENT TO ESTABLISH A PROCEDURAL ANNEX TO THE EXISTING U.S. FDA-RUSSIA MOU ON PHARMACEUTICAL REGISTRATION AND ANNOUNCED THE ESTABLISHMENT OF A JOINT U.S.-RUSSIAN WORKING GROUP TO EXAMINE ISSUES RELATED TO ENHANCING

PHARMACEUTICAL TRADE AND INVESTMENT. SHALALA ALSO FLAGGED THE POTENTIALLY NEGATIVE EFFECT OF IMPORT TARIFFS ON THE PHARMACEUTICAL SECTOR. VICE PRESIDENT GORE AND PRIME MINISTER CHERNOMYRDIN CONGRATULATED THE COMMITTEE ON ITS ACHIEVEMENTS. THE VICE PRESIDENT URGED THAT THE COMMITTEE PAY SPECIAL ATTENTION TO INCREASING THE

AVAILABILITY IN RUSSIA OF TECHNOLOGIES, SUCH AS GLUCOMETERS, FOR PATIENT MANAGEMENT OF DIABETES. THE VICE PRESIDENT ALSO ASKED THE HEALTH COMMITTEE TO EXAMINE WHETHER EXISTING TARIFFS WERE IMPEDING SUCH PRODUCTS FROM BECOMING MORE WIDELY AVAILABLE IN THE RUSSIAN MARKET. END SUMMARY.

2. ON JUNE 30TH, SECRETARY FOR HEALTH AND HUMAN SERVICES DONNA SHALALA AND RUSSIAN HEALTH MINISTER EDWARD NECHAYEV REPORTED TO THE FULL GORE-CHERNOMYRDIN COMMISSION ON THE HEALTH COMMITTEE'S ACTIVITIES SINCE ITS INAUGURAL MEETING IN DECEMBER 1994. SECRETARY SHALALA OPENED THE PRESENTATION BY NOTING THAT THE HEALTH COMMITTEE HAD HELD A SECOND HIGHLY PRODUCTIVE MEETING IN MOSCOW ON JUNE 28. IN JUST SIX MONTHS, THE COMMITTEE HAD DEVELOPED ACTION PLANS FOR EIGHT PRIORITY AREAS (DIABETES, HEALTH EDUCATION AND PROMOTION, PREVENTION AND CONTROL OF INFECTIOUS DISEASE, STRENGTHENING PRIMARY CARE PRACTICE, TUBERCULOSIS TREATMENT, MATERNAL AND CHILD HEALTH, HEALTH REFORM AND POLICY DIALOGUE AND ENVIRONMENTAL HEALTH). RUSSIAN-AMERICAN

TEAMS HAD BEEN ASSEMBLED TO IMPLEMENT ACTIVITIES IN EACH AREA. IN SEVERAL OF THESE AREAS DIRECT AND CONTINUING COMMUNICATIONS LINKS WERE BEING ESTABLISHED VIA THE INTERNET. COMPUTER SOFTWARE AND PROGRAMS WERE ALSO BEING EXCHANGED.

3. SHALALA REPORTED THAT THE COMMITTEE HAD AGREED TO EXAMINE A NUMBER OF TRADE AND INVESTMENT RELATED ISSUES AFFECTING THE PHARMACEUTICAL SECTOR. AS A FIRST STEP, AGREEMENT HAD BEEN REACHED ON ADDING A PROCEDURAL ANNEX TO THE EXISTING MEMORANDUM OF UNDERSTANDING (MOU) BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND THE RUSSIAN GOVERNMENT. THE MOU, CONCLUDED IN 1994, IS DESIGNED TO FACILITATE THE IMPORTATION OF FDA-APPROVED PHARMACEUTICALS INTO RUSSIA. WHILE GOOD PROGRESS HAD BEEN MADE IN IMPLEMENTING THIS AGREEMENT, SH
ALALA REPORTED THAT BOTH THE U.S. AND RUSSIA HAD DECIDED THAT U.S. PHARMACEUTICAL FIRMS COULD MAKE BETTER USE OF THE MOU IF SPECIFIC PROCEDURES WERE MORE CLEARLY UNDERSTOOD. THE PROPOSED ANNEX

TO THE MOU WOULD INCLUDE PROVISIONS FOR STANDARDIZING EXISTING APPLICATION FORMS AND DEVELOPING A JOINT TRAINING PROGRAM FOR U.S. FIRMS AND RUSSIAN OFFICIALS WHICH WOULD HELP CLARIFY MOU PROCEDURES.

4. AS A SECOND STEP TOWARDS ENHANCING MUTUALLY BENEFICIAL TRADE AND INVESTMENT, THE U.S. AND RUSSIA HAD AGREED TO THE ESTABLISHMENT OF A WORKING GROUP, INCLUDING THE U.S. DEPARTMENTS OF COMMERCE, DEFENSE, AND HEALTH AND HUMAN SERVICES, THE OVERSEAS PRIVATE INVESTMENT CORPORATION AND THE U.S AGENCY FOR INTERNATIONAL DEVELOPMENT, WHICH "WOULD ADDRESS SPECIFIC OPPORTUNITIES AND OBSTACLES TO THE AVAILABILITY OF CRITICAL DRUGS AND MEDICAL SUPPLIES." THE WORKING GROUP WOULD FOCUS, IN PARTICULAR, ON POSSIBLE TRADE AND INVESTMENT OPPORTUNITIES IN THE AREAS OF DIABETES, FAMILY PLANNING AND VACCINES AND SERA,

AND WOULD COORDINATE CLOSELY WITH THE MEDICAL EQUIPMENT, PHARMACEUTICAL AND HEALTH SERVICES SUB-GROUP OF THE BUSINESS DEVELOPMENT COMMITTEE. SHALALA ALSO NOTED THE COMMITTEE'S GENERAL CONCERN ABOUT THE POTENTIALLY NEGATIVE EFFECT OF TARIFFS ON TRADE INT HE PHARMACEUTICAL SECTOR.

5. IN CLOSING, SHALALA DREW THE COMMISSION'S ATTENTION TO SOME OF THE COMMITTEE'S CONCRETE ACHIEVEMENTS OF THE PAST SEVERAL MONTHS. IN THE AREA OF DIABETES, THE COMMITTEE HAD REACHED AGREEMENT TO PURSUE ALTERNATIVE MODELS FOR CASE MANAGEMENT WHICH WILL FOCUS ON PATIENT EDUCATION. SHALALA NOTED THAT THE U.S. WILL FOCUS ON PATIENT EDUCATION. SHALALA NOTED THAT THE U.S. FIRM ELI LILLY WILL BE DONATING INSULIN IN SUPPORT OF SEVERAL U.S.-BASED PRIVATE ORGANIZATIONS WORKING IN THIS AREA. THE COMMITTEE HAD ALSO AGREED TO COOPERATE IN ASSESSING THE EFFECTIVENESS OF

AMBULATORY THERAPY FOR TUBERCULOSIS TREATMENT IN RUSSIA. THE U.S. FIRM MARIAN MERRELL DOW HAD OFFERED TO DONATE TWO OF ITS LEADING TUBERCULOSIS TREATMENT DRUGS FOR USE IN TREATMENT TRIALS. IN THE AREA OF DIPHTHERIA CONTROL, PILOT STUDIES OF ENHANCED CONTROL MECHANISMS, WILL SOON GET UNDERWAY IN TWO OBLASTS. FINALLY, SHALALA DREW THE COMMISSION'S ATTENTION TO A RECENTLY RELEASED REPORT COMPILED JOINTLY BY U.S. AND RUSSIAN RESEARCHERS ENTITLED "VITAL AND HEALTH STATISTICS: RUSSIAN FEDERATION AND THE UNITED STATES, SELECTED YEARS 1988-93." THE REPORT REPRESENTED THE FIRST SERIOUS EFFORT TO PROVIDE STANDARDIZED DATA BASED ON INTERNATIONALLY RECOGNIZED DEFINITIONS THAT COULD BE USED BY POLICY MAKERS TO BETTER ADDRESS PUBLIC HEALTH PROBLEMS.

6. MINISTER NECHAYEV THANKED SHALALA FOR HER REPORT AND FOR THE SUPPORT THE U.S. SIDE HAD PROVIDED FOR THE COMMITTEE'S WORK. HE NOTED THAT FROM THE RUSSIAN PERSPECTIVE THE COMMITTEE'S WORK HAD ALREADY PROCEEDED WITH GREAT SUCCESS. HE WELCOMED U.S. INTEREST IN WORKING ON DIABETES TREATMENT AND NOTED THAT RUSSIA HAD ALREADY DEVELOPED ITS OWN INSULIN THAT WOULD SOON BE WIDELY AVAILABLE THROUGHOUT RUSSIA. COMMENTING ON THE FDA MOU, NECHAYEV REMARKED THAT THE REGISTRATION PROCESS HAD ALREADY BEEN GREATLY SIMPLIFIED AND THAT MORE THAN 150 U.S.-MANUFACTURED DRUGS HAD ALREADY BEEN REGISTERED IN

RUSSIA. IN ADDITION, A FURTHER 100 APPLICATIONS WERE UNDER REVIEW. NECHAYEV EMPHASIZED THAT HE WOULD WELCOME FURTHER WESTERN INVESTMENT IN THE RUSSIAN PHARMACEUTICAL SECTOR, AND NOTED THAT THERE WERE MANY EXISTING FACILITIES THAT COULD BE MADE AVAILABLE TO WESTERN FIRMS. HE URGED THAT BOTH POTENTIAL INVESTORS AND RUSSIA "ACT MORE BOLDLY" TO MAKE SUCH INVESTMENTS POSSIBLE. IN

E

CLOSING, HE NOTED THAT THE COMMITTEE HAD ALSO AGREED TO ORGANIZE AN EXHIBITION ON HEALTH EDUCATION AND PROMOTION IN ST. PETERSBURG NEXT JUNE.

7. THE PRIME MINISTER AND VICE PRESIDENT CONGRATULATED THE COMMITTEE ON ITS ACCOMPLISHMENTS. THE VICE PRESIDENT NOTED THAT

THE PUBLICATION OF "HEALTH AND VITAL STATISTICS" MARKED TH
E FIRST TIME THAT SUCH CRITICAL INFORMATION, COMPARING U.S. AND RUSSIAN DATA, WOULD BE AVAILABLE TO POLICY MAKERS. THE VICE-PRESIDENT URGED THAT THE COMMITTEE EXAMINE CAREFULLY HOW U.S. TECHNOLOGIES FOR THE TREATMENT OF DIABETES -- SUCH AS GLUCOMETERS AND PATIENT INSULIN KITS WHICH PERMIT DIABETES SELF-MANAGEMENT THROUGH BLOOD GLUCOSE MONITORING -- COULD BE MADE MORE READILY AVAILABLE IN RUSSIA. GORE URGED THAT THE COMMITTEE EXPLORE WHETHER

EXISTING TARIFFS WERE IMPEDING THE IMPORTATION OF SUCH GOODS.

8. SEPTEL FOLLOWS WITH TEXTS OF THE COMMITTEE'S JOINT REPORT AND PRESS RELEASE.
PICKERING
UNQUOTE CHRISTOPHER

GORE-CHERNOMYRDIN COMMISSION
HEALTH COMMITTEE

Joint Report to the Commission
on
Second Health Committee Meeting
Moscow, Russian Federation

The Health Committee held its second meeting on 28 June, 1995, at the Ministry of Health and Medical Industry. Dr. Donna Shalala, Secretary of Health and Human Services, and Dr. Edward Nechayev, Minister of Health and Medical Industry, co-chaired the meeting.

The Committee reviewed progress since its first meeting on December 14, 1994. It was noted that initial work plans have been developed in all of the eight priority areas identified by the Committee in December. There have been six exchange visits for strategic planning and related purposes in five of the eight priority areas, one visit of the U.S.-based secretariat to Russia plus numerous telephone discussions and electronic mail (E-mail) and other communications at the Secretariat level. Additionally, informal discussions have occurred between Minister E. Nechayev and senior U.S. health officials during the May World Health Assembly in Geneva. The quality and openness of these discussions and other communications have set a standard and tone of collegiality and mutual respect for this cooperative relationship.

The Committee heard a summary report on the USAID-funded Women's Reproductive Health Initiative and the Pharmaceutical Sector Cooperation programs, which had been announced at its 14 December Committee Meeting. The first program is directed toward reducing levels of maternal morbidity and mortality by increasing knowledge and use of modern contraceptives. Progress since December 1994 includes the development of one model family

planning center in each of three oblasts: Leningrad, Sverdlovsk and Ivanovo. Training activities are already underway in each of these locations, with nearly 800 health professionals trained to date. Educational materials for women and adolescents on the health benefits of modern contraceptives are being developed and consultations are underway with private sector contraceptive manufacturers to ensure enhanced commercial distribution of contraceptive products in project oblasts. In addition, discussions are being initiated at both the oblast and federal level to promote broad-based, long-term support for reproductive health activities. By early 1996, project activities will be expanded to three additional locations, including sites in Siberia and the Far East. The second program, called the Medical Technology Transfer Activity (MTTA) is designed to accelerate U.S. investment in the production and distribution in Russia of critically needed pharmaceuticals. Three U.S. pharmaceutical companies--Bristol Myers-Squibb, Mir Pharmaceutical, and Searle--have been awarded Phase One grants by USAID for technical assistance and training. Implementation funding will be provided based on review of these companies' proposals.

The Committee noted the updated summary of cooperation carried out primarily under the Agreement on Cooperation in the Fields of Public Health and Biomedical Research, signed on 14 January 1994. Activities have included continuation of cardio-pulmonary research, cancer research including a special program for supporting young investigators, work in immunology, viral diseases, substance abuse, the neurosciences, AIDS-related research in primates and radiation health effects research.

The Committee approved plans of action for each of the eight priority areas agreed upon at the first Committee Meeting. Highlights are as follows:

HC1 - Diabetes: -- Establishment of an effective, nationwide surveillance system for diabetes in Russia. Initiation of clinical training programs to facilitate improved diabetes professional education, and work towards the establishment of a professional diabetes association. Active involvement of private companies will be sought through the U.S. Overseas Private Investment Corporation (OPIC) and the Department of Commerce (DOC) to start joint ventures of pharmaceutical and medical supplies production in Russia, particularly for patients with diabetes.

HC2 - Health, Education and Promotion: -- Initiation of a strategy to promote better health of children and adolescents through a parent and school health education focus. A joint exhibition on contemporary technologies in health education and health promotion will be organized in Russia in 1996.

HC3 - Infectious Diseases: -- Enhancement of efforts, through bilateral exchange of scientists and experts and know-how (computer programs), to carry out training, epidemiologic studies and applied research in infectious diseases, and technical collaboration to evaluate and strengthen Russian efforts to control the ongoing diphtheria epidemic. Also included is the strengthening of programs to improve control of food-borne diseases.

HC4 - Strengthening Primary Care Practice: -- Initiation of a series of activities directed toward developing models for family practice in Russia, including appropriate revisions in curricula for medical education.

HC5 - Tuberculosis: -- Initiation of projects to assess the effectiveness of short-course ambulatory therapy in Russia. Development and use of computerized systems for surveillance of the disease and case management.

HC6 - Maternal and Child Health: -- Convening of seminars on modern contraceptive technologies and the development of related training of trainers programs. Exchanges of experts and information on sudden infant death syndrome (SIDS), sharing approaches to clinical case management of major childhood illnesses, and use of vital statistics in effective targeting of child health programs.

HC7 - Health Reform and Policy Dialogue: -- Joint exploration and exchange of information on issues facing Ministers of Health seeking to develop multi-sectoral collaboration in decentralized health systems. Policy areas for exploration include: evaluating the impact of health care reform; provision of cost-effective quality health services; health manpower planning; standardization of data; and promoting primary health care.

HC8 - Environmental Health: -- Convene an interagency, multi-sectoral conference on adverse effects of lead and heavy metals in vulnerable populations, such as children. Included will be the underlying science and epidemiology, risk assessment and risk communication. A new strategy was announced to reduce health risks from environmental pollution through research, support for programs of professional training, environmental health policy development, and public education.

Telecommunications: -- Crosscutting all of the above areas is the exchange of information through telecommunications linking U.S. and Russian experts and connecting U.S. and Russian data bases. Here, the Russian side has agreed to expedite purchase of local access to the Internet at several locations and the U.S. side has agreed to use this communication link to share information and data through electronic mail (e-mail).

The Committee applauded the strategic planning efforts of the binational teams which had developed the action plans and urged that specific action steps be further developed and implemented in as timely a fashion as possible in areas of highest priority and report back to the Committee at its third Meeting.

The Committee took note of and expressed appreciation for the joint National Center for Health Statistics (U.S.)-MedSocEconInform (Russian) publication on "Health: Russian Federation and United States," on health status in the two countries. This document was cited as a land-mark joint effort by both countries to help establish a basis for an agenda for action, through forthright presentation of health statistics for decision-making at national, oblast/state and local levels to improve health of the people of the respective countries. This publication reflects important advances in standardization of data and harmonization of definitions used.

The Committee noted the significant progress made toward implementation of the U.S. Food and Drug administration-Russia Memorandum of Understanding (MOU) on the importation of FDA-approved pharmaceuticals. It was agreed that better use of the MOU

by U.S. pharmaceutical firms could be achieved through: the addition of a procedural annex which clearly specifies guidelines for U.S. companies to follow; the development of standardized forms; and through a joint Russian Ministry of Health and Medical Industry and U.S. FDA training program.

Throughout the discussion of each priority area the importance of availability of adequate supplies of high-quality pharmaceutical, medical supplies and products was highlighted. The Committee commissioned an ad hoc, time-limited work group, consisting of representatives of: on the U.S. side, the Agency for International Development, the Department of Health and Human Services, the Overseas Private Investment Corporation, the Department of Commerce, and Department of Defense; and, on the Russian side, the Ministry of Health Medical Industry and other appropriate organizations. The group was charged with making recommendations to the Committee on specific opportunities for investment, joint production, and the removal of barriers to assure availability of essential drugs and medical products in the specific areas of diabetes, family planning, and serums and vaccines, which complement the Committee's priority areas.

The Committee noted the problems faced by the disabled, particularly those in need of assistive technologies to help assure fuller lives. A proposal for a specific project was suggested. It was agreed that details will be sent to the U.S. side for further consideration.

The next meeting will be held in the United States at a date to be mutually agreed upon.

For the United States

Donna E. Shalala, Ph.D.
Co-chair

For the Russian Federation

Edward Nechayev, M.D.
Co-Chair

TAB C

Gore-Chernomyrdin Health Committee

Комиссия Черномырдина-Гора: Комитет по здравоохранению

JOINT STATEMENT
UPON THE ISSUANCE
OF

VITAL AND HEALTH STATISTICS: RUSSIAN FEDERATION AND UNITED STATES, SELECTED YEARS 1980-1993

It is with great pleasure that we congratulate the Institute MedSocEconInform of the Russian Ministry of Health and Medical Industry and the National Center for Health Statistics of the U.S. Department of Health and Human Services on the publication of the first joint Russian-U.S. report on vital and health statistics of our two countries.

We believe the compilation, analysis and reporting of accurate health statistics is a valuable mechanism for assuring that policy-makers at multiple levels in our respective countries are better able to identify health issues and to make good decisions on programs and related allocation of resources. Identification of areas of strength and weakness in health status in our respective countries helps to provide a sound foundation upon which to launch goal-oriented programs to better serve our two nations. It is also an important way to assure availability to the private sector useful data in a user-friendly form.

This first joint report is an important beginning. We encourage continuation of this effort and look forward to future reports from the Russian and U.S. cooperating institutions.

Donna E. Shalala, Ph.D.
Secretary of Health and
Human Services

Eduard Nechayev, M.D.
Minister of Health and
Medical Industry

June 28, 1995, Moscow

TAB D

HC1 - DIABETES

Background:

Diabetes is a major cause of death and disability in both the United States and Russia. The toll from diabetes also contributes significantly to health expenditures nationally in both countries. Deficiencies in our respective systems for the delivery of care to those with chronic diseases, such as diabetes, and the high cost associated with such care, make it important to transfer knowledge to patients and family, so that they, supported by medical teams, can take greater responsibility in management of their disease. In the U.S., a 10-year government-supported "Diabetes Control and Complications Trial" (DCCT) demonstrated that patients with diabetes could delay the onset and slow the progression of clinically important retinopathy, including vision- threatening lesions, nephropathy, and neuropathy by a range of 35 to 70 percent, if given intensive therapy which maintains blood glucose levels near normal levels ("secondary prevention"). In addition, previous studies have indicated that blindness, amputations, and renal failure from diabetes can be substantially reduced by early detection and treatment ("tertiary prevention"). In both countries we need to develop cost effective models for chronic disease care and these will undoubtedly rely on patients being better informed and responsible for their own care.

U.S. and Russian leads have met twice in the U.S. (once in April and again in June) which have included visits to the Centers for Disease Control and Prevention, the National Institute of Diabetes and Digestive and Kidney Diseases, NIH, (responsible for the DCCT) and the Agency for Health Care Policy and Research which conducts medical effectiveness research. Contact was also made with the International Diabetes Center (Minneapolis) for which there is a well- established collaboration, and the American Diabetes Association (ADA).

Both sides have identified experts to serve as leads for this cooperation as well as initial organizational focal points for initiation of cooperation, including appropriate involvement of relevant industry in both countries. It is understood that there are alternative approaches to diabetes case management which should be considered and that additional organizations will be brought into the network of cooperation after initial activities are successfully launched and some experience is gained.

The contacts and discussions thus far have led to identification of a number of priority concerns for U.S.- Russian collaboration: improved diabetes surveillance and epidemiology; improved diabetes professional education; expansion of the number of specialized diabetes treatment centers; assistance in establishment of a strong voluntary diabetes association, and establishment of a partnership for the production and distribution of insulin and other relevant diabetic supplies.

Near -Term Objectives and Activities:

- Establish initial surveillance system for diabetes and associated complications in Russia. This effort will build upon activities initiated in Russia in January, 1994 and commence with participation in a 4-6 week epidemiology/surveillance program at the CDC in September/October, 1995 given in Russian for three public health professionals. Subsequently, visits to Russia by CDC personnel will occur in the late fall.

- Initiate discussion concerning the production and distribution of, and reimbursement mechanisms for diabetes related supplies, especially insulin. These near-term activities will include appropriate governmental, private and industrial segments of both Russia and the United States.

- Establish initial clinical training activities in diabetes for approximately three Russian health care professionals. The content of this training will be "TEAM" management of diabetes and occur at the International Diabetes Center, Minneapolis, MN. It is anticipated that these initial Russian health care professionals will be responsible for establishing similar health education programs in Russia. Subsequent training in the U.S. will occur at other diabetes "centers of excellence," e.g., Joslin Diabetes Center. A visit to Russia following initial training by U.S. diabetologists will serve as a follow-up mechanism to insure implementation.

  The Ministry of Health and Medical Industry, with assistance from the American International Health Alliance and the U.S. pharmaceutical firm Eli Lilly, will seek to replicate a highly successful, community-based program for the treatment of diabetes in Dubna, Russia at six other locations in the Moscow region. The program at these six new sites will focus on educating patients in optimal self management of their condition. Eli Lilly will provide a 2-year supply of insulin for the treatment of diabetes at the six sites.

- The diabetes area will receive priority attention in establishing electronic communications through Internet E-mail connections. This will permit already established centers and networks on both sides to better communicate and relay information.

- National Diabetes Center - as an initial activity, the Russian Ministry of Health (MOH) wishes to establish a central "National Diabetes Facility" in Moscow to coordinate subsequent expansion of diabetes services throughout Russia. The specific nature of this Center will be further elucidated prior to and during a meeting in Moscow in September, 1995. It is anticipated that this facility will include clinical care facilities; clinic, basic and epidemiologic research activities; and advanced training services.

- To facilitate development of a "Russian Diabetes Association," i.e., a diabetes voluntary health organization, initial discussions have occurred between Dr. Alex Ametov and senior leadership of the American Diabetes Association (ADA). The ADA has indicated an interests and willingness to assist the Russian MOH as well as serve as an "advisory board." In addition, initial conversations have occurred with the American Dietetic Association and the American Association of Diabetes Educators regarding participation in these efforts.

Long-Term Objectives and Activities for Future Consideration:

- It is anticipated that 3-5 years will be required to fully implement these programs in Russia to the point that they will be mostly self-sustaining, as well as effective in improving diabetes health care in Russia.

- In addition to continued efforts to expand the six initial components mentioned above, the following activities will need to occur to insure long-term progress:

  1. Identify other organizations, individuals, etc., that could help facilitate the implementation of the above programs.

  2. Identify other diabetes activities and program occurring at present or in the near future in Russia which are not an official component of the GC Health Committee activities.

  3. Establish an appropriate organizational structure that will facilitate further development and implementation of diabetes activities in Russia as part of the GC Health Committee activities.

Area Leads and Key Participants

U.S.

Frank M. Vinicor
Director, Diabetes Translation Division
Centers for Disease Control and Prevention

Russia

A. S. Ametov
Chief Diabetologist
Head of the Department of Endocrinology of the
Russian Medical Academy of Post-Graduate Studies

Relevant Key Background Documents:

Barriers to the Translation of the Diabetes Control and Complications Trial; F.Vinicor; *Diabetes Review*, Vol. 2:4, Fall, 1994; pg. 371-83.

The Diabetes Control and Complications Trial; R. Lasker; *Diabetes Reviews*, Vol. 2:4; Fall, 1994; pg. 350-8.

The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-dependent Diabetes Mellitus; DCCT Research Group; *NEJM*, Vol. 329:14; Sept 30, 1993; pg. 977--86.

The Diabetes Control and Complications Trial: Implications for Policy and Practice (Editorial); R. Lasker; *NEJM*, Vol. 329:14; Sept 30, 1993; pg. 1035-6.

Is Diabetes A Public Health Disorder? F. Vinicor; *Diabetes Care*, Vol. 17:(S1); June, 1994.

American Diabetes Association Position Statement on the DCCT.

HC2 - HEALTH EDUCATION AND PROMOTION

Background:

Both Russian and U.S. leaders in the fields of health and education agree that health education and health promotion are essential to the vitality and future of their countries. We both recognize the need for health to be valued by children and adults in order that behavioral, social, and environmental conditions can be improved and unacceptably high rates of disease, preventable disabilities, and premature death can be reduced. We believe that carefully designed health education and promotion activities can lead to a general acceptance of health as a social and individual value and, consequently, to necessary health-enhancing behavioral patterns, social mores, and environmental conditions.

The U.S. and Russia have developed blueprints for improving health that can be used as guidelines for our respective health education and promotion endeavors. For Russia, the blueprint is entitled Toward a Healthy Russia; for the United States, it is Healthy People 2000. These plans have been developed by a broad range of professional experts and enjoy the support of many leaders in the field of health of each country. They are less well known and embraced by other sectors that have crucial roles to play in achieving sustained improvements in the health status of our respective populations.

The GC Commission and its Health Committee provide an historic opportunity for renewed leadership for both Russia and the U.S. in crafting more effective health promotion and education strategies. By undertaking these strategies in consultation with each other and with open and frequent exchange of information, materials, and expertise, we can effectively claim this opportunity and achieve measurable gains in the health status of the people of our countries.

Strategy:

Through the Joint Commission and the Health Committee, we propose a strategy that focuses on the essential importance of health education and promotion for the well being of our nations' children. Children are to be found in families and in schools. Therefore, the strategy that guides the specific activities that we are putting forth here also directs principal attention to activities that apply to parents and schools. In addition, we recognize our common need to address the health problems and health-damaging behaviors of youth. They, too, may be reached through schools, but they are especially influenced by entertainment media.

To carry out a strategy that focuses on children in schools and homes and youth as consumers of entertainment, we strongly endorse the need for development of collaboration, starting with health and education sectors but also including the cultural sector. Each sector is an essential partner in order to engage the resources of health care providers, teachers and school personnel, libraries, museums, the mass media, and others that are now and will be needed to promote health effectively.

Near-Term Activities:

1. By October 1995, develop and implement a training-educational visit of selected Russian professionals from the Ministry of Health, the Ministry of Education, the public library system, and oblast/community health and education systems to the United States. The training visit will include the opportunity to explore with U.S. counterparts joint proposals in school health education, teacher training, communication technology and its use in distance learning for health education, and use of the media and cultural channels of communication and influence. It will also allow the Russian team to form with U.S. counterparts a binational network to steer future joint projects and maintain ongoing communication.

2. By January 1996, establish communication links via electronic mail over Internet to link Russian and U.S. counterparts on the Health Education and Promotion subcommittee. This technological forum will be used to communicate about the implementation of jointly planned activities and ongoing programs, to share appropriate health promotion materials, and to explore new areas for collaboration.

3. Begin immediately to exchange results of surveys about health status, behaviors, and programs -- especially of children and youth, study findings, educational curricula, and public education materials, and commit on each side to undertake translation and dissemination of those documents and materials that are deemed to be useful.

4. By January 1996, arrange a joint publication in Russia's "*Medical Gazette*" and "*Russian Health Care*" and its newspaper for school teachers and in The American Medical Association's Medical News, the American Public Health Association's "*Nation's Health*" and the newspaper of the U.S. National Education Association of the shared vision and mandate of the subcommittee regarding the integral roles of health and school professionals in achieving improved health for children, youth, and their families.

Longer-Term Activities:

1. Seek through the Joint Commission collaboration with the Russia-U.S. Space Committee to support satellite-linked communication technology, in order that health education can be considered as content material for the newly developed communication systems and be more effectively transmitted to homes, schools, community centers, medical facilities, libraries, and health centers and the general intelligence of our populations on matters of health can be raised.

2. Seek the influence of national leaders, through the Joint Commission, to recruit a joint U.S.-Russia team of entertainment "stars" to act as ambassadors for good health to Russian and American youth. In collaboration with their agents and/or entertainment brokers, seek commercial sponsorship from Russia and American sources to support activities that can be used as platforms for them to convey messages supporting health-enhancing behaviors.

3. Define up to three oblasts or communities in Russia and lead organizations (Regional Centers for Preventive Medicine) and counterparts at state or local levels in the U.S. to link in partnership for developing their own joint health education and promotion pilot projects related to families, schools, or youth.

Area Leads and Key Participants

U.S.

James A. Harrell
Acting Director, Office of Disease Prevention and Health Promotion
U.S. Public Health Service

Lloyd Kolbe
Director, Division of Adolescent and School Health
Centers for Disease Control and Prevention

Jeanne Jehl
Special Assistant to the Assistant Secretary for Elementary and Secondary Education
U.S. Department of Education

Ruth Hegyeli
Deputy Director, International Office
National Heart, Lung, and Blood Institute

Patricia Kuntze
Deputy Director, Office of Consumer Affairs
Food and Drug Administration

Russia

V. A. Polessky
Director, Research Center for Formation of Healthy Lifestyles

Grigory A. Avvakumov
Deputy Director, Preventive Medicine Department
Ministry of Health and Medical Industry

Maria N. Lazutova
Deputy Minister, Ministry of Eduction

Galina Kislovskaya
Deputy Director General, Library for Foreign Literature
Moscow

Relevant Key Background Documents:

Toward a Healthy Russia -- Executive Summary

Healthy People 2000 -- Executive Summary

HC3 - PREVENTION AND CONTROL OF INFECTIOUS DISEASES

Background:

Scientists and public health authorities from Russia and the United States (U.S.) identified areas of mutual interest among vaccine preventable, food-borne, and other infectious diseases. Participants acknowledged the successful multi-year collaboration that has involved training in newer methods of Good Manufacturing Practices and in the quality control of vaccines and in vitro diagnostic kits; training in the epidemiology of infectious diseases and vaccine preventable diseases; projects on control of diphtheria, and support for health information dissemination and for strengthening the laboratory and/or epidemiologic capability of relevant institutes (e.g., Gabrichevsky and Tarasevich Institutes).

Diphtheria control was cited as one of the high priority areas for cooperation due to the resurgence of the disease in Russia and other New Independent States and due to the potential for an epidemic to occur in the highly susceptible U.S. adult population. Collaborative efforts to examine the Russian diphtheria control experience will be invaluable to design appropriate control efforts for other countries and prevention efforts in the U.S. Other areas of mutual importance focus on collaborative efforts to reduce the burden of vaccine preventable diseases and prevention of food-borne diseases. The need for cooperation in the area of tuberculosis was discussed; suggestions are provided in HC5, which deals specifically with tuberculosis.

Ongoing Support in Infectious Disease Control:

The Health Committee endorses and supports the continuation of the following ongoing activities in the area of infectious diseases being carried out by experts from the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) with Russian counterparts under Agreements supported largely by USAID.

1. **Training and Exchange of Scientists/Experts:** Forty (40) epidemiologists received USAID-funded training in epidemiology at the U.S. Centers for Disease Control and Prevention in August 1994 and March/April 1995. An additional twenty (20) epidemiologists will be trained in FY 1996. Ten exchanges in the areas of biologics, food and drug regulation and quality control are planned by the U.S. Food and Drug Administration for this year. [In prior years, twenty (20) infectious disease and vaccine/regulatory scientists were trained at FDA.]

2. **Diphtheria Surveillance and Control:** Agreement has been reached and collaboration initiated between CDC, the Ministry of Health, and the State Committee for Sanitary and Epidemiological Surveillance on a plan for improving disease surveillance and control, with a focus on diphtheria. Planned activities in this area have included the development of a pilot project for diphtheria control in two oblasts. During the week of May 22 a plan was endorsed by all parties to -

support activities focused on: the evaluation of national and oblast level diphtheria incidence to identify critical lessons learned through Russian diphtheria control efforts to date, and to finalize the design of pilot projects for enhanced diphtheria control in two oblasts. Key elements of enhanced diphtheria control are likely to include optimal implementation of the current diphtheria control strategy in Russia, achieving high coverage (80%) with a second dose of Td vaccine among adults with the highest mortality and the initiation of information, education, and communication activities aimed at the general public and health care professionals. FDA and the Tarasevich Institute will be consulted on vaccine quality control as part of this effort.

3. **Food-borne Infectious Diseases:** In January 1995, the U.S. Food and Drug Administration (FDA) and the State Committee for Sanitary and Epidemiological Surveillance, and other Russian Government organizations held meetings to identify areas of collaboration on food safety issues. Possible areas of cooperation include consultations on the development of food safety legislation and consultation on laboratory testing methods for imported foods.

Strategy:

The primary strategy for collaborative efforts should continue to be the bilateral exchange of scientists and associated training activities which have proven mutually beneficial during the last several years. Specific projects (such as studies of vaccine immunogenicity/efficacy or applied research projects) and additional training workshops will be developed within the context of the scientific exchanges. Elaboration of these projects will require further consultation with relevant government and non-government institutions representing each country.

Near Term Objectives and Activities:

1. **Training and Exchange of Scientists/Experts:** The exchange of scientists in epidemiology and in the control of vaccines and vaccine preventable diseases has been extremely valuable in both countries. Current efforts should be expanded to include additional collaborating institutions (e.g. Ministry of Health); to focus on other health concerns of mutual interest (e.g. measles, meningococcal meningitis, food-borne diseases); strengthening surveillance systems and data analysis; and collaborative efforts in operational and applied research. The CDC training course in epidemiology for other NIS countries, scheduled for August 1995, will be expanded to include four (4) Russian scientists from the Ministry of Health. FDA will consult with the Ministry of Health and the State Committee for Sanitary and Epidemiological Surveillance to develop specific training opportunities for the 10 Russian scientists to be completed by September, 1995.

2. **Diphtheria Control:** During the next several months, finalization of a plan for a pilot project of enhanced diphtheria control efforts in two oblasts and selection of the oblasts will be completed by collaborating parties, and activities will be initiated. In addition to the above ongoing efforts in the area of diphtheria control, scientists and public health authorities for the U.S. and Russia support the expansion of collaborative investigations between CDC/FDA and Russian (Gabrichevsky and Tarasevich Institute) scientists using molecular biologic techniques to characterize current diphtheria isolates to include the adequacy of current vaccine production strains in the prevention of diphtheria. It is proposed that 1-2 Tarasevich scientists visit the U.S. for one month as part of this project.

3. **Improve Scientific Communications:** Publication of a joint quarterly or semiannual epidemiology bulletin would enhance transfer of each country's experience in epidemiology. Publication of a first issue which summarizes/reprints articles on specific areas (vaccine-preventable diseases, tuberculosis, etc.) for each country's previous 1-2 years will be initiated during the next three months.

   Exchange of new information and publications on laws, immunization schedules, safety and efficacy of vaccines, safety of blood and blood products, food safety and control, etc. by the CDC and FDA with the Ministry of Health and the State Committee for Sanitary and Epidemiological Surveillance should be expanded beyond current levels. Internet connections between collaborating institutions in the U.S. and Russia should be established.

4. **Food-borne Infectious Disease Prevention:** The FDA and the State Committee for Sanitary and Epidemiological Surveillance will consult on planning a workshop to discuss U.S. and Russian approaches to food inspection and control.

5. **Legislative Aspects of Control of Infectious Diseases:** Russian and U.S. authorities share perspectives on legislation to prevent and control infectious diseases, **particularly vaccine preventable diseases,** by exchanging existing and proposed legislation and regulations and by direct discussions of respective experts.

6. **Tetanus Strains:** Adequate strains of tetanus antigen during Clostridium tetani propagation are necessary for the production of diphtheria and tetanus containing vaccines. FDA and Immunogen firms should continue to discuss the possibility of production strain(s) of tetanus for antigen expression, and if appropriate, modifications to the strain and/or media made based on its outcome.

Longer-term Objectives and Activities

1. **Other Potential Areas for Collaboration-Vaccine Preventable Diseases:** Other potential areas for collaboration which merit further discussion include poliomyelitis (viral surveillance); measles (diagnosis, epidemiology, virology, neurovirulence, and duration of immunity);

rubella (vaccine development, control and epidemiology); meningococcal meningitis; hepatitis B (vaccine control strategy); blood safety (hepatitis B and C in vitro diagnostic kits); hepatitis A; and use/development of immunoglobulins to prevent opportunistic infections (e.g. cytomegaloinclusion virus (CMV); herpes simplex; Epstein Barr virus; and varicella zoster). Further discussions with relevant institutions in each country will be necessary to identify possible foci for information and scientific exchange.

2. **Diphtheria Control:** Potential collaborative projects which were discussed (but not resolved) include: (1) assessment of the impact of one versus two versus three doses of diphtheria toxoid on immunity levels among adults; and (2) evaluation of diagnostic criteria for diphtheria during the resurgence ("hyperdiagnosis").

3. **Manufacture and Control of Diphtheria/Tetanus containing Vaccines:** An adequate supply of good quality, safe and effective vaccines is critical to the control of vaccine preventable diseases. Currently the quantity of diphtheria/tetanus containing vaccines is sufficient to meet existing needs; however, the equipment of many of the Russian facilities is in critical need of updating and renovating to assure ability to meet production demands of GMP quality vaccines. New equipment in addition to newer techniques should make production capacity more cost efficient. Further discussion with Russian vaccine production firms are needed to support the development of a plan for the phased-in renovation and updating of a single facility, e.g., Biomed, and for instituting a program of GMP compliance, maintenance and evaluation. This plan would allow for either domestics or other funding to be sought.

Area Leads and Key Participants

U.S.

Stephen C. Hadler
Director of Epidemiology & Surveillance Division
Centers for Disease Control and Prevention

Elaine Esber
Assoc. Dir. for Medical & International Affairs
Food and Drug Administration

Russia

M. I. Narkevich
Deputy Director of the Department of Preventive Medicine
Ministry of Health and Medical Industry

A. A. Yassinsky
Chief, Department of Programmes
Deputy Head Sanitary Doctor
State Committee for Sanitary-and-Epidemiological Surveillance

HC4 - STRENGTHENING PRIMARY CARE PRACTICE

Background:

Both in the U.S. and in Russia, there is agreement that medical practice has become too specialized and expensive. A statement developed for a working paper of the World Health Organization and World Organization of Family Doctors, "*Making Medical Practice and Education More Relevant to People's Needs: The Contribution of the Family Doctor*," summarizes the global situation as follows:

> "To meet people's needs, fundamental changes must occur in the health system, in the medical profession, and in medical schools and other educational institutions. The family doctor (general practitioner/family physician) should have a central role in the achievement of quality, cost effectiveness, and equity in health care systems. To fulfill this responsibility, the family doctor must be highly competent in patient care and must integrate individual and community health care...."

To achieve its health care reform goals, the Russian Federation has proposed a transition to a new system based on the principles of primary care, mandatory health insurance, and the provision of family-centered health care. The principles, structure and transition to family-centered health care, provided by broadly trained family doctors and nurses, have already been promulgated by the Ministry of Health in 1992.

U.S. - Russian cooperation in this area was started by private sector initiative and exchange of family medicine professionals and academic teachers. The Maine Academy of Family Physicians, the Department of Family Medicine, Brown University, and the Moscow Medical Academy were among the initiators. In the fall of 1993, with support from the Health Resources and Services Administration (HRSA), PHS/HHS, an international conference on the Education of Family Physicians was held with major Russian participation. This has led to further efforts to secure funding for educational reform efforts and the development of family practice models.

Strategy:

Using the series of recommendations, arising from the WHO-WONCA 1994 Conference and paper (cited above), combined with the restructuring efforts of the Ministry of Health and Medical Industry and others such as the Moscow Medical Academy, effort will be made to identify opportunities at the governmental, academic, and community levels, as well as professional societies, to explore and develop appropriate models for reform and strengthening of family centered heath care in Russia.

Near-Term Objectives and Activities:

1. The U.S. and Russian area leads plan to meet in Moscow, this summer (mid-July?), in order to further develop the action plan and agree on participants for various exchange activities.

2. Using the AID-funded NET Program, a Russian team would be invited to the U.S. and divided into two sub-groups. The first group would focus on the practice of "Family Medicine" and the delivery of primary health care. Site visits would provide exposure to several models of "managed care" delivery including Health Maintenance Organizations (HMO's) where there is a strong family practice orientation and community involvement. The second group would focus on the education, teaching, and accreditation of "family physicians." The core host would be the Health Resources and Services Administration in Rockville, Maryland. There will also be links made to Brown University, Rhode Island, and their existing program with Russia for training family physicians and to the American Academy of Family Physicians (AAFP) in Kansas City.

3. Help Russian counterparts to meet established requirements to promulgate family practice.

   a. Monitor US projects already underway.

   b. Help Russian counterparts meet the existing requirements to promulgate family practice, by sharing resource materials and providing assistance with curriculum, faculty training, certification and accreditation.

   c. Develop educational and training materials in family medicine and use electronic E-mail to begin to build a network for disseminating information.

Longer-Term Objectives and Activities for Future Consideration:

1. Hold a five day "Workshop on Family Medicine Practice and Education" in Russia for 25 to 30 invited participants from the 8 to 10 medical schools in Russia. Presentations and workshop proceeding would focus on implementation status and strategies. (Time frame - April to May, 1996; needs funding to be carried out).

2. Establish standards and credentialing systems for both academic institutions training family physicians and individual family doctors.

3. Organization and sponsorship of a initial series of annual conferences on family medicine held at various locales in Russia to build an identifiable network of those involved in developing family medicine.

Ongoing Efforts in Primary Care Finance:

The Health Committee recognizes and endorses current USG-sponsored activities being carried out by USAID to assist Russia in its efforts to strengthen primary care practice. Such efforts consist of technical and financial support for the development of new models of primary care in four oblasts in Siberia; training of Russian health care policy makers, managers, and practitioners in the U.S. and Russia; and, technical support for legal and regulatory reforms necessary to establish and validate primary care practice in Russia. Part of the effort is directed towards restructuring polyclinics to form free-standing primary care units staffed by family physicians.

Area Leads and Key Participants

U.S.

Marc Rivo
Director, Division of Medicine
Health Resources and Services Administration

Russia

A. N. Demenkov
Director of the Department for the Organization
of Medical Assistance to the Population
Ministry of Health and Medical Industry

Relevant Key Background Document:

"Making Medical Practice and Education More Relevant to People's Needs: The Contribution of the Family Doctor," A Working Paper of the World Health Organization and the World Organization of Family Doctors, From the WHO-WONCA Conference, Ontario, Canada, Vov. 6-8, 1994

"On the Stage-by-Stage Transition to the Organization of Primary Care by the Principle of General Practitioner (Family Doctor)," Ministry of Health of the Russian Federation, Order No. 237, 26 August 1992,

"Fundamental Legislation of the Russian Federation on the Protection of Citizen's Health," House of Soviets of Russia, 22 July 1993, No., 5489-1.

HC5 - TUBERCULOSIS TREATMENT AND CONTROL

Background:

Both the United State and Russia have recently seen striking increases in the incidence of tuberculosis (TB) after years (or decades) of steady decline. In the U.S. the rise began in 1985 and has fortunately been turned around in the past two years. In Russia, the resurgence began in 1992 and there has been a nearly 40% increase in reported incidence in the past three years. In both countries multi-drug resistant tuberculosis (MDR TB) has become a serious problem, with nearly 30% of the organisms isolated in New York City in one period being resistant to at least two antibiotics and 40% of the isolates from Khabarovsk having similar resistance characteristics. In both countries deterioration of the public health infrastructure and migration from high prevalence areas have been important factors. Consequently, there is much the two countries have in common with respect to this new "old" problem.

Useful discussions have occurred (May 1995) between officials of the U.S. Centers for Disease Control and Prevention (CDC) and the Russian Scientific and Practical Institute of Phthisiopulmonology and the Central Tuberculosis Research Institute of the Russian Academy of Medical Sciences and a visit by experts to the Kaliningrad Tuberculosis Dispensary occurred.

Ten areas of collaboration are jointly proposed for the near term. Most of these involve specific actions during the period June-August, 1995, but a few will require further discussions and development of more specific plans of action as a prerequisite for further decision making and action.

Strategy:

A number of operational areas have been identified for which there is mutual interest. The most important technical and policy areas are: Ambulatory management of tuberculosis cases; multidrug resistant tuberculosis; tuberculosis in children; and extra-pulmonary tuberculosis. There is joint interest in the development of diagnostic tests and assessment of new drugs. Collaboration will be achieved principally by exchange of scientists, sharing of information and collaboration and collaboration in assessments and field tests.

Near-Term Objectives and Activities:

1. **Projects to Assess the effectiveness of Short-Course Ambulatory Therapy in Russia.** A project is planned in Ivanovo oblast with participation by WHO and Marion-Merrell-Dow with additional financial support from Operation Know How (U.K.). At least one additional similar project is proposed to be carried out, probably in Stavropol. CDC will participate with the Institute of Phthisiopulmonology in the design and technical oversight of these projects. CDC will also work with the Iowa Hospital Association to increase its involvement with Stavropol partners.

2. **Development and use of computerized systems for surveillance and case management.** CDC will provide copies of its software, documentation, and manuals for surveillance and case management (the latter as soon as it is made final). Copies of Russian programs will similarly be provided to CDC. A Russian language version of EpiInfo will also be provided by CDC. Should it appear useful, visits by information system specialists could be arranged, either to the U.S. or to Russia.

3. **Improving public education about tuberculosis.** The U.S. and Russia will exchange materials currently in use for public education about TB and CDC will contact the American Lung Association to seek their active participation with the Inter-Regional Tuberculosis Association (TUBASS) of Russia in developing educational materials outside the governmental sector.

4. **Epidemiological studies on tuberculosis.** Both countries have significant problems with multidrug-resistant TB. Information will be exchanged on the epidemiology of MDR TB and joint efforts will be undertaken to use Restriction Fragment Length Polymorphism (RFLP) and other molecular techniques to characterize the epidemiology of TB, particularly MDR TB, in various settings such as prisons, etc.

5. **Evaluation of diagnostic tests.** In both countries, exciting developments are taking place in the area of TB diagnosis, using polymerase chain reaction (PCR) technology, serological methods, and other rapid tests. Ways will be explored to share experiences and perhaps to jointly assess promising approaches. In addition, it may be possible to exchange antigen and antibody kits and other reagents.

6. **Exchange of Scientific publications.** Beginning immediately, the two institutions will share scientific publications and other programmatic documents.

7. **Studies on tuberculosis in children.** In both countries, there has been an increase in incidence of TB in children. A workshop was recently held in the United States to develop a research and action agenda addressing this problem. The proceedings of the workshop will be provided to the Institute as a basis for discussions of further collaboration.

8. **Studies on extrapulmonary tuberculosis.** In both countries there has been an increase in extrapulmonary tuberculosis, particularly in persons with compromised immune systems (in the U.S. primarily as the result of HIV infection). Information about extrapulmonary TB will be shared as a basis for discussions of further collaboration.

Longer-Term Objectives and Activities for Future Consideration:

1. **Evaluation of Newer Therapeutic regimens.** CDC is involved in a consortium of 10 institutions which have agreed to use common protocols in assessing new drugs or combinations. There will be further exploration of incorporating one or more Russian institutions into this consortium.

2. **A Joint U.S.-Russia Tuberculosis Conference** has been preliminarily agreed on, to be held in 1996 or 1997. Much work remains to be done to make this a reality.

Several other areas for collaboration seem promising but these are felt to be of highest priority at present. It is anticipated that the Director, Division of Tuberculosis Elimination, CDC, (U.S. co-lead) will visit Russia during mid-1995 to carry forward the planning.

Area Leads and Key Participants

U.S.

Alan Hinman
Assistant Surgeon General and
Senior Advisor to the Director
Centers for Disease Control and Prevention

Kenneth G. Castro
Director, Division of Tuberculosis Elimination
Centers for Disease Control and Prevention

Russia

A. A. Priymak
Director, Russian, Research Institute of Phthisiopulmonology
Ministry of Health and Medical Industry

HC6 - MATERNAL AND CHILD HEALTH

Background:

At the request of the Government of Russia (GOR), the G-C Health Committee decided at its first meeting to focus on the area of maternal and child health (MCH) as one of eight priority areas. Both the GOR Ministry of Health and the U.S. Government through the Agency for International Development (USAID), had already initiated activities in this area prior to the formation of the GCC Health Committee. The GOR had developed a federal-level "Safe Motherhood" initiative to reduce the maternal morbidity and mortality and improve infant health through a program of professional training, public education, and enhanced clinical technologies. The GOR also had introduced an initiative entitled "Children of Russia," designed to promote family planning and to address the special needs of handicapped children, orphans, and minority children. USAID had already initiated an oblast-level women's reproductive health project to reduce the maternal mortality and improve infant health through the promotion of modern contraceptive methods.

Ongoing USG-Support Efforts to Address MCH Issues:

In late 1994, USAID initiated a program in women's reproductive health designed to reduce levels of maternal morbidity and mortality by increasing knowledge and use of modern contraceptives. To date, a model family planning center has been developed in each of three oblasts: Leningrad, Sverdlovsk and Ivanovo. Training activities are underway in each of these locations. Educational materials for women and adolescents on the health benefits of modern contraceptives are being developed and consultations are underway with private sector contraceptive manufacturers to ensure enhanced commercial distribution of contraceptive products in project oblasts. In addition, discussions are being initiated at both the oblast and federal levels to promote broad-based, long-term support for reproductive health activities. By early 1996, project activities will be expanded to three additional locations, including sites in Siberia and the Far East.

In addition, USAID had also provided funding for a number of partnerships between U.S. and Russian hospitals which have resulted in small-scale activities in the areas of neo-natal resuscitation, infant cardiology, and reconstructive surgery.

Strategy:

In May 1995, the U.S. and Russian lead organizations in MCH, the Russian Academy of Medical Sciences, Center for Obstetrics and Gynecology and USAID, met to review the possible areas of collaboration. Both sides agreed that to the maximum extent possible it would be important to focus on activities that: (1) have public health impact; (2) build on existing programs; and (3) if practical, compliment other Health Committee priority areas. Both sides agreed that this collaboration would best be implemented via consultations of specialists, training programs, -

conferences, and the exchange of technical information such as treatment and diagnostic protocols.

Objectives:

The U.S. and Russian counterparts agreed that since both governments are currently undertaking activities in reproductive health, a first priority would be to support these activities, which among other things, would advance the common goal of decreasing reliance on abortion as a primary method of family planning. In addition, U.S. and Russian counterparts will explore ways and means by which these core activities can be expanded and strengthened to enhance the overall impact on health service delivery in this area. For example, the Russian side expressed an interest in USAID-sponsored seminars on current contraceptive technologies and the organization of "training of trainer" programs in reproductive health. The Russian side also expressed interest in an exchange of technical information on the major causes of infant and maternal mortality and appropriate treatment protocols.

In addition, the Russian side requested information about how the U.S. health information system records and categories maternal and infant mortality, and how this information is used to target health interventions. Finally, the Russian side indicated that it may be useful to exchange information on Sudden Infant Death Syndrome, as well as the psychological counseling of terminally-ill children.

Proposed Areas for Near-Term Collaboration:

1. In support of the GOR's goal of enhancing professional training in reproductive health, USAID and the Ministry of Health will jointly develop a three to four day seminar to be held in Moscow in early 1966 which will include discussions of modern contraceptive technologies, the organization of "training of trainers" programs, and interventions to reduce maternal mortality. USAID will provide speakers in each of these fields, as well as professional literature for participants. The MOH will organize the event and will recruit participants from outside Moscow with a special focus on oblasts not benefitting from ongoing USAID programs in reproductive health.

2. In response to the GOR's interest in establishing professional-level dialogue on Sudden Infant Death Syndrome, the USG, through the U.S. Public Health Service will investigate the possibility of providing a U.S. expert to the Ministry for short-term consultation and possible implementation of a MOH-sponsored seminar.

3. Through the U.S. Public Health Service, an effort will be organized to exchange U.S. diagnostic and treatment protocols for major childhood diseases, as well as the principle causes of maternal mortality and morbidity.

4. Through the U.S. Public Health Service, the U.S. and Russian sides will attempt to identify key elements of the U.S. health information

and vital statistics systems that may be relevant to and replicable in Russia. Special emphasis will directed towards how vital statistics can inform decision making.

Longer-term Objectives and Activities:

Both sides will continue discussions on additional activities that may be of mutual benefit. For example, the GOR has expressed an interest in the psychological counseling of terminally-ill children, as well as promoting breastfeeding through the adoption of the World Health Organization's "Baby Friendly Hospital" program. While no resources are currently available to fund such initiatives, it may be possible over time to build private sector support both in Russia and the U.S. for activities in these areas.

The MCH priority area will also look for opportunities for collaboration with the health education and infectious disease priority areas, especially in the area of childhood immunizations.

Area Leads and Key Participants

U.S.

Terrence Tiffany
Director, Office of Environment and Health
Agency for International Development

Russia

V. I. Kulakov
Director, Center for Obstetrics, Gynecology
and Perinatology of the Russian Academy of
Medical Sciences

Relevant Key Background Documents:

Summary of USAID Women's Reproductive Health Project

HC7 - HEALTH REFORM AND POLICY DIALOGUE

Background:

The United States and Russia share much in common and are each working on the national level to ensure that appropriate, affordable, quality health and public health services at affordable cost will be available to their respective peoples. As both countries work to meet their health care goals and implement health care reforms, many common threads can be found. Some of these common issues include quality of care, consumer access & satisfaction, health technology assessment and application, public health infrastructure, financing, data systems, and the role of the national ministry of health in this era of rapid change and reform. The rational application of data from health services research is key to successful improvements in these areas of health care.

Strategy:

Each country must find its own sovereign path through the complex series of technical, economic, and social issues to organize and help provide its citizens with health care. Nonetheless, in several areas an exchange of information and technical capabilities can lead to more effective approaches than might otherwise be explored. This area of cooperation is intended to bring together the senior officials representing the U.S. and Russian health authorities, their respective policy advisors, as well as selected organizations in both countries which are engaged in health policy and related work in the private sector. It will promote the exchange of relevant technical information.

Near-Term Objectives and Activities:

1. Meeting of the principals in settings and with sufficient time to engage in constructive dialogue and exchange of views.

2. Participation in respective policy meetings & seminars where key health issues are discussed, such as Russia's Public Health Forum in St. Petersburg, June 22-25, 1995. U.S. and Russian area leads are meeting for the first time at this conference.

3. Sharing of major publications (in print and electronic form) that frame health issues and help define priorities.

4. Collaborative efforts to exchange data and information on vital statistics and other indicators of public health status and health services utilization.

Long-Term Objectives and Activities for Future Consideration:

- consultation on health policy research methodology.
- consultation on topics of mutual benefit, including: ways to identify and enhance quality and consumer satisfaction; data collection and analysis methods; decentralization of health services; and health policy aspects of primary health care.
- exchange of health services researchers to observe development of clinical practice guidelines and other activities promoting improvements in data, quality of care, and cost-effectiveness in health care.

Other Ongoing Efforts to Address Health Policy Issues:

USAID has initiated a comprehensive program to increase economic efficiencies, quality of care, and access to provider choice through market-oriented reforms in the health finance and delivery system. Assistance has been focused on developing financing mechanisms which support the delivery of cost-effective services, creating health information systems so that rational resource allocations can be made, promoting quality assurance and expanded consumer choice.

Area Leads and Key Participants

U.S.

Clifton Gaus
Administrator
Agency for Health Care Policy & Research

Russia

Yuri M. Komarov
Director, Scientific Industrial Union of Medico-Social Research, Economics and Information
Ministry of Health and Medical Industry

HC8 - ENVIRONMENTAL HEALTH

Background:

In the U.S. and in Russia health authorities agree that human health is being adversely affected by environmental pollution. As a complex public health matter, there is need for cooperation at Federal, state (oblast) and local levels. Responsible action needs to be based on sound, science-based investigation and data. Given scarce resources for prevention, clean-up, and treatment, efforts need to be focused on problems of greatest risk. Actions ranging from legislation and regulation, to community and individual household effort need to be appropriately focused and decisions made to resolve problems should be based on data and include societal values.

This area of cooperation under the GC Health Committee, more than any other, is interdisciplinary and interagency in nature. It needs long-term government support, especially for the epidemiology and determination of causal linkages based on evidence. There is also a wide range of opportunities for public involvement, awareness, modifying behaviors, and community participation. Care must be taken, however, to be responsible in communicating risks and advocating change.

Strategy:

Under the Health Committee of the Gore-Chernomyrdin Commission and in close consultation with the GC Environment Committee, federal health and environmental authorities in the U.S. and Russia have agreed to address environmental health as a priority issue and begin planning a constructive program of cooperation. It will begin with a modest and low-key effort to work together on one or two sample issues that can be tackled within existing resources. The idea is to build linkages and long-term relationships across Ministry/agency lines and from federal-to-local government levels. Also involved will be academic research institutions and private voluntary organizations. A conference with breakout work group sessions will be the first activity. The topic selected is the adverse health effects of lead and heavy metals on children. Both U.S. and Russian data will be presented, epidemiologic approaches and analytic techniques examined, and conclusions challenged. Questions will focus on establishing causal relationships. If these can be demonstrated, then the focus shifts to problem solving and determining what to do to clean up, abate, or at least protect the most vulnerable populations such as newborns and growing children. Long-term collaboration will be enhanced by strengthening communication linkages and by sharing relevant computer software, programs, and establishing electronic mail connections via Internet among the major participating institutions.

Near-Term Objectives and Activities:

1. Over the next three months, gather relevant data, information, and summaries of analytic techniques useful for assessing adverse health effects of lead and heavy metals in vulnerable populations, such as children. Translate appropriate documents and research papers. Prepare notebooks for conference participants.

2. In preparation for this conference, and for the long term, establish internet e-mail connections among the participants.

3. By October 1, 1995, hold a conference/workshop, hosted by the Russian State Committee for Sanitary and Epidemiologic Surveillance and involving representatives from the Ministry of the Environment, the Ministry of Health, and the Academy of Medical Sciences. On the U.S. side, the Environmental Protection Agency and the U.S. Public Health Service, HHS will be major co-sponsors. Representation from State Department, U.S. AID, and other public and non-governmental organizations will be solicited.

4. Begin to collect, organize, and exchange data and information on environmental health issues. Begin with lead and heavy metals, gradually expand to cover other topics.

Long-Term Objectives and Activities for Future Consideration:

- Establishment of a Russian repository of environmental health data. Equip with computer, CD-ROM reader, and information expert to retrieve and exchange data from the wide range of sources available from using the Internet.

- Exchange information and analytic techniques for graphic representation of environmental health data, such as the use of maps. Exchange appropriate software and documentation.

- Start by working with one or two specific local sites in Russia, [Pair with a small number of U.S. locations with like problems, or past history] and work on problem solving at the State and community level. [Needs Discussion]

Ongoing Efforts in Environmental Health:

A substantial amount of existing and planned environmental activities are already underway which are being carried out under USAID support. These collaborative efforts involve U.S. and Russian organizations at the national and oblast levels consist of: pilot projects in four large industrial cities that address various pollution-related risks to human health; grants to Russian non-governmental organizations for environmental health education; environmental economics and policy support, including technical assistance for environmental risk assessment; pollution control; and monitoring equipment. USAID intends to strengthen and expand these efforts in the future, to the extent that resources permit. The Health

Committee will monitor the progress of these activities and explore ways in which it can lend additional support to these efforts.

Area Leads and Key Participants

U.S.

Anthony Rock
Director, Technical Competitiveness and Health
Department of State

Peter Henry, Ph.D.
Director, Office for Europe and the NIS, OIH/OASH
U.S. Public Health Service, HHS

Gary Waxmonsky, Ph.D.
Executive Secretary, U.S.-Russia Environmental Agreement
Environmental Protection Agency

Henry Falk, M.D.
Director, Division of Environmental Hazards and Health Effects
National Center for Environmental Health
Centers for Disease Control and Prevention, PHS, HHS

Russia

G. G. Onishchenko
Vice Chairman of "GOSKOMSANEPIDNADZOR"
Member of the Health Committee

Dr. Vladimir Chiburaev
Deputy Head Sanitary Physician of the Russian Federation
GOSKOMSANEPIDNADZOR

Dr. Alex Savinykh
Head, Foreign Relations Department
GOSKOMSANEPIDNADZOR

Ministry of Environment - To be Determined
Russian Academy of Medical Science - To be Determined

Relevant Key Background Documents:

USAID Environmental Health Strategy for the Russian Federation

TAB E

STATEMENT BY
DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES
GORE-CHERNOMYRDIN COMMISSION
JUNE 30, 1995
MOSCOW

VICE PRESIDENT GORE, PRIME MINISTER CHERNOMYRDIN,

I HAVE THOROUGHLY ENJOYED THE OPPORTUNITY TO WORK WITH MY RUSSIAN COUNTERPART, MINISTER EDWARD NECHAYEV.

RUSSIA HAS HAD A STRONG LEGACY OF ASSURING ACCESS FOR ALL ITS PEOPLE TO HEALTH SERVICES AND OF INTERNATIONALLY-RECOGNIZED RESEARCH IN BIOMEDICAL AND CLINICAL SCIENCES.

THE HEALTH COMMITTEE HAS MADE REMARKABLE PROGRESS SINCE ITS FIRST MEETING IN DECEMBER.

IN JUST SIX MONTHS WE HAVE DEVELOPED ACTION PLANS FOR OUR EIGHT PRIORITY AREAS AND ASSEMBLED RUSSIAN-AMERICAN TEAMS TO IMPLEMENT THEM.

OVER 100 RUSSIANS AND AMERICANS FROM MANY DIFFERENT GOVERNMENT AGENCIES AND THE PRIVATE SECTOR HAVE CONTRIBUTED THEIR TIME AND EXPERTISE TO CREATE THESE ACTION PLANS WHICH WILL ENABLE THE COMMITTEE TO TACKLE A WIDE VARIETY OF IMPORTANT HEALTH ISSUES.

PROGRAMMATICALLY, THIS COOPERATION INCLUDES ISSUES IN WHICH OUR COUNTRIES CAN LEARN FROM EACH OTHER AND WHICH HAVE DIRECT IMPACT ON OUR CITIZENS -- SUCH AS CONTROL OF TUBERCULOSIS AND DIPHTHERIA, SUPPORT OF IMPROVEMENTS IN MATERNAL AND CHILD HEALTH, AND HEALTH PROMOTION AND HEALTH EDUCATION, WITH A SPECIAL EMPHASIS ON REACHING OUR CHILDREN AND YOUTH EARLY TO INFLUENCE THEM TO MAKE HEALTHY CHOICES FOR THE REST OF THEIR LIVES.

TO FACILITATE WORK IN OUR PRIORITY AREAS, WE HAVE REACHED AGREEMENT ON THE USE OF E-MAIL AND OTHER INFORMATION TECHNOLOGIES FOR EXCHANGE OF DATA, EVERYDAY COMMUNICATIONS AND FOR ACCESSING EACH OTHER'S DATA BASES.

WE INTEND TO TAKE FULL ADVANTAGE OF THE INFORMATION SUPER HIGHWAY SO THAT EXPERTS IN OUR TWO COUNTRIES CAN COMMUNICATE REGULARLY. WE ARE ALSO EXCHANGING COMPUTER SOFTWARE AND PROGRAMS IN SPECIALIZED AREAS TO ACHIEVE SHORT-TERM RESULTS AND TO BUILD LONG-TERM CAPACITY.

AS YOU KNOW, WE HAVE HAD A MEMORANDUM OF UNDERSTANDING BETWEEN THE U.S. FOOD AND DRUG ADMINISTRATION AND RUSSIAN AUTHORITIES TO FACILITATE IMPORTATION OF FDA-APPROVED PHARMACEUTICALS INTO RUSSIA.

WE ARE PLEASED WITH THE PROGRESS MADE TOWARDS IMPLEMENTATION OF THIS AGREEMENT. AT OUR MEETING, HOWEVER, WE RECOGNIZED, THAT U.S. PHARMACEUTICAL FIRMS COULD MAKE BETTER USE OF THE AGREEMENT IF A PROCEDURAL ANNEX WERE DEVELOPED TO MAKE IT MORE USER-FRIENDLY TO U.S. FIRMS. OUR NEW GOALS INCLUDE STANDARDIZING THE APPLICATION FORMS AND DEVELOPMENT OF A JOINT TRAINING PROGRAM.

WE ALSO AGREED TO SET UP A NEW WORK GROUP, INCLUDING THE U.S. DEPARTMENTS OF COMMERCE AND DEFENSE, THE OVERSEAS PRIVATE INVESTMENT CORPORATION, USAID AND MY DEPARTMENT, ON THE U.S. SIDE, AND THE MINISTRY OF HEALTH AND MEDICAL INDUSTRY AND OTHER APPROPRIATE ORGANIZATIONS ON THE RUSSIAN SIDE TO ADDRESS THE SPECIFIC OPPORTUNITIES AND OBSTACLES TO THE AVAILABILITY OF CRITICAL DRUGS AND MEDICAL SUPPLIES IN OUR PRIORITY HEALTH AREAS, ESPECIALLY DIABETES, FAMILY PLANNING, AND VACCINES AND SERA.

I BELIEVE OUR AGREEMENT TO CREATE A WORK GROUP REFLECTS OUR ENTHUSIASM FOR ADDRESSING ISSUES RELATED TO TRADE AND INVESTMENT IN THE HEALTH SECTOR. WE WILL COORDINATE OUR EFFORTS WITH THE MEDICAL EQUIPMENT, PHARMACEUTICAL AND HEALTH SERVICES SUBGROUP OF THE BUSINESS DEVELOPMENT COMMITTEE IN THIS EFFORT.

OUR COMMITTEE ALSO SHARES SOME OF THE CONCERNS DISCUSSED YESTERDAY ABOUT TARIFFS, PARTICULARLY FOR THOSE PHARMACEUTICALS AND OTHER MEDICAL PRODUCTS WHICH ARE NOT PRODUCED IN ADEQUATE SUPPLY IN RUSSIA AND ARE DESPERATELY NEEDED.

ON WEDNESDAY, MINISTER NECHAYEV AND I VISITED BAXTER INDUSTRIES' MOSMED PLANT, A JOINT VENTURE WITH A RUSSIAN PARTNER THAT USED TO MANUFACTURE MISSILE GUIDANCE SYSTEMS. THIS SUCCESSFUL DEFENSE CONVERSION IS NOW PRODUCING WORLD CLASS SURGICAL INSTRUMENTS. [HOLD UP SURGICAL CLAMP THIS IS AN EXCELLENT EXAMPLE OF WHAT TRUE PARTNERS CAN DO AND OF THE BUSINESS OPPORTUNITIES THAT EXIST IN THE HEALTH SECTOR.

OUR COMMITTEE AGREED UPON MANY ACTIVITIES AND PROJECTS, BUT THERE ARE A FEW WHICH I WOULD LIKE TO HIGHLIGHT --

DIABETES IN WHICH MODELS FOR ALTERNATIVE APPROACHES TO DIABETES CASE MANAGEMENT WILL BE PURSUED, INCLUDING TRAINING OF HEALTH PROFESSIONALS IN A TEAM MANAGEMENT APPROACH, WHICH STRESSES

EDUCATION OF PATIENTS AND THEIR FAMILIES. ON THE U.S. SIDE, A NUMBER OF PRIVATE SECTOR ORGANIZATIONS ARE INVOLVED, INCLUDING ONES IN MINNEAPOLIS, MINNESOTA, AND LACROSSE, WISCONSIN. OUR AMERICAN DIABETES ASSOCIATION AND OTHER NON-GOVERNMENTAL ORGANIZATIONS ARE INTERESTED AS WELL, ALONG WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION IN MY DEPARTMENT. U.S. INDUSTRY

WILL ALSO BE A PARTNER. I SHOULD NOTE THAT ELI LILLY HAS DONATED HUMULUN INSULIN FOR PROJECT ACTIVITIES WITH THE LACROSSE/DUBNA PROJECT.

COOPERATION ON TUBERCULOSIS WILL INCLUDE ASSESSMENT OF EFFECTIVENESS OF SHORT-COURSE AMBULATORY THERAPY IN RUSSIA. MARION MERRELL DOW WILL DONATE TWO OF ITS LEADING PRESCRIPTION PRODUCTS FOR USE IN A TREATMENT TRIAL, WHICH WILL BEGIN NEXT MONTH.

WE ARE EXTREMELY PLEASED TO WORK WITH THE RUSSIAN FEDERATION ON THE DIPTHERIA ISSUE, INCLUDING PILOT STUDIES OF ENHANCED DIPTHERIA CONTROL IN TWO OBLASTS. THESE WILL BE CARRIED OUT WITH USAID SUPPORT AND INVOLVE OUR CENTERS FOR DISEASE CONTROL AND PREVENTION IN CLOSE COOPERATION WITH RUSSIAN AUTHORITIES. BOTH OF OUR COUNTRIES AND OTHERS IN THIS REGION AND THE REST OF THE WORLD WILL BENEFIT FROM THE INFORMATION GAINED.

WITH THE SUPPORT OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY, THE STATE DEPARTMENT AND OUR CENTERS FOR DISEASE CONTROL WE WILL COOPERATION WITH RUSSIAN COLLEAGUES ON A WORKSHOP STYLE CONFERENCE THIS FALL ON HEALTH EFFECTS OF LEAD AND OTHER HEAVY METALS ON CHILDREN. THIS COMPLEMENTS PLANS FOR THE BROAD PROGRAM, SUPPORTED BY USAID, TO REDUCE ENVIRONMENTAL RISKS TO PUBLIC HEALTH ADOPTED BY THE ENVIRONMENTAL COMMITTEE.

LASTLY, THE MINISTER AND I WERE HONORED ON WEDNESDAY TO ANNOUNCE THE FIRST U.S.-RUSSIAN PUBLICATION OF VITAL AND HEALTH STATISTICS. THIS VERY IMPORTANT EFFORT TO PROVIDE STANDARDIZED DATA, USING INTERNATIONALLY RECOGNIZED DEFINITIONS THAT CAN GUIDE HEALTH PLANNERS AT ALL LEVELS TO IMPROVE PUBLIC HEALTH. **(HOLD UP DOCUMENT)** IT IS BEING TRANSLATED NOW INTO RUSSIAN. IT WILL BE UPDATED REGULARLY.

AGAIN, AS YOU CAN SEE, OUR COMMITTEE HAS BEEN VERY PRODUCTIVE, LARGELY BECAUSE OF THE STRONG LEADERSHIP OF MY DISTINGUISHED COLLEAGUE AND GOOD FRIEND, MINISTER NECHAYEV.

THANK YOU MR. VICE PRESIDENT AND MR. PRIME MINISTER

Shalala Urges US Investment in Medicine

By Andrea Smith
The Moscow Tribune

Putting on a pair of goggles and a toothy grin, US Secretary of Health and Human Services Donna Shalala gave every indication of being genuinely interested in the filing and polishing of surgical instruments during a tour of the US-Russian MosMed joint venture on Wednesday.

"I want to say to the workers that they demonstrate Russian workers can do world-class work," she said as she fiddled with a sample pair of stainless steel surgical clamps.

Shalala is in Moscow this week to meet with her Russian counterpart Health Minister Eduard Nechayev within the framework of the commission formed by US Vice President Al Gore and Russian Prime Minister Viktor Chernomyrdin, one of the goals of which is to promote US investment in Russia.

A joint venture between the medical manufacturing giant Baxter International and the NIIAP factory of the Research Institute for Automation and Instruments, the MosMed plant has been held up as a model endeavour since it began production of stainless steel surgical instruments in autumn of 1993.

At a Ministry of Health press conference that evening, Shalala played down federal sources for Russian health funding and played up private investment: "We want to attract American companies into joint ventures as well as provide them access [to the market to sell their products]."

On Wednesday evening, the two senior health officials said they had worked out six action plans and were finalising two others.

"This week in the Russian newspapers there was a discussion of the very high mortality rates for children. Two of our projects aim to work on that issue," Shalala said, naming the Health Promotion Project which focuses on women's nutrition, and the Project on Primary Care, whose goal is ensure there are enough family doctors.

The ministers also announced that a report of the vital health statistic of Russia for the past several years had been prepared as well. It will be presented to Chernomyrdin this week and was not immediately available to the public.

While Shalala stressed the commission's concern with providing prenatal care to women and the health of young children, Nechayev said perhaps the most serious agreement concerned a "mutually trusting approach" on the quality control of drugs.

One of the new programmes aims to speed up US investment into the production and distribution of pharmaceuticals. Three US pharmaceutical companies — including Bristol Myers Squibb — have received USAID grants to render technological help and prepare personnel.

Photo by Olga Shalygin/AP

MosMed employee Lyudmila Borisova, left, finishes a pair of surgical clamps produced at the Moscow facility while US Secretary of Health Donna Shalala watches. Shalala is in Moscow in connection with the Chernomyrdin-Gore Commission meetings.

fax to bacon

FAX TRANSMISSION
DEMOCRATIC OFFICE OF
THE UNITED STATES SENATE
COMMITTEE ON LABOR & HUMAN RESOURCES

TO: Melanne Verveer

FROM: Nick Littlefield

FAX #: 202-456-6244

DATE: September 4, 1997 **TOTAL PAGES *INCLUDING COVER*** 5

If there are any problems receiving this transmission, please call (202) 224-0767.

Return fax #: *(202) 224-5128*

United States Senate
WASHINGTON, DC 20510-2101

September 4, 1997

Melanne Verveer
Deputy Assistant to the President
and Chief of Staff to the First Lady
The White House
1600 Pennsylvania Ave, NW
Washington, DC 20500

Dear Melanne:

After you have a chance to look at this memo, I hope we can talk.

It's our best hope for new funding for children. We need the President and the First Lady to make it happen.

Sincerely,

Nick

Nick Littlefield

Analysis Of Federal Claims For Compensation From The Tobacco Industry

I. Doubling the settlement amount is reasonable.

1. The federal government's claim to recover costs incurred to treat tobacco-induced illnesses under Medicare and other federal health programs is directly analogous to the claims of the states for recovery of Medicaid costs. Having already conceded the industry's liability for Medicaid costs by agreeing to settle those claims for billions of dollars, tobacco companies cannot credibly deny similar liability for costs under Medicare and other federal programs. Currently, the proposed settlement does not contain even one dollar in compensation for these large federal costs.

2. The amount of the proposed settlement between the tobacco industry and the State Attorneys General has been described by them as $368 billion over 25 years, covering both the state and federal share of Medicaid costs. An analysis done by MIT Health Economist Dr. Jeffrey Harris found that the present value of the settlement is $194.5 billion. (Testimony before Senate Judiciary Committee July 30, 1997)

3. Dr. Harris also analyzed the costs of tobacco-induced illnesses under Medicare and determined that it is $9.3 billion per year. Others estimate the costs to be substantially higher. The present value of the cost of smoking under Medicare over the next 25 years would be $192 billion. Thus, to compensate the federal government for Medicare on the same terms as the states are to be compensated for Medicaid would require a doubling of the current settlement amount.

4. The federal government also incurs large costs for treating tobacco-induced illnesses in veterans health programs and in health care programs for active duty military personnel and civilian government employees. Therefore, the overall uncompensated costs as a result of smoking are enormous. Estimates of the overall costs to the federal government exceed $20 billion per year.

II. The industry can afford to pay double the current settlement amount.

1. Except for the initial $10 billion payment, all tobacco industry payments will come from price increases. Unless there is a dramatic reduction in the number of cigarette packs purchased, the size of the settlement will not significantly affect the tobacco industry's bottom line. The tobacco industry is merely acting as a pass-through agent for funds raised from tobacco consumers.

2. Because of the addictive nature of tobacco, adult cigarette consumption is relatively immune to price increases. The most substantial reduction which occurs as prices rise is in the youth market. Because youth are not yet addicted they can be deterred by higher prices. A major increase in cigarette prices will produce a double benefit -- substantial additional funds, and a substantial reduction in youth smoking.

3. The current settlement proposal would increase the price of a pack of cigarettes by approximately sixty-five cents to a post-settlement price of about $2.60 per pack. Dr. Harris has determined that if the per pack price is raised by $1.50, to a total price of $3.45, the present value of the settlement over the next 25 years would be $427 billion, as compared to $194.5 billion under the current proposal. A price increase in the range of $1.50 per pack would substantially reduce youth sales, and would compensate the federal government for its Medicare claim and a portion of its other claims.

4. Cigarette prices in Europe are already far higher than the $2.60 post-settlement price of cigarettes in America. Notwithstanding the substantially higher prices, cigarette consumption rates in Europe are equal to or higher than the American rates. In Germany, cigarettes sell for $3.18 per pack. In France they sell for $3.47 per pack. In Denmark they sell for $4.75 per pack. In Ireland, they sell for $4.94 per pack. And in Great Britain, they sell for $5.27 per pack. Clearly, the cost of a pack of cigarettes in the United States can be raised substantially above the proposed settlement amount and still be well below the price in most European countries.

5. There is broad support in the public health community for a price increase of as much as two dollars per pack. Dr. Koop and Dr. Kessler, and the members of their commission have endorsed such an increase, and the American Cancer Society is strongly supporting it. These public health advocates have been the Administration's strongest allies in the battle against the tobacco companies.

6. The tobacco industry will ultimately agree to pay a substantially larger settlement amount. The industry is unlikely to walk away from a settlement at this point. By entering into a highly publicized agreement with the State Attorneys General, the industry has admitted (1) that cigarettes are deadly, (2) that tobacco companies owe billions of dollars in compensation for tobacco-induced illness, and (3) that broad new restrictions on cigarette marketing are reasonable and appropriate. Having made these admissions to the American public, the industry cannot return to the days of total denial. The only real issue to discuss is the amount of compensation which the industry should pay. Doubling the amount of the proposed settlement is both justifiable and affordable.

III. **Funds from the tobacco settlement could be a substantial source of revenue for new federal programs.**

1. Funds obtained from the tobacco settlement are likely to be one of the largest sources of new revenue for major initiatives for the remainder of the Clinton Administration. The tobacco companies can and should pay more -- either through a higher settlement amount or a higher federal cigarette tax.

2. There are many possible uses for the additional $10-$15 billion a year that can be raised from a fair and responsible tobacco settlement. The opportunity to capitalize on the new knowledge about the critical role that the 0-3 years play in child development seems most promising. With this amount, the President could launch an initiative that could transform the lives of literally millions of children. There are few more important achievements for the President's second term. Another possibility would be to take a major step toward completing the work begun in the recently enacted children's health insurance program by extending insurance to low and moderate income working adults.

CHART #3 -- INTERNATIONAL TOBACCO PRICES

(Note: In U.S. dollars)	TAX (Federal, State, and Sales)	PRICE OF CIGARETTE PACK	TAX AS % OF RETAIL PRICE
Denmark	$4.02	$4.75	85%
Ireland	$4.16	$4.94	84%
United Kingdom	$4.30	$5.27	82%
France	$2.61	$3.47	75%
Germany	$2.28	$3.18	72%
Sweden	$3.13	$4.47	70%
Canada	$2.05	$3.06	64%
U.S. (w/$1.50 hike)	**$2.15**	**$3.44**	**63%**
U.S. (w/62-cent hike)	**$1.27**	**$2.56**	**50%**
U.S. (currently)	$0.65	$1.94	33%

file tobacco

POLITICS & POLICY

Opponents of Tobacco Pact Face Big Hurdle

By MICHAEL K. FRISBY
Reporter of THE WALL STREET JOURNAL

WASHINGTON – At a White House meeting on tobacco, Vice President Al Gore displayed a kids' puzzle featuring the Marlboro Man. It was a toy, he told the group, but if you looked closely, cigarettes were plastered all over it.

As President Clinton's tobacco advisers met with former Surgeon General C. Everett Koop and ex-Food and Drug Administration chief David Kessler, administration officials said, Mr. Gore sent a strong message with the toy: When you think the tobacco industry is on the run, they still find ways to market their products.

Al Gore

Mr. Gore said the puzzle belonged to a teenager who had quit smoking. "Whenever he played with the puzzle, he said that it made him want to smoke again," the vice president told the meeting last month.

It was a brief but important moment in the White House's review of the proposed tobacco settlement. Mr. Gore, who is skeptical of the deal, was able to outline some of his differences with the industry. The vice president, Health and Human Services Secretary Donna Shalala and First Lady Hillary Rodham Clinton have long been among the administration's strongest opponents of smoking. But in this latest fight, they face a major hurdle: The person who matters most, the president, wants to approve a deal.

Uncomfortable Positions

Clearly, this puts Mr. Gore, Ms. Shalala and their antismoking allies in uncomfortable positions. Whatever their views, it is their job to help Mr. Clinton succeed at policy missions. Still, there are signs that they are finding ways to express their doubts about the settlement, as well as bring about changes they believe are needed.

The settlement channels $368.5 billion from the industry toward public health and imposes restrictions on tobacco advertising and marketing, while granting the industry immunity from punitive damages for past misconduct and making it harder for the FDA to regulate nicotine.

At a cabinet meeting yesterday, Ms. Shalala voiced her belief that FDA regulations must not be weakened by any settlement with the industry, and her cabinet colleagues strongly agreed. Even before that meeting, Ms. Shalala flashed her skepticism, saying in an interview that the industry has "sophisticated marketers" who no doubt already are dreaming up sales pitches for decades ahead. "Any agreement must leave the FDA nimble and flexible enough to respond to changes in the market in order to achieve our public-health goals," she said.

Donna Shalala

Mr. Gore, moreover, was instrumental in getting the White House to lay down two important requirements: that any deal couldn't limit the government's ability to regulate nicotine, and that there must be increases in the penalties to be paid by tobacco companies if they don't reduce youth smoking.

At times, though, Mr. Gore seems awkward with his dual roles. During the Kessler-Koop meeting, which Mr. Gore ran in place of the president, he repeatedly fired off objective questions to the guests. When making critical remarks, he would begin by saying, "I personally think. . . ." Still, he used the forum to focus attention on the penalties issue, which he later championed.

Critics Worry

Outside critics of the tobacco deal, however, worry about whether their allies in the administration are influencing the review enough. "My sense is that the president has his mind made up and that he wants a deal," says Alan Morrison, a lawyer with Public Citizen, a public interest group. In advocating changes, Mr. Morrison said antismoking groups find it more effective to funnel information through lower-level people instead of meeting with principals.

Missing in action has been Mrs. Clinton. She created a public flap by criticizing the smoking of actress Julia Roberts in the movie, "My Best Friend's Wedding." But neither the first lady nor her top advisers have attended meetings related to the settlement review, and they haven't been calling HHS looking for information. Administration officials describe Mrs. Clinton as a strong opponent of smoking, but someone who isn't yet playing a role in the settlement.

Health organizations hope that Ms. Shalala will help fill the void, but she, too, may be handicapped by the process.

On most issues involving a number of agencies, cabinet secretaries funnel their positions to Bruce Reed, who heads the White House Domestic Council. He, then, plays the honest broker and forwards to Mr. Clinton the information that will help the president shape his policy decision. In this case, Ms. Shalala has been appointed to head the task force review with Mr. Reed, giving her the added responsibilities of channeling advice to the president from her colleagues along with her own opinions. There is some concern among the antismoking people that the dual role may prevent Ms. Shalala from being as critical of the settlement as she might otherwise be.

Doing Both Jobs

Still, the HHS secretary may have found a way to do both jobs. With Mr. Reed, and sometimes alone, she has met with numerous groups that have problems with the settlement proposal. Some who have talked with her are convinced that she is gathering information that she can use to advocate major changes in the deal when she delivers her recommendations to Mr. Clinton.

After meeting with Ms. Shalala, Mohammad N. Akhter, executive director of the American Public Health Association, said, "She was very sympathetic to the concerns that I raised." Mr. Akhter, whose organization represents public-health associations, wants to make the industry apologize for its past behavior and to prevent the industry from selling more potent cigarettes overseas.

Those familiar with Ms. Shalala's view agree that she, like the vice president, is skeptical about the deal. She does, however, see it as an opportunity to get some things from the industry – a focus on nonsmoking that goes beyond teenagers to all Americans, and substantial money for public health – that greatly exceeds what the administration would have achieved solely with its FDA regulations.

Her big difference with Mr. Reed, however, is in their views of what the courts are likely to do with the FDA regulations. A federal court in North Carolina has upheld the FDA's jurisdiction to regulate tobacco but has struck down the agency's proposed limits on tobacco advertising. Ms. Shalala is said to believe strongly that the regulations will be upheld in the courts, while Mr. Reed is less certain the administration can win back the advertising limits. Both the government and the industry are appealing parts of the decision.

Those diverging views mean that Ms. Shalala may push for a tougher deal, since she believes the regulations are a strong fall-back if the industry refuses to give up more. Ms. Shalala is also very concerned that any package coming out of Congress may not look like what the administration recommended. Meanwhile, Mr. Reed, as well as Bruce Lindsey, another key Clinton tobacco adviser, argue that a negotiated deal is needed because they could lose in court.

GOP 2000: Outsiders Are Back In

Potomac Watch

By Paul A. Gigot

There may be a silver lining in the overstuffed, overhyped budget deal signed this week by President Clinton: It means Bob Dole won't be the Republican nominee for president in 2000.

Not literally Mr. Dole, who had his run. But the Dole type, the congressional baron, a Cal Ripken of Sunday talk—every such Beltway insider suddenly looks much less formidable. The budget deal may help GOP House and Senate incumbents in 1998. But the deal's deflating, quarter-loaf compromises also hurt the chances that any of these pols will lead the party back to the White House in 2000.

That's bad news for ambitious House potentates Newt Gingrich and John Kasich. But it's good news for Dan Quayle and Steve Forbes and the many governors mulling a run against Al Gore's Washington. Republican outsiders are in again—which can't be all bad, considering that the last two GOP presidential campaigns were lost by insiders.

John Kasich

The return of the outsider would restore what used to be a Republican strength: The sense that the GOP wanted to change Washington, not just occupy it. This is the natural posture for the party skeptical of federal power.

It was turned on its head in 1996 amid the euphoria of the 1994 GOP congressional takeover. Republican primary voters didn't need another insurgent hero because the barbarians were already inside the gates. Once Bob Dole aligned himself with the reformers as their adult supervision, he was impossible for any other Republican to beat.

But, paradoxically, he was easier for Bill Clinton to beat. There was no candidate of change in the race, merely two versions of the Washington status quo. Mr. Gingrich, not given to self-doubt, still won't admit this. On Fox News Sunday this week, he dismissed Jack Kemp's gentle critique of the tax cut with the sneer that "Jack didn't win" as Mr. Dole's running mate. Never mind that the ticket was hauling around a 1,000-pound political ball-and-chain called Speaker Gingrich.

Even Republicans won't don this deadweight again. It's no accident that two GOP senators with presidential hopes, Fred Thompson and John Ashcroft, both voted against the budget deal. And outsiders are caustic. Steve Forbes says the GOP Congress "acted like a legislative party instead of a national majority, agenda-setting party. In every group I've spoken to there's a deep sense of frustration that the revolution has been lost."

Dan Quayle, now ensconced in Arizona, says, "I understand the virtue of compromise, but their mistake was to make compromise their top priority. This was supposed to be a Contract With America, not a Contract With Clinton." That's a good line and smart triangulation, targeting both the incumbent Democrat and Beltway GOP.

Untainted by Clintonism, the outsiders will be able to lead with bolder colors. They can concentrate on taking power, not just preserving it. For all of his talk of vision, Mr. Gingrich's priority now is keeping control of the House. Trent Lott has shown himself to be a transaction politician, "Dole with a drawl," as his colleagues put it. The insider with the best chance to resist this taint is Arizona Sen. John McCain, whose war record gives him status beyond Congress.

As for Mr. Kasich, a "balanced budget" was supposed to launch him onto the national stage. His admirers now say he'll pocket that achievement, such as it is, and move on to bigger themes. But his hyperbolic selling of the budget deal—calling it a "dream come true"—reveals a man who's inhaled too much Clintonian spin. Having passed the most complicated tax bill in history, he also isn't the most credible salesman for tax reform. If the balanced budget evanesces in recession, Mr. Kasich can pack for Columbus.

Frank Keating

It's impossible to know, this early, which GOP outsiders stand to benefit the most. Texas Gov. George W. Bush is on everyone's short list. But the field is wide open because for the first time since 1967 the GOP has no clear national leader. And for the first time since perhaps 1940, it has no clear front-runner for the nomination.

The field may be wide open enough to entertain even longshot unknowns like Oklahoma Gov. Frank Keating. His approval rating is 67%, he's passed numerous reforms through a Democratic legislature, and he handled a genuine crisis, the 1995 Oklahoma City bombing, in presidential fashion. He has also been shrewder than Mr. Bush on taxes, capping property levies with a statewide referendum, rather than trying to raise some taxes in order to cut others.

If he wins re-election in 1998, says Mr. Keating about a presidential run, "yes, I'm going to look at it."

Oklahoma Secretary of State and Keating adviser Tom Cole says the 2000 GOP contest now looks to him like the 1976 race among Democrats. The media focused on Beltway runners, but Democrats nominated an obscure, clean-living peanut farmer. After eight years of Clintonism and six of the Gingrich Congress, Republicans will want their own new voice. And they will need one.

THE WALL STREET JOURNAL FRIDAY, AUGUST 8, 1997