NLWJC - Kagan
DPC - Box 052 - Folder-014

Tobacco-Settlement: Public Health Reports [1]

ToL-re-public health reports

Office of Communications and Advocacy
1150 Connecticut Avenue Northwest Suite 810 Washington, DC 20036
Tel 202 785 7900
Fax 202 785 7950
http://www.americanheart.org

American Heart AssociationSM
Fighting Heart Disease and Stroke

For Release:
April 20, 1998

Contacts:
Robyn Landry or Mary Wood
(202) 785-7900

cc: EK
Chris
CR+CD

Statement of M. Cass Wheeler
Chief Executive Officer
American Heart Association

Regarding Tobacco Control Legislation
Introduced by Senator McCain

Now is the best opportunity Congress has ever had to enact strong tobacco control legislation. The bill sponsored by Senator John McCain is a good starting point, but the American Heart Association feels it should go further in protecting the health of our children.

The legislation has many positive points. It places strong restrictions on youth access to tobacco and limits the industry's ability to market and advertise to children. We also support the bill's international tobacco control provisions.

While the bill provides a good foundation for Congress to build on, the American Heart Association has identified a number of areas that need strengthening:

- The proposed price increase of $1.10 over five years is too low to drive down youth smoking rates. A price increase of $1.50 over two to three years is necessary to stop kids from using tobacco.
- Tobacco companies should pay higher penalties if they fail to meet their goals to reduce teen smoking rates. The penalties should be company-specific and should not be capped.
- The bill does not specify the levels of funding dedicated to tobacco-related public health programs. The American Heart Association wants to make sure any legislation includes adequate funding for programs like counter marketing and tobacco cessation.
- The legislation should include stronger measures to protect people from the hazards of second-hand smoke. States must not be allowed to opt out of clean indoor air provisions.
- Since the tobacco industry is no longer at the table, we question why any industry immunity is even included in the legislation.

The American Heart Association will continue to work with Congress to pass the best possible tobacco control plan. We also want to ensure that the Food and Drug Administration has comprehensive authority over tobacco products.

But the industry is trying once again to frame the tobacco control legislation as being all about "big taxes" and "big government." This is just another in a long string of tobacco industry lies, and the American people aren't falling for it. We all know that this fight is about saving lives and protecting our children.

Each day that America waits for Congress to act, 1,000 more people die from tobacco-related illnesses. And 3,000 more children start using tobacco products. America has waited long enough. Because waiting isn't just a matter of lost days – it's a matter of lost lives.

-30-

Tob-rr-public health outreach

THE WHITE HOUSE

WASHINGTON

April 29, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Meeting with David Kessler

While both Drs. Koop and Kessler have been critical of the McCain bill -- particularly with regard to the liability cap and the lack of company specific lookback penalties -- Dr. Kessler has been the less outspoken of the two. He has said that the bill's programs to reduce the number of children who smoke are too weak, and its protections for the tobacco industry are too strong. He believes that the price per pack of cigarettes needs to be raised by $2 to prevent teens from smoking, instead of the $1.10 contained in the bill.

Your goal for this meeting should be to persuade him that we need to work hard, and work together, in order to ensure passage of comprehensive tobacco legislation that achieves our public health goals. He needs to understand that we should be reasonable in our demands, and that we will need to work hard to preserve the gains we have made in terms of the FDA provisions. You may want to say:

- The McCain bill represents dramatic progress. The 19-1 vote in the Senate Commerce Committee shows that we have real momentum in both parties to pass comprehensive tobacco legislation this year.

- You have done a tremendous job over a number of years to reduce youth smoking, and we very much appreciate your ongoing efforts in this area.

- We agree that there need to be strong company specific lookback penalties, and we will continue to work with Congress toward achieving that goal. However, we also believe that we need to be reasonable in our demands.

- We will work hard to make sure the public health programs such as cessation and counter-advertising get funded.

- We have to work every bit as hard to protect the progress we have already made on FDA and other issues. Our #1 enemy is a skinny bill.

- We need the public health community to go all-out at the grassroots, in the media, and on the Hill to get this done. This is crunch time, and only a concerted push will counter the industry's $50 million ad campaign.

Tob-sr-
public health outreach

THE WHITE HOUSE

WASHINGTON

April 28, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: Bruce Reed

SUBJECT: Meeting with ENACT

Secretary Shalala will join you for your meeting with ENACT. This list of group participants will be:

Matthew Myers, Vice President and General Counsel, Campaign for Tobacco-Free Kids
Bill Novelli, President, Campaign for Tobacco-Free Kids
Marilyn Hunn, Chairman of the Board, American Heart Association
Dr. Joel Alpert, President-Elect, American Academy of Pediatrics
Dr. John Seffrin, CEO, American Cancer Society
Rich Deem, Vice President of Federal Affairs, American Medical Association
Dr. D. Robert McCaffree, President, American College of Chest Physicians
Dr. Jonathan Fielding, American College of Preventive Medicine
Dr. Bob Graham, CEO, American Academy of Family Physicians
Jud Richland, Executive Director, Partnership for Prevention
Tom Milne, Executive Director, National Association of City and County Health Officials
Diane Canova, Vice-President, American Heart Association; Chair, ENACT Coalition

As you know, ENACT is a coalition of public health groups interested in the youth smoking issue. These groups are generally more moderate than Drs. Koop and Kessler; indeed, Campaign for Tobacco-Free Kids was intimately involved in the negotiations that led to the June 20th settlement. Like the Administration, ENACT is generally supportive of the McCain bill, but would like to see some improvements to it. In a recent Washington Post op-ed piece, Matt Myers called for: a price increase of $1.50 per pack, tougher lookback penalties, a stronger environmental tobacco smoke provision, and sufficient funding for public health purposes (cessation, prevention, counteradvertising, etc.).

You should use the meeting to make three points: (1) that they must keep insisting on a comprehensive approach with the McCain bill as the vehicle, so that Speaker Gingrich and others know that a piecemeal or "skinny" bill will not fly; (2) that we have to set priorities, and be reasonable in our demands, so that we do not kill the chances for good legislation; and (3) that this is a make-or-break time, and we need them to pull out all the stops on the Hill and at the grass roots. You can say:

- You have played a tremendous role in keeping the pressure on Congress to pass comprehensive tobacco legislation designed to reduce youth smoking, and you should be

commended for all your hard work.

- The McCain bill represents dramatic progress. The 19-1 vote in the Senate Commerce Committee makes the McCain bill the vehicle to use to pass comprehensive tobacco legislation this year.

- Our #1 enemy is a skinny bill -- one that raises the price of cigarettes without restricting advertising or including public health efforts. You can play a key role by letting House Republican members know that the public health community will never support a skinny bill. We hope that you will get all your members involved in this effort.

- We will insist on strengthening McCain, but we know how important it is to get good legislation this year, and we will be reasonable in our demands. We will seek the following improvements:

  1. Strengthen the penalties, by including a company-specific component, and increasing the industry-wide surcharge cap above $3.5 billion.

  2. Eliminate the "opt-out" provision that allows states to adopt weaker environmental tobacco smoke ("second-hand smoke") laws.

  3. Eliminate or narrow the antitrust exemption.

  4. Ensure spending on research and public health.

Tobac - scr - public health reports

The Advisory Committee on Tobacco Policy and Public Health
Co-Chairs: C. Everett Koop, M.D., and David A. Kessler, M.D.

FAX to Ron Klain

cc: EK

(DRAFT) February 17, 1998

House Speaker Newt Gingrich
Senate Majority Leader Trent Lott
U.S. Congress
Washington, DC

Dear Sirs:

This year may be the most important moment in the history of the tobacco wars, a moment when America chooses between a path toward social repair or one toward irrevocable public loss. After years of growing public awareness of the addictiveness of nicotine, the adverse health effects of tobacco, and the tobacco industry's extensive efforts targeted at young children, the public is excited about the prospect that federal laws may be enacted that will bring about fundamental change in how the tobacco industry does business and that will save millions of lives. Conversely, there is the risk that the tobacco industry could further entrench its ability to stand outside the ordinary rules of commerce in society.

Despite all of the disclosures of tobacco industry maleficence during the last four years, tobacco use among children is up, the long term decline in tobacco use among African-American teenage boys has been reversed, and the decline in adult rates has stopped. The need for decisive action to protect the public's health has never been greater. No one should underestimate the importance of Congress acting now and acting decisively, nor the proven ability of the tobacco industry to make a mockery of its implied ethical and moral responsibilities to society.

We the undersigned are in agreement. We support comprehensive tobacco legislation that represents American principles and protects the public's health. We oppose granting the tobacco industry immunity against liability for past, present, or future misdeeds. Congress should focus its efforts on public health, not on the concessions the tobacco industry seeks. Comprehensive legislation should not shield the tobacco industry from future liability or cover it with a blanket of financial security for decades to come.

Congress should not alter the legal system in any way that would weaken its ability to protect the public health, or permit the tobacco industry or others the freedom to operate outside the normal legal constraints of the civil justice system and engage in any behavior that otherwise would be condemned. Congress must make sure that any legislation does not make it more difficult for injured citizens to exercise their fundamental right to seek just compensation for their injuries.

With evidence of tobacco industry misdeeds and mendacity on hand and growing, with sound public health proposals on the table, with broad popular support for action, Congress has the opportunity to make fundamental changes in tobacco policy based solely and exclusively on what is good for the public health without itself engaging in negotiations with the tobacco industry. Only a comprehensive approach that combines the best of what we know today with a process for making change as we learn more tomorrow should be enacted.

The recent disclosure of RJR-Mangini, Philip Morris and BAT documents confirm what the public health community has said for years, namely, that the tobacco industry aggressively marketed cigarettes to young children. Additional evidence of renegade tobacco industry behavior is beginning to emerge in the case currently being brought against the industry by the state of Minnesota and Minnesota Blue Cross and Blue Shield, as well as from other cases. For this reason, it would not be responsible public stewardship to grant more favors to this industry, especially since it has diligently tried to hook young children on nicotine and deny their own research findings on the harmful effects of tobacco.

The public health community is united in the type of legislation that should be enacted. Essential public health goals include:

1) FDA: Provide the FDA with full authority to regulate all areas of nicotine and all constituents and ingredients in tobacco. The FDA must have the authority to increase its tobacco research and scientific communication abilities and be provided with adequate funds to implement all of its various regulatory, enforcement, public education and research activities. New, burdensome requirements placed on the FDA would be unfair and erode public health.

2) Youths: Protect children and youths from influences that create demand for or acceptance of tobacco use; and prevent their obtaining tobacco, an illegal substance for youth. Specific measures that reduce youth demand and access include:

a) Provide for a well-funded nationwide education campaign.

b) Significantly increase the price of cigarettes and other tobacco products so that youths are discouraged from buying them. An increase of $1.50 per pack is a reasonable starting point. Once implemented, an independent National Academy of Sciences/Institute of Medicine commission should be set to determine what additional increases will significantly affect youth smoking behavior.

c) Ban advertising and marketing that entices young children. This should be coupled with tough restrictions on youth access to tobacco products, large, strong and effective warning labels on cigarette packs and other tobacco products, necessary funds to monitor compliance, and other deterrents.

d) Levy substantial penalties for underage use. Assessments should be on a company by company basis if reduced youth smoking targets are not met soon; e.g., there must be specific fines at specific times for specific shortfalls from user target levels.

3) Cessation: Provide adequate funds for sound, scientifically established cessation programs to help nicotine-dependent adults and youths quit smoking or using spit tobacco. Such programs should be integrated into health care financing systems, including managed care programs; accredited professional and public education programs; and behavioral and cessation research.

4) ETS: Refine and expand environmental tobacco smoke (ETS) regulations. Authorities and appropriations should permit full enforcement of smoke-free public and work environments and risk assessment research.

5) Justice: Protect and administer the justice system so that evidence of tobacco industry misdeeds become public. All legal remedies should remain available and the opportunity for groups of individuals to recover should not be diminished. It is critical, for instance, to know whether companies added certain ingredients to enhance the nicotine effect for young children and how they used sophisticated marketing techniques to reach those same children. Only when we know these things can we make sure they never happen again.

6) Preemption: Protect state and local government by shielding them from federal preemption clauses that weaken, incapacitate or make onerous the ability of states and local governments to develop novel public health approaches and pursue public health standards which are higher than federal standards. Federal laws designed to protect public health should always be a "floor" that state and local governments can add to and strengthen.

7) Farmers: Adequately compensate tobacco farmers as the opportunity to sell their domestic product to manufacturers declines.

8) International: Implement strong international trade policies that use the same public health standards applied to tobacco products marketed and sold here. U.S. trade policies should reflect domestic policy; no funds should be spent to promote the sale of tobacco products abroad; and the U.S. should take a leadership role in bringing the protections provided to Americans to all citizens of the world.

If public health-based tobacco control measures are enacted, and the threat of litigation is not removed in the process, this nation will finally experience improvement in the public's health. Youth smoking will almost certainly begin to decline, individuals who wish to quit smoking will find the scientifically sound professional help they need (including benefiting from an increasing array of effective FDA-approved pharmacological agents) and the public will be healthier and the nation stronger.

In the presence of a massive, ubiquitous, agonizing public burden -- including more than 1,100 deaths each day -- strong anti-tobacco public health measures are long overdue. The public will approve of such measures and expects ethical, courageous, bold action. We urge you to heed their call.

Sincerely,

C. Everett Koop C-Chair	David A. Kessler Co-Chair	Matt Myers National Center for Tobacco-Free Kids	John Garrison American Lung Association
John Seffrin American Cancer Society	Randolph Smoak American Medical Association	Mohammad Akhter American Public Health Association	Cass Wheeler American Heart Association
John Banzhaf Action on Smoking and Health	Robert Graham American Academy of Family Physicians	Richard Heyman American Academy of Pediatrics	D. Robert McCaffree American College of Chest Physicians
George Anderson American College of Preventative Medicine	Eileen McGrath American Medical Women's Association	Julia Carol Americans for Nonsmokers Rights	Martin Wasserman Assoc. Of State and Terr. Health Officials
Randy Schwartz Maine Dept. Human Services	Jeff Nesbit Science and Public Policy Institute	Yvonnechris Smith Veal National Medical Association	Rev. Jesse Brown The Onyx Group
Jonathan Fielding Partnership for Prevention	Tom Houston Smokeless States National Program	Judy Sopenski Stop Teenage Addiction to Tobacco	Richard Daynard Tobacco Products Liability Project

cc: House Commerce Chairman Tom Bliley
House Judiciary Chairman Henry Hyde
Rep. Deborah Pryce
Senator Don Nickles
Senate Commerce Committee Chairman John McCain
Senate Labor and Human Resources Chairman James Jeffords
Senate Judiciary Chairman Orrin Hatch

CAMPAIGN for TOBACCO-FREE Kids

Kathryn Kahler Vose
DIRECTOR, COMMUNICATIONS

NATIONAL CENTER FOR TOBACCO-FREE KIDS
1707 L STREET, NW • SUITE 800 • WASHINGTON, DC 20036
PHONE (202) 296-5469 • FAX (202) 296-5427
E-MAIL kkahlervose@tobaccofreekids.org

Tobacco - settlement - public health outreach

CAMPAIGN for TOBACCO-FREE Kids

October 3, 1997

Elena Kagan
Domestic Policy Office
The White House
Washington, DC 20502

Dear Elena:

Enclosed are several press packets announcing the formation of a new coalition of public health groups, ENACT. The group will work with the Administration, the Congress, the public health community, and the American people to help pass comprehensive, sustainable, effective, well-funded, national tobacco control legislation that embodies the President's principles.

ENACT represents 11 of the nation's largest and most prestigious public health organizations.

At our press conference, we released new polling data that shows very strong support for the principles outlined by the President. It was the first poll taken after the President announced his five key elements.

We hope that you will share this information with Bruce Lindsay, Bruce Reed and other working on the tobacco issue.

The ENACT coalition has committed its members, its volunteers and its resources to accomplish this important goal of enacting comprehensive legislation.

Many thanks for your help. We look forward to working with you.

Sincerely,

Kathryn Kahler Vose

Kathryn Kahler Vose
Director, Communications

NATIONAL CENTER FOR TOBACCO-FREE KIDS
1707 L STREET, NW • SUITE 800 • WASHINGTON, DC 20036
PHONE (202) 296-5469 • FAX (202) 296-5427

E N A C T

Effective National Action to Control Tobacco

– A Public Health Coalition –

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
Association of State & Territorial Health Officials
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

ENACT News Conference
October 1, 1997

Speaker List
(in order of appearance)

Randolph D. Smoak, Jr., M.D.
Vice Chair
American Medical Association Board of Trustees

John R. Seffrin, Ph.D.
Chief Executive Officer
American Cancer Society

Michael C. Caldwell, M.D., M.P.H.
Board Member and Tobacco Committee Chair
National Association of County and City Health Officials

Ronald Davis, M.D.
Director, Center for Health Promotion and Disease Prevention
Henry Ford Health System/Member, Partnership for Prevention
Fellow
American College of Preventive Medicine

###

P.O. Box 65168
Washington, DC 20035
Phone: (202) 293-1405

American Medical Association

Physicians dedicated to the health of America

Randolph D. Smoak, Jr., MD
Secretary-Treasurer
American Medical Association

Randolph D. Smoak, Jr., MD, a surgeon from Orangeburg, South Carolina, was elected Secretary-Treasurer of the American Medical Association (AMA) in December 1995. He has been reelected to a second term on the AMA Board of Trustees in June 1995. Since 1994 Dr. Smoak has served on the Board's Executive Committee and as chair of its Finance Committee. A member of the Board since 1992, he had served as secretary-treasurer of the AMA Physicians Health Foundation from 1992 to 1993. Since 1993 Dr. Smoak has served as chair of the Board's Subcommittee on Membership, and since 1994 he has represented the AMA on the National Health Council. He continues his service in both of these capacities. As lead spokesperson for AMA's anti-smoking campaign, he represents the AMA on the Department of Health and Human Services' Interagency Committee on Smoking and Health. In addition, he is currently an AMA commissioner to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Prior to his service on AMA's Board of Trustees, he served as alternate delegate to the AMA House of Delegates for the South Carolina Medical Association (SCMA) in 1983, and as delegate in 1987. Serving on the AMPAC Board since 1984, he was elected secretary in 1986 and chair in 1988. He had worked with the Council on Legislation as the AMPAC observer since 1988.

Dr. Smoak's dedication to organized medicine has been evident through his years of service on the state level. Since being elected to the SCMA Board of Trustees in 1972, he has served in virtually every leadership position including president, SCMA; chair, SCMA; chair, South Carolina Political Action Committee; president, SCMA Members' Insurance Trust; and president, South Carolina Medical Care Foundation. Dr. Smoak is a founding member of the South Carolina Oncology Society and is currently serving as Governor from South Carolina to the American College of Surgeons. He is also an active member of the Southeastern Surgical Congress, the Southern Society of Clinical Surgeons, the Society of Head & Neck Surgeons, the South Carolina Surgical Society and the South Carolina Chapter of the American College of Surgeons.

Born in Bamberg, South Carolina, Dr. Smoak received his BS degree from the University of South Carolina (USC) and his MD degree from the Medical University of South Carolina (MUSC). He served his internship at Grady Memorial Hospital in Atlanta, Georgia, and completed his residency training at the Medical University of South Carolina. Dr. Smoak completed a senior surgical fellowship at MD Anderson Hospital and Tumor Institute in Houston, Texas. He then returned to his home state to establish a surgical practice.

Dr. Smoak is a fellow of the American College of Surgeons and a diplomate of the American Board of Surgery. He is a clinical professor of surgery at MUSC and clinical associate professor of surgery at the USC School of Medicine. He is the past chair of the Department of Surgery at the Orangeburg Regional Medical Center.

Dr. Smoak's involvement in civic activities includes service as president, South Carolina Division of the American Cancer Society; Lt. Governor, Kiwanis Club; Board of Directors, Orangeburg County Chamber of Commerce; and Board of Directors, Orangeburg Chapter of the American Red Cross. He has also served on the Cancer Advisory Committee of the South Carolina Department of Health and Environmental Control and as chair of the Statewide Health Coordinating Council.

Dr. Smoak and his wife, Saundra, have four daughters and reside in Orangeburg, South Carolina.

JOHN R. SEFFRIN, PHD
Chief Executive Officer
American Cancer Society

Biography

John R. Seffrin, PhD, is the Chief Executive Officer of the world's largest voluntary health organization, the American Cancer Society. He is also a Trustee of the Society's Foundation.

Prior to being named the American Cancer Society's top staff executive in 1992, Dr. Seffrin was Professor of Health Education and Chairman of the Department of Applied Health Science at Indiana University. During his years in academia, he distinguished himself as a national and international leader in health education, disease prevention, and public health.

As a 20-year ACS volunteer, Dr. Seffrin served the Society at local, state, and national levels. He chaired the Society's Indiana Division Board of Directors and was Chairman of the National Board from 1989 to 1991.

An Indiana native, Dr. Seffrin is listed in Who's Who in America. He has also been recognized with high honors by two Indiana governors for his outstanding public service contributions and was awarded an honorary Doctor of Science degree from his undergraduate alma mater, Ball State University.

Dr. Seffrin has served on the Boards and Committees of a number of other public service and governmental agencies, and he is a past Vice President of the American Lung Association's National Board of Directors. In addition to serving on the US Surgeon General's Advisory Committee on Smoking and Health, he has also provided consultant services to a number of agencies, including the US Centers for Disease Control and Prevention.

A sought after speaker, Dr. Seffrin has spoken on public health issues throughout North America, Australia, Europe and Asia. He is the author of a number of scientific and professional articles and book chapters, and he was selected by the Association for the Advancement of Health Education as its National Scholar for 1996 -- which is this professional society's highest honor.

He was recently appointed to the new National Cancer Policy Board, which was formed by the National Academy of Sciences to advise our country on policy issues regarding cancer research and control.

1997

316 PENNSYLVANIA AVE., S.E., SUITE 200, WASHINGTON, DC 20003-1146 • 202-546-4011 • FAX 202-546-1682

RONALD M. DAVIS, MD, FACPM
DIRECTOR
CENTER FOR HEALTH PROMOTION & DISEASE PREVENTION
HENRY FORD HEALTH SYSTEM
ONE FORD PLACE, 5C
DETROIT, MI 48202
TELEPHONE: 313/874-6276

Ronald M. Davis, MD, FACPM became the director of the Center for Health Promotion and Disease Prevention of the Henry Ford Health System in September 1995. From 1991-1995, he served as Chief Medical Officer in the Michigan Department of Public Health. From 1987 to April 1991, Dr. Davis served as the director of the U.S. Centers for Disease Control's Office on Smoking and Health. He completed the Epidemic Intelligence Service program and the preventive medicine residency program at CDC, received his MD and Master of Arts degree in Public Policy Studies from the University of Chicago and a Bachelor of Science degree from the University of Michigan. Dr. Davis was elected as the first resident physician member of the American Medical Association's Board of Trustees and served in that capacity from 1984 through 1987. He was elected to the AMA Council on Scientific Affairs in June 1993 and became chair of the Council in June 1997.

Dr. Davis has published widely in peer-reviewed journals and has received many awards and honors, including the Surgeon General's Medallion and the American Public Health Association's Jay S. Drotman Memorial Award. He is a member of the World Health Organization's Technical Advisory Group on Tobacco or Health and is the editor of *Tobacco Control: An International Journal*, which was launched by the British Medical Association in March 1992. Dr. Davis is a fellow of the American College of Preventive Medicine and he is the College's alternate delegate to the AMA House of Delegates; the Henry Ford Health System is a member of Partnership for Prevention.

Biographical Narrative of

Michael C. Caldwell, MD, MPH

Dutchess County Commissioner of Health

Dr. Michael C. Caldwell became Commissioner of the Dutchess County Department of Health on August 8, 1994. He oversees the health of 260,000 people over an 800 square mile area with 150 employees and a budget of $25 million. One of the youngest physicians ever to be appointed Health Commissioner in the United States, he received his Baccalaureate Degree in Art History from Columbia University in 1986 and his Medical Degree from the Mount Sinai School of Medicine in 1990. Dr. Caldwell then completed an Internal Medicine Residency at the Mount Sinai Medical Center in 1993. He received his Masters of Public Health Degree from Harvard in 1994 and is Board Certified in Internal Medicine.

His numerous awards and honors include: **1996 and 1997 NY State Health Department *Public Health Education Awards*** ; a David Scherf Cardiology Award from the New York Academy of Medicine; and being chosen as the Honorary Chairperson for the *Great American Smokeout* by the Dutchess County Chapter of the American Cancer Society. He is a **Board member** of the **National Association of County and City Health Officials (NACCHO)** and also Chairs their **Tobacco Prevention & Control Committee.** He continues to see patients regularly as a physician at the Castle Point Veterans Administration (VA) Hospital in Dutchess County.

Since becoming Commissioner of Health, Dr. Caldwell has participated in a nationwide ***Lyme Disease Research Vaccine Trial*** and an investigational ***Herpes Vaccine Trial***. He chairs the Dutchess County ***HIV/AIDS Primary Care Task Force***, overseeing a federal Ryan White Funding Grant and has recently formed a local ***Violence Prevention Coalition*** which focuses on the public health approach to violence. He is a member of the Board of Directors of the Dutchess County Chapters of: the *American Cancer Society*, the *American Heart Association* and *Big Brothers/Big Sisters*. Dr. Caldwell holds academic appointments at the Harvard and Columbia Schools of Public Health and the Mount Sinai School of Medicine and is a **Fellow** of the **New York Academy of Medicine.**

He is married to Dr. Maryanne Wysell, a Rheumatologist and they have one son Brian Anthony who was born in March 1995 and are expecting their second child in January 1998. Dr. Caldwell enjoys musical theater, playing the guitar and singing in his spare time. 09-97

News Release

American Academy of Family Physicians
The doctors who specialize in you

8880 Ward Parkway ◆ Kansas City ◆ MO 64114-2797
WATS (800) 274-2237 ◆ Phone (816) 333-9700
◆ Fax (816) 822-8857 ◆ E-Mail: fp@aafp.org
◆ http://www.aafp.org

HOLD FOR RELEASE
9:00 AM EDT, October 1, 1997

CONTACT: Sarah Thomas
800-274-2237, ext. 4200

AMERICAN ACADEMY OF FAMILY PHYSICIANS TAKES ROLE IN HEALTH COALITION TO REDUCE AND CONTROL TOBACCO USE

AAFP Aims to Reduce Smoking for Children and Adults

(Washington, D.C.) The American Academy of Family Physicians (AAFP) today announced that it is joining 10 other major public health groups to form ENACT: A Public Health Coalition. ENACT (Effective National Action to Control Tobacco) will work with the Administration and Congress to enact legislation that will create the nation's first comprehensive program to prevent and dramatically reduce tobacco use among children and adults.

"We have an incredible opportunity to create a national program that will establish real goals and real penalties for the tobacco companies if they fail to reduce tobacco use," said Neil Brooks, MD, AAFP President. "It's more important that the nation get a strong tobacco settlement rather than a quick one."

The AAFP has been a leader in discussions with Congress, the Administration and with other health care leaders on the elements of a strong tobacco control policy, including participation in the Advisory Committee on Tobacco Policy and Public Health chaired by Drs. Koop and Kessler.

The physician group believes that the current settlement will do little to reduce overall smoking in America because it fails to address adult tobacco use and does not penalize the industry adequately for missing youth tobacco use goals. In addition to efforts to curb teen smoking, an acceptable settlement must also include financial penalties against the tobacco industry if adult smoking rates do not decline.

"The current proposed settlement allows the tobacco industry to shift advertising and marketing practices from children to young adults," said Brooks. "That is unacceptable -- and in order to prevent this from happening, we must set specific goals for the reduction of adult tobacco use."

The AAFP has been involved in tobacco education and cessation efforts for much of its 50-year history. Through its "Tar Wars" program, family physicians throughout the United States have educated tens of thousands of school-aged children about the dangers of tobacco, and have helped them think critically about tobacco advertising.

###

The American Academy of Family Physicians (AAFP) represents more than 84,000 family physicians, family practice residents and medical students nationwide. Family physicians are medical specialists trained to treat the medical problems of patients of all ages and both sexes.

American Academy of Pediatrics
601 Thirteenth Street, N.W.
Suite 400 North
Washington, DC 20005

News Release

CONTACT: Marjorie Tharp
Gem Benoza
202/347-8600; 800/336-5475

For Release: October 1, 1997
9 a.m. (EST)

PEDIATRICIANS HELP FORM TOBACCO CONTROL COALITION

Washington, D.C. -- The American Academy of Pediatrics, representing 53,000 pediatricians, joined 10 other public health organizations today in announcing the formation of ENACT, a coalition that will work with the Administration, Congress and the public to help shape and pass comprehensive tobacco control legislation as soon as possible.

"We believe a united public health community, with its resources dedicated and coordinated, will help finish the job so many health professionals have worked for decades to achieve," AAP President Robert Hannemann, M.D., said. "ENACT is going to be an efficient and effective tobacco control coalition."

The American Academy of Pediatrics has had a long-standing commitment to reducing tobacco use among adolescents and children. A few key policy issues for the Academy include marketing prohibitions, price increases, public health initiatives and secondhand smoke hazards, all of which are a part of ENACT's legislative agenda. ENACT stands for Effective National Action to Control Tobacco.

"We'll meet with legislators, talk to parents and their children, hold community events, work with local media -- anything within our means to achieve our goal," Dr. Hannemann said.

###

The American Academy of Pediatrics is an organization of 53,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents and young adults.

Note to Editors: The American Academy of Pediatrics will focus its Child Health Month activities this October on tobacco prevention.

AMERICAN CANCER SOCIETY®

GOVERNMENT RELATIONS OFFICE

STATEMENT BY JOHN R. SEFFRIN, PH.D., CHIEF EXECUTIVE OFFICER,
AMERICAN CANCER SOCIETY, INC.
Made at a press conference announcing the formation of ENACT - A Public Health Coalition
at the National Press Club, Washington, DC
October 1, 1997

It is an honor to join my colleagues here today to announce the formation of ENACT - A Public Health Coalition. Eleven national public health organizations, representing millions of volunteers, members and staff, have formed the coalition to help enact comprehensive, sustainable, effective, well-funded tobacco control legislation. The coalition will build upon decades of work by the public health community, the 1996 assertion of jurisdiction over tobacco by the US Food and Drug Administration, the principles outlined in the recent Koop-Kessler report, and the June 20th agreement negotiated by the state Attorneys General and the tobacco industry to ensure that legislation is passed by a bipartisan Congress and signed into law by President Clinton.

The commitment made by all eleven organizations to come together to pass legislation as significant as this is unprecedented. By sharing resources we can educate the public about the need for a national tobacco control policy. By joining forces we can activate millions of public health advocates across the country. By uniting, we can overcome any obstacle we face to take advantage of this historic opportunity.

Uniting our coalition is a consensus statement which clearly states the elements that we believe must be a part of any tobacco control legislation for it to be effective. The elements include:

- Full FDA authority over all tobacco products and nicotine delivery systems.
- Tough penalties against the industry if tobacco use among children does not drop substantially.
- Significant price increases on the cost of tobacco products.
- No marketing aimed at children.
- Broad disclosure of industry documents.
- Provisions to ensure that federal law does not preempt more restrictive state and local laws.
- Support for a variety of public health initiatives.
- Funding for implementation of international tobacco control initiatives.
- Protections from secondhand smoke hazards.
- Help for tobacco farmers and their communities.

We promise the American people that we will use the strength of our coalition to defeat our opposition and get tobacco control legislation that includes our key elements passed.

316 PENNSYLVANIA AVE., S.E., SUITE 200, WASHINGTON, DC 20003-1146 • 202-546-4011 • FAX 202-546-1682

AMERICAN COLLEGE OF CHEST PHYSICIANS

FOR IMMEDIATE RELEASE : October 1, 1997

Contact: Lynne G. Marcus
Vice President, Membership & Public Affairs
(847) 498-1400

ACCP Vision: *The College is the leading resource for the improvement in cardiopulmonary health and critical care worldwide.*

ACCP Mission: *To promote the prevention and treatment of diseases of the chest through leadership, education, research and communication*

The American College of Chest Physicians (ACCP) is a not-for-profit organization of over 16,000 physicians, allied health professionals, and individuals with PhD degrees in the United States and internationally. The ACCP provides continuing medical education in the specialties of pulmonology, cardiology, cardiovascular and cardiothoracic surgery, hypertension, critical care medicine, and related disciplines.

Since 1960, the ACCP has been a leader in antismoking activities. In response to the alarming increase in lung cancer cases seen by our members, the ACCP published a statement in *CHEST*, the official journal of the College, emphasizing the need to find the causative agents of lung cancer. Smoking is cited as a probable cause. After several years of studying the effects of cigarette smoking on the respiratory and cardiovascular systems, the Committee on Lung Cancer of the ACCP passed a resolution urging the US Surgeon General to study the health aspects of smoking. In 1965, prompted by the ACCP and other medical society efforts to provide conclusive medical evidence on the harmful effects of cigarette smoking, Congress passed the bill requiring the Surgeon General's warning label to be printed on all cigarette packages.

These activities were soon followed by a symposium titled "Cigarette Smoking: The Physician's Role and Benefits of Cessation", in 1971, adoption of no smoking policy for ACCP educational meetings in 1972, and adoption of a no smoking pledge in 1979 which is still taken by all Fellows of the College. The ACCP also played a key role in the passage of federal legislation on February 25, 1990, banning smoking on domestic flights within the continental US, Puerto Rico and the Virgin Islands. In 1991 the ACCP filed an *amicus curiae* brief in the US Supreme Court in support of Rose Cipollone in *Cipollone vs. Liggett Group, Inc.* In 1994, the ACCP co-authored the "International Consensus Statement on Smoking or Health" published in *CHEST* and other medical journals, representing international agreement among medical organizations relating to the addictive nature of smoking, the relationship between smoking and disease, the role of physicians relating to smoking, and the need to oppose expansion of the international tobacco market. The ACCP also took a leading educational role in *Mississippi v. The American Tobacco Company, et al.* providing the Courts medical evidence on the addictive nature of tobacco, and in 1996 submitted an *amicus curiae* brief to the Mississippi Supreme Court in support of the Attorney General's case. In 1997, the ACCP participated on the Advisory Committee on Tobacco Policy and Public Health co-chaired by Drs. C. Everett Koop and David Kessler, and the AMA Task Force on the Proposed Tobacco Settlement Agreement.

With this 30-year history of anti-smoking activities, the ACCP is committed to building on its work and the work of other public health groups to dramatically reduce the use of tobacco products among children and adults. The ACCP believes it is of major importance to the health of our children, especially to those Americans who are not yet addicted to nicotine, and not yet our patients, to move quickly to make the most of this historic opportunity.

ACCP supports President Clinton's initiatives. ACCP is committed to work to strengthen the resolve of Congress to act responsibly at this important time in the history of tobacco's influence on the nations health. The ACCP now joins with the other members of ENACT to support an effective national policy on tobacco control. The time to ENACT such a program is now.

###

ACPM
American College of
Preventive Medicine

Leadership in the Science, Policy and Practice of Preventive Medicine

PRESS RELEASE

Embargoed until 9:00am
October 1, 1997

Contact: Hazel Keimowitz or Suzy Leous
202-466-2044

ACPM CONTINUES TOBACCO CONTROL EFFORTS; JOINS "ENACT"

Washington, DC -- Today the American College of Preventive Medicine (ACPM) joins with ten other public health organizations in the formation of a new tobacco control coalition called ENACT (Effective National Action to Control Tobacco). By signing the consensus statement which formalizes the call for bipartisan, comprehensive, sustainable, effective and well-funded legislation, ACPM pledged its staff, members and scientific expertise to assist in the enactment of the best possible tobacco control policy.

ACPM fellow Ronald Davis, MD, FACPM, who assisted both the ACPM and the American Medical Association (AMA) with their responses to the June 20th agreement between the state Attorneys General and the tobacco industry, spoke on behalf of ENACT at a press conference in Washington, DC, announcing the coalition. Referring to recent polling data, Davis added "It is clear that the American people support tough tobacco policy designed to protect children and adults." By incorporating FDA's full authority to regulate tobacco, placing tough penalties on the tobacco industry if tobacco use among children is not reduced, greatly increasing tobacco advertising and promotion restrictions, and encouraging a commitment to international tobacco concerns, ACPM is in lock step with several other organizations working to represent these and other important tobacco related issues on Capitol Hill.

ACPM President Jonathan Fielding, who has participated in several ENACT organizational meetings, commented, "Without legislation, we will not have the large increase in tobacco product prices that reduce demand nor the billions for an anti-tobacco mass media campaign, for cessation activities, for expansion of state and broad based community anti-tobacco efforts, and for enforcement of FDA regulations to limit youth access to tobacco. ENACT has an historic opportunity to work with Congress and the Administration, as well as with the entire public health community and the American people, to craft tobacco control policy which invests industry dollars to use proven approaches to reduce smoking, primarily in youth but also in adults. That is what we owe to our children and their children. We challenge Congress to join us in achieving this goal."

The American College of Preventive Medicine is the national medical society of physicians whose primary interest and expertise are in disease prevention and health promotion, areas vital to protecting and improving the nation's health. Specialists in preventive medicine are uniquely trained in both clinical medicine and public health. They have the skills needed to understand and reduce the risks of disease, disability and death in individuals and in population groups.

###

1660 L Street, NW • Suite 206
Washington, DC 20036-5603
(202) 466-2044 • FAX (202) 466-2662
E-Mail: info@acpm.org
www.acpm.org/acpm

Office of Communications and Advocacy
1150 Connecticut Avenue Northwest Suite 810 Washington, DC 20036
Tel 202 785 7900
Fax 202 785 7950
http://www.americanheart.org

American Heart Association℠
Fighting Heart Disease and Stroke

For Release:
October 1, 1997

Contact:
Trish Moreis (202) 785-7900

STATEMENT OF THE AMERICAN HEART ASSOCIATION ON JOINING A PUBLIC HEALTH COALITION TO ENACT COMPREHENSIVE TOBACCO CONTROL LEGISLATION

The American Heart Association has joined a number of public health groups to form the coalition ENACT (Effective National Action to Control Tobacco). By joining this coalition, the AHA has committed its more than 4 million volunteers to working with Congress and the Administration to pass comprehensive national tobacco control legislation.

The American Heart Association has made eliminating the health hazards of tobacco a priority for many decades. Current estimates for the United States are that 26.0 million men and 23.1 million women are smokers, putting them at increased risk for a heart attack. Nearly one fifth of all cardiovascular deaths -- approximately 190,000 -- are attributable to smoking. In addition, an estimated 4.2 million adolescents aged 12 to 17 are smokers.

The Coalition has pledged to support the following principles as comprehensive national tobacco control legislation is developed: full FDA authority to regulate tobacco, tougher penalties for the tobacco industry, price increases on tobacco products, no marketing to children, disclosure of tobacco industry documents, no preemption, public health initiatives, international leadership, secondhand smoke, and protection of tobacco farmers and their communities. In addition, the AHA believes strongly that any national tobacco control legislation must not grant immunity for past criminal wrongdoing to tobacco companies or their agents.

The American Heart Association remains steadfast in its efforts to hold the tobacco industry accountable for the death and disability it has caused. We are committed to assuring that the Congress and regulatory agencies enact appropriate measures to correct past wrongdoing and protect the health of children and adults.

-30-

American Medical Association
Physicians dedicated to the health of America

Statement

FOR IMMEDIATE RELEASE October 1, 1997

Statement attributable to: Randolph Smoak, Jr., M.D.
AMA Vice Chair

AMA PROUD TO BE PART OF ENACT COALITION
Pledges to lobby vigorously for national tobacco control legislation

"The American Medical Association is proud to be here today to announce its active participation in the ENACT -- Effective National Action to Control Tobacco -- Coalition.

"The tobacco industry's bullying power to stall anti-tobacco legislation is legendary. The AMA comes together today with 10 other prestigious public health groups to build a coalition whose power comes from millions of voices firmly united against the scourge of tobacco death and disease -- and firmly united for bipartisan tobacco control legislation.

"The poll released today shows that we will not be alone: the public wants what we want. We are confident the voices of citizens from coast to coast will join with ours to let Congress know that we are serious about stopping tobacco's toll on our nation.

"Through the work of many people on the front lines of the fight against tobacco, we have made tremendous progress in the battle to save lives and protect children from tobacco addiction. We will use this progress we've made as a springboard toward legislation that will do much, much more.

"As physicians, we see too often the suffering and death caused by tobacco, and we are here today to prescribe a cure: the cure for a country suffocating from the ills of tobacco is a strong national tobacco control policy -- now.

"Since the announcement of the tobacco settlement, almost 300,000 children have taken their first puff. As physicians, we do what it takes to save lives. Each day we delay action on a national tobacco control policy, we risk not one life -- but thousands."

#

For more information, please call:

Brenda L. Craine
AMA Washington Office
202/789-7447

1101 Vermont Avenue, NW
Washington, DC 20005
202 789-7400

CAMPAIGN for TOBACCO-FREE Kids

NATIONAL CENTER FOR TOBACCO-FREE KIDS

Statement of Bill Novelli
President

We are proud to join with other public health leaders in forming ENACT, and unifying behind the common goal of enacting into law a comprehensive national tobacco control program. The unity of these leading public health groups sends a powerful message of our commitment to action. We look forward to attacking the epidemic of youth smoking in America through our combined resources.

Through ENACT, we will work closely with the American people, Congress and the President to seize the opportunity that exists to pass historic tobacco control legislation. Working together, we will seek a legislative solution that truly reduces both youth and adult smoking rates and reduces the dangers of second-hand smoke.

We join with the other members of ENACT in embracing the principles outlined by President Clinton to accomplish this goal. We are now committed to working toward the enactment of legislation that finally saves lives and protects children from tobacco.

###

1707 L Street, NW Suite 800 Washington, DC 20036
Phone (202) 296-5469 Fax (202) 296-5427
www.tobaccofreekids.org

NACCHO

440 First Street, NW, Suite 450
Washington, DC 20001
(202) 783-5550 (202) 783-1583 (Fax)

National
Association of
County & City
Health Officials

LOCAL PUBLIC HEALTH OFFICIALS URGE NATIONAL TOBACCO CONTROL LEGISLATION

The National Association of County and City Health Officials (NACCHO) supports an effective, comprehensive national policy on tobacco products as a vital tool for improving the health of people in the United States. The proposed settlement negotiated between the state Attorneys General and the industry and President Clinton's commitment to federal legislation have provided an opportunity and a foundation for establishing a national policy that includes measures to prevent youth from beginning to use tobacco, decrease consumption by adults, and reduce the hazards of environmental tobacco smoke.

NACCHO urges enactment of legislation providing for the full range of available public health tools to reduce the massive toll tobacco takes on the nation's health. These include community-based public health education, smoking cessation programs, enforcement of prohibitions on sales to children, bans on marketing and advertising designed to appeal to youth, restrictions on tobacco use in workplaces and public areas, and reduction of demand through substantial price increases. Federal legislation must explicitly ensure that local and state governments are free to enact or retain tobacco control laws that are more stringent than any minimum federal requirements.

Effective national tobacco control legislation must provide for full jurisdiction of the Food and Drug Administration over all tobacco products, ingredients, and devices that deliver nicotine, so that the agency may regulate them under the same standards and procedures applicable to all other substances. Tobacco companies must be given powerful financial incentives to discourage youth tobacco use and to reduce it measurably. NACCHO also believes that each tobacco company must be required, without limitation, to disclose promptly and fully all company documents relating to the health effects of tobacco products and their ingredients.

NACCHO is the primary national organization representing the health officials who direct the 3,000 local public health departments in the United States. They are charged with promoting and protecting the health of people in their communities. They work in partnership with community members on the front lines of America's tobacco prevention and control efforts. NACCHO joins ENACT in seizing the opportunity before our nation to decrease the use of tobacco, the single greatest preventable cause of premature death and disability.

October 1, 1997

Contact: Donna B. Grossman
202-783-5550

PARTNERSHIP FOR PREVENTION

Today's **Solution** *for Tomorrow's* **Health**

October 1, 1997

Contact:
Jud Richland
Kelly O'Brien Yehl
(202) 833-0009

PARTNERSHIP FOR PREVENTION URGES CONGRESSIONAL ACTION ON TOBACCO CONTROL

Washington, DC --*Partnership for Prevention* joined today with ten of the nation's leading public health organizations to announce the formation of a new coalition called "ENACT" and to urge Congress to pass comprehensive legislation to control tobacco.

"We pledge to work with our ENACT colleagues to mobilize Congressional action that reflects the public health values set forth in the ENACT consensus statement," said *Partnership* Chairman William Roper, MD, MPH.

According to Roper, *Partnership for Prevention* believes that any legislation must have a high likelihood of achieving "progressive and sustained" reductions in tobacco use among youth primarily and adults secondarily, both through primary prevention and through cessation of all forms of tobacco use.

Ronald Davis, MD, a renowned tobacco control expert and member of *Partnership for Prevention* said that "the formation of ENACT shows there is widespread agreement within the public health community on what must be done to reduce tobacco use in the United States and abroad."

Partnership for Prevention is a national nonprofit group whose aim is to increase the priority for disease prevention and health promotion in health policy and practice. As an organization with a diverse membership that includes corporate as well as nonprofit members, *Partnership's* participation in ENACT brings with it the potential to broaden the coalition significantly.

###

Partnership for Prevention is a national non-profit organization committed to increasing visibility and priority for prevention in national health policy and practice.

1233 20th Street, NW
Suite 200
Washington, DC 20036
(202) 833-0009
(202) 833-0113 Fax

BOARD OF DIRECTORS

Chairman

William L. Roper, MD, MPH
Dean
School of Public Health
University of North Carolina at Chapel Hill

BOARD MEMBERS

Catherine M. Baase, MD
Global Medical Director
The Dow Chemical Company

Howard L. Bailit, DMD, PhD
Professor, Department of Community Medicine and Director of the Health Policy and Primary Care Research Center
University of Connecticut School of Medicine

Karen A. Bodenhorn, RN, MPH
Executive Director
California Center for Health Improvement

Daniel P. Bourque
Senior Vice President
VHA Inc.

Peggy Clarke, MPH
President
American Social Health Association

Glenna M. Crooks, PhD
President
Strategic Policy & Politics International, Inc.

Gordon H. DeFriese, PhD
Director, Cecil G. Sheps Center for Health Services Research
University of North Carolina at Chapel Hill

Jonathan E. Fielding, MD, MPH, MBA
Co-Director
UCLA Center for Healthier Children, Families & Communities
Professor of Health Services & Pediatrics
UCLA School of Public Health

The Honorable Bill Gradison
President
Health Insurance Association of America

Christine Grant, JD, MBA
Vice President, Public Policy
Pasteur Mérieux Connaught

Robert Harmon, MD, MPH
National Medical Director
United HealthCare Corporation

Karen Ignagni, MBA
President and CEO
American Association of Health Plans

Glendon E. Johnson
Chairman and CEO
John Alden Life Insurance Co.

Stanley G. Karson, MA
Consultant
Corporate Community Involvement

Jeffery P. Koplan, MD, MPH
President
The Prudential Center for Health Care Research

Wayne Lednar, MD, PhD
Corporate Medical Director
Eastman Kodak Company

Philip R. Lee, MD
Senior Advisor to the Dean of the School of Medicine and Professor Emeritus of Social Medicine
Institute for Health Policy Studies
University of California at San Francisco

J. Michael McGinnis, MD
Scholar-in-Residence
National Academy of Sciences

Lois G. Michaels, MSHy
President Emeritus
Health Education Center
Highmark Blue Cross Blue Shield

Woodrow A. Myers, Jr., MD, MBA
Director
Health Care Management
Ford Motor Co.

Michael P. O'Donnell, PhD, MBA, MPH
Editor-in-Chief and President
American Journal of Health Promotion

Gilbert S. Omenn, MD, PhD
Professor and Dean
School of Public Health and Community Medicine
University of Washington

Mary Pittman, DrPH
President
Hospital Research and Educational Trust

Ronald J. Saldarini, PhD
President
Wyeth-Lederle Vaccines and Pediatrics

John R. Seffrin, PhD
Chief Executive Officer
American Cancer Society, Inc.

P. John Seward, MD
Executive Vice President
American Medical Association

Hugh H. Tilson, MD, DrPH
Senior Medical Advisor for Health Affairs
Glaxo Wellcome

Thomas M. Vernon, MD
Executive Director
Medical, Scientific & Public Health Affairs
Merck Vaccine Division
Merck & Co., Inc.

Donald M. Vickery, MD
Chairman and Chief Medical Officer
Health Decisions International, LLC

Martin P. Wasserman, MD, JD
Secretary
Maryland Department of Health and Mental Hygiene

Chairman Emeritus

The Honorable Richard S. Schweiker
Former Secretary
Department of Health and Human Services

E N A C T

Effective National Action to Control Tobacco

-- A Public Health Coalition --

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
Association of State & Territorial Health Officials
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

FOR IMMEDIATE RELEASE
October 1, 1997

Contacts: Emily Smith, ACS 202-546-4011
Trish Moreis, AHA 202-785-7900
Marjorie Tharp, AAP 202-347-8600
Brenda Craine, AMA 202-789-7447
Jennifer Thorp, CFTFK 202-296-5469
Sarah Thomas, ASFP 800-274-2237

-- Public Health Groups Form Powerful Coalition to Enact Comprehensive Tobacco Control Legislation and Release Poll Showing Broad Public Support for National Efforts to Curb Smoking --

Washington, D.C. (October 1, 1997) -- Eleven of the nation's most prestigious public health organizations have formed the coalition ENACT (Effective National Action to Control Tobacco) and have pledged to work with the Congress and the Administration to help pass comprehensive, sustainable, effective, well-funded, national tobacco control legislation.

"The commitment made by all eleven organizations to come together to help pass legislation as significant as this is unprecedented," said John R. Seffrin, Ph.D., chief executive officer of the American Cancer Society. "By sharing resources we can educate the public about the need for national tobacco control policy. By joining forces we can activate millions of public health advocates across the country. By uniting we can overcome any obstacle we face to take advantage of this historic opportunity."

ENACT also released a letter it sent to members of Congress pledging to work together to help pass strong bipartisan legislation.

The group also released new national polling data that show strong public support for a comprehensive plan to control tobacco use. Seventy-one percent of those polled during the week following President Clinton's tobacco policy announcement think it is important that the Congress address a national tobacco control policy in the next six months. The survey also

- more -

P.O. Box 65168
Washington, DC 20035
Phone: (202) 293-1405

found that 87 percent of the public is concerned about tobacco use by kids as a public health issue.

An advertisement announcing the formation of ENACT and its pledge to help pass comprehensive legislation appears in *The Washington Post* and *The Washington Times* today.

"The American Academy of Family Physicians, American Academy of Pediatrics, American Cancer Society, American College of Chest Physicians, American College of Preventive Medicine, American Heart Association, American Medical Association, Association of State and Territorial Health Officials, Campaign for Tobacco-Free Kids, National Association of County and City Health Officials, and Partnership for Prevention are standing together here today to say to the American people that we will work with Congress, the Clinton Administration and anyone else who will join us in the fight to enact national tobacco control legislation," said Dr. Randolph Smoak, Jr., vice chair of the American Medical Association's Board of Trustees.

Building on decades of work by the public health community, the 1996 assertion of jurisdiction over tobacco by the U.S. Food and Drug Administration, the principles in the recent Koop-Kessler Report, the June 20th agreement negotiated between the state Attorneys General and the tobacco industry, and President Clinton's call for bipartisan legislation, ENACT members released a consensus statement that outlines the important elements for effective legislation. These elements include:

- Full FDA authority over all tobacco products and nicotine delivery systems.
- Tough penalties against the industry if tobacco use among children does not drop substantially.
- Significant price increases on the cost of tobacco products.
- No marketing to children.
- Broad disclosure of industry documents.
- Provisions to ensure that federal law does not preempt more restrictive state and local laws.
- Support for important public health initiatives.
- Funding for implementation of international tobacco control initiatives.
- Protections from secondhand smoke.
- Help for tobacco farmers and their communities.

In addition to documenting concern over youth tobacco use and the need for Congress to address national tobacco control policy in the next six months, the poll also revealed that:

- By a margin of two to one, the public favors President Clinton's approach to building on the proposed tobacco settlement agreement to enact a national tobacco policy. Fifty-nine percent of those polled favored the approach, with 29 percent opposed and 12 percent undecided.
- A majority also supports many of the more specific provisions of the president's plan for a national tobacco policy, including: full authority for FDA with no special restrictions (60% v. 28% opposed); a national minimum tobacco purchasing age with required photo

identification checks to reduce youth access to tobacco (85% v. 10% opposed); stiff industry penalties if youth smoking does not decline (57% v. 34% opposed); a cigarette price increase of as much as $1.50/pack if youth smoking does not decline (59% v. 33% opposed); restricting smoking in public places (78% v. 16% opposed); and funding a national tobacco use prevention/education program (70% v. 20% opposed).

- Seventy-three percent of respondents agreed that a national tobacco policy is important to help parents discourage kids from smoking. Two-thirds (67%) believe that a national tobacco policy is likely to reduce youth tobacco use, and almost one-half (49%) believe a national tobacco policy is likely to reduce tobacco use by adults.

Findings from the poll, commissioned by the CAMPAIGN FOR TOBACCO-FREE KIDS, were released at today's ENACT news conference.

"It's clear that there is overwhelming support for a comprehensive plan to protect both kids and adults from tobacco," said Dr. Ronald M. Davis, director of the Center for Health Promotion and Disease Prevention at the Henry Ford Health System in Detroit, which is a member of Partnership for Prevention. He also is a fellow of the American College of Preventive Medicine.

ENACT members said they thought Congress could pass legislation as early as the spring of 1998. Hearings on the issue are already taking place on Capitol Hill.

"We stand ready to work with the Congress and the American people to accomplish this important goal," said Dr. Michael C. Caldwell, Dutchess County (NY) health commissioner and a board member and tobacco committee chair of the National Association of County and City Health Officials.

###

Note to editors: A full summary of poll findings is available.

CAMPAIGN for TOBACCO-FREE Kids

PUBLIC SUPPORT FOR A NATIONAL TOBACCO POLICY

FINDINGS FROM A NATIONAL POLL

A recent telephone survey commissioned by the Campaign for Tobacco-Free Kids reveals that the public is concerned about the tobacco issue and supports President Clinton's approach to enacting a national tobacco policy. The results demonstrate broad support for the president's approach and the specifics of the plan, as well as the belief that a national tobacco policy can reduce tobacco use by kids. The random national survey of 1,000 adults, conducted by Market Facts' TeleNation during the week following the president's announcement (September 19-25), has a margin of error of $\pm$ 3 percentage points.

1. IMPORTANCE OF NATIONAL TOBACCO POLICY

Almost all respondents to the survey expressed concern about tobacco use by kids. A large majority believes Congress should address the issue in the next six months.

- **Eighty-seven percent of the public is very (66%) or somewhat (22%) concerned about tobacco use by kids as a public health issue. Similar levels of concern are expressed for illegal drug use (91%) and AIDS (90%), while drunk driving (97%) and violence (96%) draw slightly more concern.**

- **Seventy-one percent of the public thinks it is very (42%) or somewhat (29%) important that the Congress address a national tobacco control policy in the next six months. Ninety percent believe Medicare reform is as important, while campaign finance reform and fast track trade legislation are considered as important by 76 percent and 70 percent, respectively.**

- **Seventy-two percent of those surveyed agree with the statement that it is important to establish a national tobacco policy now rather than waiting for lawsuits against the industry to conclude. Sixteen percent disagree, while 13 percent neither agree nor disagree, or do not know.**

2. REACTIONS TO PRESIDENT CLINTON'S APPROACH

Respondents to the survey were told that the president issued guidelines for building on the proposed agreement between the state attorneys general and the tobacco industry to enact a national tobacco policy by: 1) Strengthening the FDA's authority to regulate tobacco products; 2) Increasing the penalties on the tobacco industry if smoking by

- more -

1707 L Street, N.W. Suite 800 Washington, DC 20036
202-296-5469 (Phone) 202-296-5427 (Fax) www.tobaccofreekids.org (Internet)

young people does not decrease; 3) Increasing the price of tobacco products to further discourage use by young people; and 4) Helping farm communities to develop alternatives to tobacco.

- **The public favors the president's approach by a margin of two to one, with 59 percent in favor, 29 percent opposed, and 12 percent undecided.**

- **A majority of the public also supports many of the more specific provisions of the president's plan for a national tobacco policy, including:**

	Favor	Oppose	DK
Full Authority for FDA With No Special Restrictions	60%	28%	13%
Stiff Industry Penalties and Price Increases			
Stiff industry penalties if youth smoking does not decline	57%	34%	9%
Increase price by as much as $1.50 if youth smoking does not decline	59%	33%	9%
Expanded Efforts to Reduce Youth Access to Tobacco			
National minimum age with required ID checks	85%	10%	5%
Reduce access by banning vending machines and placing all tobacco products behind the counter	83%	13%	4%
Public Education, Counter Advertising, Cessation Assistance			
Funding national prevention/education program	70%	20%	11%
Funds for programs to help smokers quit	77%	16%	7%
Restrictions on Smoking in Public Places	78%	16%	6%
Limits on Tobacco Advertising			
Eliminating outdoor tobacco advertising	63%	28%	9%
Limit magazine advertising to black and white/text only in publications with 15% youth readership	55%	29%	16%
Prohibit tobacco sponsorship of sports/entertainment	51%	36%	13%

3. USE OF TOBACCO INDUSTRY FUNDS FROM NATIONAL TOBACCO POLICY

Support for the various elements of the president's plan is also evidenced by support for the use of potential funds from a national tobacco policy for various purposes:

	Favor	Oppose	DK
Enforce youth access laws	85%	10%	5%
Fund public education campaign	80%	12%	8%

Provide cessation programs	**79%**	**16%**	**6%**
Conduct research on tobacco	**78%**	**15%**	**7%**
Help farmers develop alternatives	**78%**	**13%**	**9%**
Reimburse states for Medicaid costs	**56%**	**33%**	**10%**
Compensate farmers for money lost	**50%**	**40%**	**11%**
Compensate sports/other events	**35%**	**50%**	**15%**
Pay smokers for damages	**33%**	**54%**	**12%**

4. PERCEIVED EFFECTS OF A NATIONAL TOBACCO POLICY

The public feels strongly that a national tobacco policy is necessary to discourage tobacco use by kids and that it can be effective in doing so.

- **Seventy-three percent of respondents agree with the statement that a national tobacco policy is important to help parents discourage kids from smoking. Twenty-one percent disagree, while 6 percent are undecided or do not know.**

- **Two-thirds (67%) of the public believe that a national tobacco policy is very or somewhat likely to reduce tobacco use by kids. Twenty-seven percent believe it is unlikely to reduce tobacco use by kids, while 7 percent are undecided. Almost one-half (49%) believe a national tobacco policy is likely to reduce tobacco use by adults; 41 percent say this is unlikely.**

###

E N A C T

Effective National Action to Control Tobacco

– A Public Health Coalition –

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
Association of State & Territorial Health Officials
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

Consensus Statement of ENACT

Building on decades of work by the public health community, the 1996 assertion of jurisdiction over tobacco by the U.S. Food and Drug Administration, the principles in the recent Koop-Kessler Report, and the June 20 agreement negotiated between the state Attorneys General and the tobacco industry, President Clinton announced on September 17 his support for comprehensive federal legislation based on five key elements to reduce tobacco use among all Americans, but particularly among children.

Our organizations support the President's call for bipartisan legislation and pledge to work with the Administration, Members of Congress, the public health community and the American people to achieve this goal.

We have an historic opportunity to prevent and dramatically reduce tobacco use among children and adults and reduce secondhand smoke in public places and worksites. Our priority is the enactment of comprehensive, sustainable, effective, well-funded tobacco control legislation.

This is a singular and unique opportunity to protect children and save lives. Therefore, we are committing our resources, including our millions of members, volunteers and staffs, to the opportunity for fundamental change that is possible now, while pledging to continue to work on longer term public health goals.

The following are important elements for effective legislation and must be adequately funded:

- **Full FDA Authority**: The FDA must have full jurisdiction over all tobacco products and nicotine delivery devices. Furthermore, the FDA must be permitted to use the same procedures in regulating tobacco, and its decisions should be subject to the same standard of review that generally apply under the Food, Drug, and Cosmetic Act.

- **Tough Penalties**: The tobacco industry must be subject to significant penalties if tobacco use among children does not drop substantially. The penalties should be non-tax deductible, uncapped, escalating and brand-specific to youth tobacco use to give the tobacco industry the strongest possible incentive to stop targeting children.

P.O. Box 65168
Washington, DC 20035
Phone: (202) 293-1405

- **Price Increases**: The cost of tobacco products should be increased well beyond the $0.62 per pack projected under the state Attorneys General agreement in order to deter children from taking up their use, whether through an increase in state and federal excise taxes, modifications in the tax treatment of annual payments, and/or price hikes from the tobacco companies due to increased settlement costs.

- **No Marketing to Children**: Tobacco marketing and advertising to children must be prohibited.

- **Document Disclosure**: To ensure that patterns of corporate malfeasance are disclosed and effectively checked in the future, tobacco legislation must provide for broad disclosure of industry documents, especially those containing scientific or other health information or relating to the industry's attempts to market tobacco to children.

- **No Preemption**: Any federal legislation should explicitly provide that state and local governments are not preempted from establishing or retaining requirements equal to or more stringent than any federal requirement (including taxation) relating to tobacco control, other than requirements regulating the content of tobacco products.

- **Public Health Initiatives**: Legislation should include improved warning labels, provisions to eliminate youth access to tobacco, public education, tobacco use cessation, research, and state and local tobacco control activities.

- **International Leadership**: A portion of any funds should be earmarked for international organizations and federal agencies for the implementation of international tobacco control initiatives. Furthermore, the President should issue an Executive Order prohibiting the U.S. Trade Representative, the Department of Commerce, U.S. Embassies, and other federal agencies from interfering in any efforts by foreign national governments to curb tobacco use.

- **Secondhand Smoke**: The public's protection from secondhand smoke hazards should be included as an integral part in any national tobacco policy. This should include federal environmental tobacco smoke restrictions for restaurants without preempting tougher local and state laws.

- **Protection of Tobacco Farmers and Their Communities**: The impact of the legislation on tobacco farmers and their communities should be addressed.

Each organization has identified additional ways to achieve our shared goal, and will work to implement those provisions which are unique to its constituency and goals.

Together, we are committed to improving public health; our organizations have long been devoted to reducing the use of tobacco, particularly among children. We join together now to support an effective national policy on tobacco control.

E N A C T

Effective National Action to Control Tobacco

– A Public Health Coalition –

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
Association of State & Territorial Health Officials
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

[Sample of letter sent to all Members of Congress]

October 1, 1997

The Honorable Trent Lott
United States Senate
Washington, D.C. 20510

Today we stand on the brink of making tremendous gains in the fight to save lives and protect children from tobacco. We applaud the work that has been done by Congress, the state Attorneys General, the Koop/Kessler Committee, public health advocates, and President Clinton to create this historic opportunity.

The President's recent action moved us a step closer to achieving a national tobacco control plan to drive down youth and adult smoking rates, help addicted smokers quit, and stop our young people from ever starting to use tobacco products. Now, we must all work to make this a reality.

Our public health organizations have joined together as a coalition, ENACT (Effective National Action to Control Tobacco), to help achieve a national, comprehensive and sustainable program to protect Americans from tobacco. We offer our assistance and urge you and your colleagues in the Congress to craft effective legislation to make this program possible.

This is an historic opportunity to protect children and save lives, and therefore we are committing our resources, including our millions of members, volunteers and staff, to this challenge. We intend to reach out to the American people, who overwhelmingly support efforts to protect children from tobacco.

A recent telephone survey found that 87 percent of the public is concerned about tobacco use by kids as a public health issue. Additionally, 71 percent of the public thinks it is important that Congress address a national tobacco control policy in the next six months.

P.O. Box 65168
Washington, DC 20035
Phone: (202) 293-1405

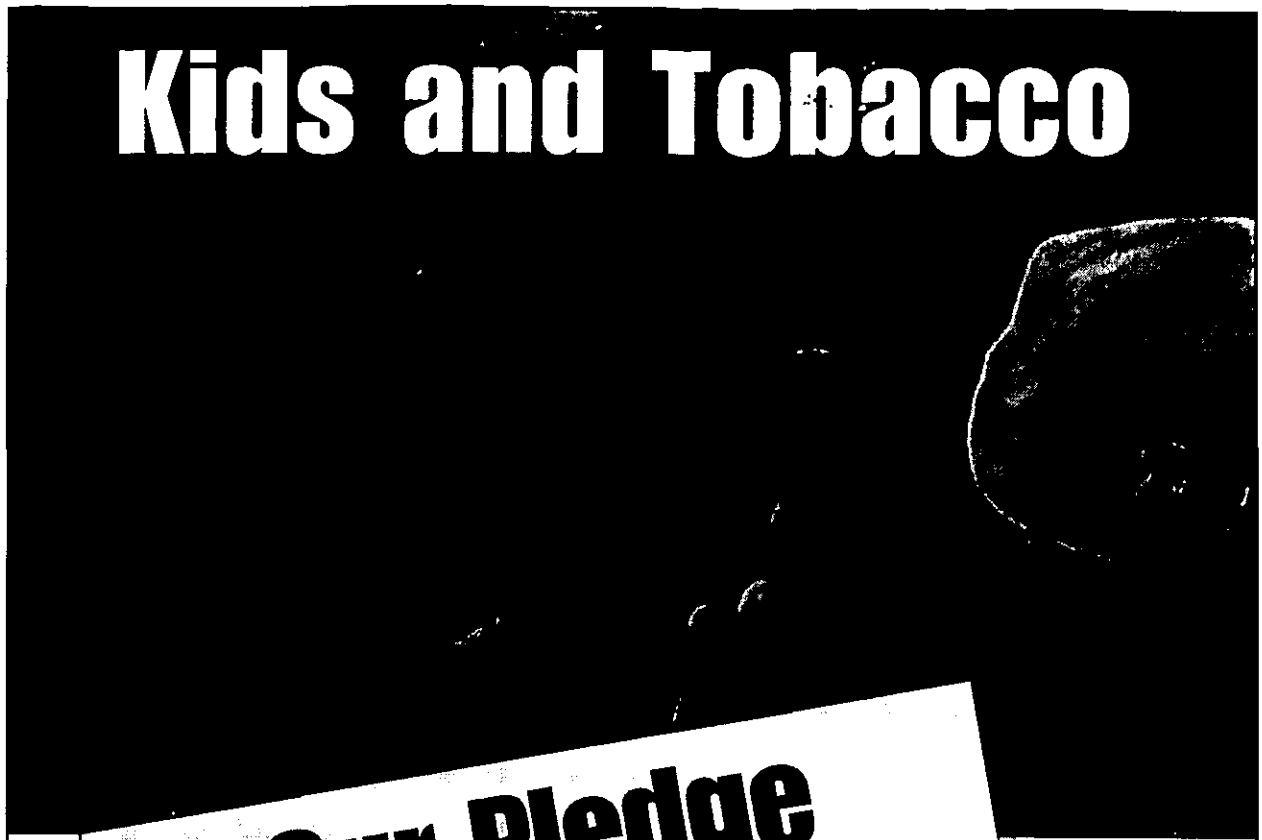
With so many of our children falling to tobacco addiction every day it is critical that we take action. We look forward to working closely with you, the Clinton Administration, the entire public health community, and the American people to ensure success in the 105th Congress.

Please let us know how we can assist you in this endeavor.

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
Association of State and Territorial Health Officials
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

(Attachment)

Kids and Tobacco



Our Pledge to America

Recently President Clinton outlined broad principles for a national tobacco control policy and asked Congress to enact legislation to significantly reduce tobacco use among our youth.

After decades of rising youth addiction and adult disease and death, we have before us the chance to kick this nation's lethal tobacco habit.

That is why our public health organizations have joined together, representing millions of members, volunteers, and staff. Today, we pledge to the American people that we are committing ourselves fully to this challenge.

We pledge to work in a true bipartisan fashion with the Congress and to take our case to the public. We pledge to work with all our collective strength to bring about the nation's first comprehensive, well-funded and sustainable program to prevent and dramatically decrease tobacco use among children and adults and to reduce secondhand smoke in public places and worksites.

We welcome your help. Join with us to enact national tobacco legislation and win the Tobacco War for America's good health.

Effective National Action to Control Tobacco

ENACT

A Public Health Coalition

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association
American Medical Association
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

ENACT (Effective National Action to Control Tobacco)
P.O. Box 65168 • Washington, DC 20035 • 1-800-227-2345

E N A C T

Effective National Action to Control Tobacco

– A Public Health Coalition –

American Academy of Family Physicians
American Academy of Pediatrics
American Cancer Society
American College of Chest Physicians
American College of Preventive Medicine
American Heart Association

American Medical Association
Association of State & Territorial Health Officials
Campaign for Tobacco-Free Kids
National Association of County and City Health Officials
Partnership for Prevention

List of contacts Members ENACT coalition:

American Academy of Family Physicians
Sarah Thomas
Director of Communications
Tel 1-800-274-2237

American Academy of Pediatrics
Marjorie Tharp
Public Affairs Manager
Tel 202-347-8600

American Cancer Society
Emily Smith
Director of Communications
Tel 202-546-4011

American College of Chest Physicians
Lynne Marcus
Vice President of Public Affairs
Tel 847-498-1400

American College of Preventive Medicine
Suzanne Leous
Director of Public Affairs
Tel 202-466-2044

American Heart Association
Trish Moreis
Manager, Public Advocacy Communications
Tel 202-785-7900

American Medical Association
Brenda Craine
Assistant Director - Media and Information Services
Tel 202-789-7447

Association of State and Territorial Health Officials
Cheryl Beversdorf
Executive Vice President
Tel 202-371-9090

Campaign for Tobacco-Free Kids
Kay Kahler Vose
Director, Communications
Tel 202-296-5469

National Association of County and City Health Officials
Donna Grossman
Director of Government Affairs
Tel 202-783-5550

Partnership for Prevention
Kelley O'Brien
Director of Government Affairs
Tel 202-833-0009

P.O. Box 65168
Washington, DC 20035
Phone: (202) 293-1405

American Medical Association
Physicians dedicated to the health of America

Tobacco - settlement - public health reports

News Release

FOR IMMEDIATE RELEASE July 31, 1997

For further information, contact: Brenda L. Craine
202-789-7447

AMA CALLS TOBACCO DEAL "A LANDMARK EFFORT" BUT MODIFICATIONS MUST BE MADE

The American Medical Association today announced support for a "comprehensive legislative solution" to reduce underage tobacco use based on the proposed tobacco settlement agreement -- if Congress adopts critical improvements.

The AMA released a 45-page report, which calls for strengthening the agreement, especially two "essential" provisions that would "achieve real, permanent, major public health benefits." The AMA recommendations would strengthen the FDA's jurisdiction over tobacco products -- so that the FDA is given the same authority over tobacco products that it has over other drugs and devices, and increase the penalty paid to the tobacco industry from $80 million to as much as $423 million for each percentage of underage use above the targets for underage smoking (based on the lifetime social costs of tobacco use).

Richard F. Corlin, MD, speaker of the AMA's House of Delegates, called the agreement a "landmark effort," which contains many otherwise unachievable benefits. The AMA outlined nine advantages to addressing the tobacco problem through an improved version of the proposed settlement, rather than continuing litigation and piece-meal legislation, including the fact that the settlement would generate between $4.5 and $7.5 billion per year in funding for public health programs, would confirm FDA jurisdiction and implement unprecedented youth access and advertising restrictions immediately, and would established an ambitious set of targets for reducing underage smoking.

1101 Vermont Avenue, NW
Washington, DC 20005
202 789-7400

"The danger is that once the tobacco industry gets the relief it seeks, there is no incentive for them to cooperate further," Dr. Corlin said. "In other words, we have to get it right the first time."

The AMA will now turn its attention to gaining public health support and legislative approval for a re-vamped settlement proposal that is modified according to task force recommendations, while offering medicine's input to the Clinton administration as it continues to evaluate the initial settlement proposal.

"We will lobby vigorously for the adoption of these changes as part of any comprehensive legislation passed by Congress and signed by President Clinton," said Randolph Smoak, M.D., AMA Vice Chair. "The AMA's commitment is to help organize a broad-based public health coalition that will engage leaders in Congress and the White House on behalf of America's young people who, for too long, have been seduced by cigarette-makers."

The Task Force report calls for several additional changes in the agreement, including certain " strongly recommended" modifications:

- increasing the price of cigarettes by $1.00 per pack as opposed to the proposed $0.62 per pack;
- allowing the FDA to progressively tighten the Look Back program after ten years with the goal of reducing underage tobacco use to incidental levels;
- clarifying the preemptive effect of federal youth access restrictions so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum;
- expanding the restrictions to tombstone-only advertising for all publications.
- assuring that the Look Back program for reducing underage use of smokeless tobacco is identical to targets for reducing underage smoking.

# # #

PROPOSED TOBACCO SETTLEMENT AGREEMENT

EXECUTIVE SUMMARY AND STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION BOARD OF TRUSTEES

The proposed tobacco litigation settlement represents a landmark effort to overcome the scourge of underage smoking and to achieve substantial and permanent reductions in tobacco use. At the same time, it effectively eliminates the most significant threats of civil liability to the tobacco industry. With these threats eliminated, the tobacco industry will have little incentive to return to the bargaining table. It is essential, therefore, that the settlement produce real, permanent, and major public health benefits. To determine the extent to which it does, the American Medical Association (AMA) commissioned a Task Force, which included members of the AMA Board of Trustees, its House of Delegates, independent physician experts in tobacco control and experienced legal and economic public policy consultants, to undertake a comprehensive analysis of the proposed tobacco litigation settlement from a public health perspective. The Task Force report is attached hereto. The Board of Trustees of the AMA endorses the report and recommendations of the Task Force in their entirety.

The AMA believes that the proposed settlement offers a promising basis for delivering on the required public health benefits. The settlement also has a number of advantages relative to continued litigation and piecemeal legislative reform. For example, the settlement provides funding for public health initiatives and enforcement, and it puts a new regulatory regime in place immediately. On the other hand, critical improvements must be made if the proposed settlement is to produce the desired results.

In particular, two changes are essential. First, the FDA must be given the same authority over tobacco products that it has over other "drugs" and "devices" under the Food, Drug and Cosmetic Act. The only exception should be the 12-year moratorium on any FDA action implementing a prohibition of traditional tobacco products or the elimination of nicotine from tobacco products. The settlement negotiators evidently agreed to this moratorium in order to provide the tobacco industry some predictability about future FDA regulation. But achieving predictability does not require burdening FDA regulation with ill-advised substantive and procedural hurdles that have not public health rationale.

To effectuate this change, the following revisions to the legislation implementing the proposed settlement, or their equivalent, should be adopted:

- There should be a constructional principle indicating that FDA has full authority over all tobacco products and nicotine delivery devices unless a specific exception is expressly set forth in the legislation.

- The settlement should be clarified by eliminating any language that suggests that FDA authority to regulate tobacco products is limited in ways other than the 12-year moratorium.

- FDA should be permitted to use the same procedures, and its decisions should be subject to the same standard of review, that generally apply under the Food, Drug and Cosmetic Act.

- The definition of "tobacco product" should be clarified to include pipe tobacco, cigars, and any other tobacco product.

Second, the Look Back surcharge program designed to create a financial incentive for tobacco companies to reduce underage smoking must be given real teeth. It must provide reasonable assurance that each tobacco company achieves the targets for reduction in underage tobacco use that are set forth in the proposed settlement. If the tobacco industry is to be relieved of any significant civil liability and if FDA jurisdiction is to be subject to a 12-year moratorium for elimination of nicotine, then it is essential that a program of financial incentives be put in place that will guarantee significant reductions in underage smoking.

To effectuate this change, the following revisions to the legislation implementing the proposed settlement, or their equivalent, should be adopted:

- The Look Back surcharge payments should not be subject to the automatic pass through and should not be tax deductible

- The Look Back surcharge payments should be assessed against each individual company based on reductions in underage use achieved by that company. They should not be assessed on the basis of collective industry responsibility.

- The Look Back surcharge payments should be based on the discounted present value of the lifetime social costs of tobacco use, not restitution of profits. We estimate that the penalty should be increased to a level of $400 to $450 million for each percentage of underage use above the target on an industry wide basis (in contrast to $80 million in the proposed settlement).

- The $2 billion cap on annual surcharge payments should be eliminated. Any cap should be based on a multiple of company profits from underage use or on total company profits in the domestic market.

- Tobacco companies that exceed the targets should be given a financial credit. There should be no abatement for compliance with regulations and corporate good faith.

Beyond these essential changes, the AMA strongly recommends the following additional modifications to the proposed settlement.

- The price of cigarettes should be targeted to rise by about $1.00 per pack, as opposed to the $0.62 per pack projected under the proposed settlement. This can be accomplished by an increase in the cigarette excise tax, by upward adjustments in the Annual Payments, or by modifications in the tax treatment of existing Annual Payments.

- The FDA should have authority progressively to tighten the targets of the Look Back program after the ten-year period addressed by the proposed settlement, with a goal of reducing underage tobacco use to incidental levels.

- The preemptive effect of federal youth access restrictions should be narrowed and clarified so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum.

- The preemptive effect of federal advertising restrictions should be narrowed and clarified so that states and local governments may regulate local advertising and marketing and may impose counter-advertising requirements on tobacco companies.

- The restriction on advertising to tombstone-only format should be extended to all publications.

- A federal agency (such as HHS) should be given overall responsibility for disbursement of the Public Health component of the annual Payments, including oversight of grant recipients and authority to make adjustments in allocations in future years.

- The provisions regarding nonsigning companies should be modified so as to avoid erecting unnecessary barriers to new entry.

- The Look Back program should have targets for reduction of underage use of smokeless tobacco identical to the targets for reduction in underage smoking.

Throughout its report, the Task Force recommends a number of additional clarifications or refinements.

If the changes that the Task Force has identified or equivalent changes are adopted by the Administration and Congress, the proposed settlement would be an historic event if the life-or-death struggle to reduce tobacco use to a minimum. Accordingly, the Board of Trustees of the AMA has committed the resources of the AMA to press for the inclusion of these changes in any legislation adopted by Congress.

ANALYSIS, REPORT, AND RECOMMENDATIONS OF THE AMERICAN MEDICAL ASSOCIATION TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT

July 31, 1997

ANALYSIS, REPORT, AND RECOMMENDATIONS OF THE AMERICAN MEDICAL ASSOCIATION TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT

George W. Anstadt, M.D., Chair

Michael J. Achinger, M.D.

Michael W. Bigelow, M.D.

David L. Callender, M.D.

Ronald M. Davis, M.D.

Patrick B. Harr, M.D.

J. Edward Hill, M.D.

David R. Holley, M.D.

Ronald H. Levine, M.D.

D. Robert McCaffree, M.D.

John Slade, M.D.

Randolph D. Smoak, M.D.

Staff:

Kirk B. Johnson
Thomas Houston, M.D.
Michael L. Ile
Richard Deem

Consultants:

SIDLEY & AUSTIN
Newton N. Minow
Jack R. Bierig
Michael W. Davis
Thomas W. Merrill
Larry J. Nyhan

TABLE OF CONTENTS

Page

Introduction 1

I. FDA Jurisdiction 4
(1) Express Conferral of Jurisdiction on FDA 4
(2) The Scope of FDA Jurisdiction 5
(3) Limitations on FDA's Jurisdiction 6
(a) Except as Expressly Stated, FDA's Authority Over Tobacco Products Should Be No Different From Its General Authority Over Drugs and Devices 6
(b) Restrictions on the FDA's Promulgation of "Performance Standards" 7
(c) The Definition of "Tobacco Product" 10

II. Advertising and Marketing Restrictions 10
(1) First Amendment Issues 11
(2) Tombstone-Only Advertising in All Publications. 12
(3) Advertising Restrictions As A Five Year Trial Period 13
(4) Miscellaneous Clarifications 14

III. Restrictions on Youth Access 14

IV. Economic Incentives – Smokers 16
(1) Interpreting the Pass Through 18
(2) Tax Deductibility 19
(3) Public Health Benefits of Price Increases 20

V. Economic Incentives – Tobacco Companies 22
(1) Automatic Pass Through and Tax Deductibility of the Surcharge 23
(2) Collective Responsibility for the Surcharge 24
(3) Use of Profits Rather Than Social Costs 27
(4) The $2 Billion Annual Cap 29
(5) Rewards for Companies that Exceed the Targets 30
(6) Future Targets and Targets for Smokeless Tobacco 32
(7) The Role of the FDA 32

VI. Funding of Public Health Programs 33

VII. Civil Liability 36
(1) Limitations on Liability 36

(2) The Impact of Limitations on Liability 38

VIII. Preserving The Integrity Of The Settlement 39
(1) Nonsigning Tobacco Manufacturers 40
(2) Enforcement Of Consent Decrees 41
(3) Severability 42
(4) Global Extension 42

IX. Recommendations 43
(1) Essential Changes 43
(2) Strongly Recommended Changes 45
(3) Recommended Changes 46

ANALYSIS, REPORT, AND RECOMMENDATIONS OF THE AMERICAN MEDICAL ASSOCIATION TASK FORCE ON THE PROPOSED TOBACCO SETTLEMENT AGREEMENT

Introduction

The proposed tobacco litigation settlement represents an historic opportunity. Structured properly, the settlement could provide a powerful and effective tool for overcoming the scourge of underage smoking and for achieving substantial and permanent reductions in tobacco use. The settlement would also permit these goals to be pursued immediately, without the uncertainty and delay of further litigation.

Yet the proposed settlement is also fraught with peril. It gives the tobacco industry what it most desperately wants: relief from the threat of significant civil liability. It is the threat of such liability, more than anything else, that has brought the industry to the bargaining table. Once that threat is removed, the industry will have little incentive to cooperate further. Thus, it is essential that the settlement produce real, permanent, and major public health benefits.

The Task Force has undertaken a comprehensive analysis of the proposed settlement. We believe the negotiators have produced a framework that provides a promising basis for delivering on the required public health benefits. On the other hand, a number of critical improvements must be made if the settlement is to produce the desired results.

In particular, the Task Force believes that two changes are essential:

- The Food and Drug Administration (FDA) must be given express authority to regulate tobacco products in the same manner, using the same procedures, as would generally apply to drugs and devices, with one exception: FDA would be subject to a 12 year moratorium against implementing action that would ban the sale of traditional tobacco products or require the elimination of nicotine from such products.

- The Look Back surcharge program, designed to provide financial incentives to tobacco companies to achieve stated targets in the reduction of underage smoking, should be given real teeth. As structured in the proposed settlement, this program would be ineffectual. We propose realistic sanctions that assure that the targets for underage smoking reduction set by the negotiators will actually be met.

An ideal legislative package for regulating tobacco products would contain all of the provisions set forth in previous AMA policy statements and many of the elements advocated in

the Koop-Kessler Advisory Committee Report.[1] Such a package might include full, immediate, and complete authority for FDA to regulate all tobacco products and their ingredients; a complete prohibition on tobacco advertising and promotion; a substantial increase in excise taxes to raise the price of tobacco products; and complete disclosure of all confidential tobacco company documents dealing with the composition of health and safety issues related to tobacco products and marketing efforts.

The proposed settlement falls short of the ideal on these and many other issues. Such, however, is the nature of settlements. The AMA remains committed to achieving all the positions set forth in its existing policy statements. Nevertheless, the fact that the proposed settlement is less than ideal does not necessarily mean that a comprehensive settlement should be rejected from a public health perspective.

There are a number of advantages to addressing the tobacco problem by a comprehensive settlement rather than by continuing litigation and piece-meal legislation. These advantages include the following:

- The settlement would generate between $4.5 billion and $7.5 billion per year in funding for public health programs, including FDA enforcement initiatives. This is far more money than would be appropriated by Congress in conjunction with stand alone legislation or continuation of FDA's current regulatory efforts.

- Because the substantial Annual Payments required by the settlement (rising to $15 billion per year after year four) must be passed through to consumers, the settlement operates like a de facto sales tax increase for cigarettes and smokeless tobacco. It is possible, but highly uncertain, that an explicit sales or excise tax increase of the same magnitude could be enacted in the near future.

- The major tobacco companies would enter consent decrees in which they would promise to abide by restrictions on advertising and other constraints even if the parallel provisions in the legislation were declared unconstitutional. This provides additional assurance that the agreement's advertising controls can be put in place and remain effective.

- The funding generated by the settlement can be disbursed to the states by the federal government, thereby providing a secure constitutional foundation for federal standards for state retail licensing statutes and other desirable measures that might exceed the authority of the federal government to impose on the states directly.

---

[1] Final Report of the Advisory Committee on Tobacco Policy and Public Health, Co-Chairs: C. Everett Koop, M.D., Sc.D. and David A. Kessler, M.D. (July 1997).

- A system of financial incentives on tobacco companies is put in place to reduce underage smoking. Imposing a similar system on companies without their consent would be difficult to achieve politically.

- The settlement provides for the establishment of a national tobacco document depository open to the public containing many previously non-public or confidential documents from the files of the tobacco industry. Although tobacco companies can still invoke common law privileges with respect to these documents, stand alone legislation requiring the creation of such a depository would encounter stiff resistance and legal challenges from the companies.

- The settlement provides for the enactment of The Smoke-Free Environment Act of 1993, which adopts tough minimal federal standards for second hand tobacco smoke in all public buildings. It is doubtful that this legislation would otherwise be adopted in this form in the foreseeable future. Although OSHA could promulgate similar rules for worksites under its current authority, to date it has not done so and any such action would be delayed by judicial challenges.

- Resolving tobacco litigation by settlement permits both sides to save litigation costs. These savings can be devoted, in part, to activities with direct public health benefits.

- Perhaps most importantly, settlement allows a new regulatory regime for tobacco products to be put into place immediately. Continuing down the current path of litigation plus efforts to regulate under FDA's and other agencies' existing authority would result in a tobacco control policy that is uncertain, uneven, and burdened by protracted delays.

Taken together, the advantages of settlement suggest that some compromise relative to the ideal package of legislative reforms is justifiable. This does not mean, of course, that the particular compromises contained in the proposed settlement are acceptable.

In this document, the Task Force has endeavored to assess the public health implications of the proposed settlement, suggest clarifications that appear to be within the overall expectations of the negotiators, and recommend certain modifications that we regard as essential if tobacco use -- particularly use by minors -- is to be meaningfully curtailed. We have approached this task as physicians whose primary concern is to promote, preserve, and protect their patients' health. We hope that our analysis will be of assistance to the Administration, the Congress, and members of the public.

The Board of Trustees of the American Medical Association has endorsed the recommendations of the Task Force. It has committed the resources of the AMA to press for their inclusion in any legislation adopted by Congress.

I. FDA Jurisdiction.

The proposed settlement calls for legislation that would expressly confer jurisdiction on FDA to regulate tobacco products. Such legislation would immediately resolve the current legal challenge to FDA's authority, and would place the full weight and authority of Congress and the American people behind FDA regulatory efforts. In these respects, the settlement is clearly desirable.

On the other hand, provisions in the proposed settlement that are likely to limit or frustrate the effectiveness of FDA oversight must be minimized. The tobacco industry would, of course, like to secure predictability about the future of FDA regulation of tobacco products. Such predictability, however, should not take the form of ill-advised substantive and procedural hurdles that may unduly burden FDA efforts to protect and enhance the public health.

(1) Express Conferral of Jurisdiction on FDA.

Although FDA has asserted jurisdiction over tobacco products under current law, its authority to do so is under challenge.

- Strong arguments have been advanced in support of FDA jurisdiction under current law. Moreover, recent revelations about the intent of tobacco companies to use tobacco products to affect the structure or function of the human body enhance the force of FDA's conclusion that these products meet the legal definitions of "drug" and "device" under the Food, Drug and Cosmetic Act.

- Further, a federal court in North Carolina has sustained FDA's jurisdiction over tobacco products in a thorough opinion.[2]

- Nevertheless, that ruling is now on appeal. Whether the Court of Appeals -- or possibly the Supreme Court -- would ultimately sustain or reject FDA jurisdiction over tobacco products under current law is a difficult question that has divided legal experts.

---

[2] Coyne Beahm, Inc. v. Kessler, 958 F.Supp. 1060 (D. N. Car., April 25, 1997).

There thus remains a possibility that the courts will ultimately decide that FDA lacks any authority, or has only limited authority, to regulate tobacco products under current law.

The settlement eliminates this legal uncertainty and expressly confers jurisdiction on the FDA to regulate tobacco products and ingredients, tobacco product manufacturing, marketing, and access to tobacco products.

- Moreover, the adoption of legislation expressly conferring authority on FDA to regulate tobacco would lend legitimacy to the agency's efforts.

- With a new legislative mandate, FDA will be more likely to receive support from the general public for its efforts aggressively to regulate tobacco products.

Of course, Congress has the power to adopt legislation confirming FDA jurisdiction to regulate tobacco products without the settlement. Realistically, however, the chances of such legislation being adopted are greater if presented as part of a settlement that has the support of the tobacco industry.

(2) The Scope of FDA Jurisdiction.

In addition to confirming FDA's jurisdiction to regulate the sale and promotion of tobacco products, the settlement expressly directs FDA to regulate in ways that go significantly beyond that contemplated in the FDA's 1996 regulations, "Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."[3] For example:

- The FDA would be authorized to promulgate rules governing the testing, reporting, and disclosure of tobacco smoke constituents about which the FDA believes the public should be informed in order to protect public health.

- Manufacturers would be required to provide FDA with a list of all ingredients, substances, and compounds which are added to their tobacco products and, within five years after enactment of the Act, to conduct safety assessments on such additives.

- Manufacturers would be required to notify FDA of any technology that they develop or acquire that reduces the risk from tobacco products and, for a reasonable fee, to license this technology to companies that are subject to the same restrictions. Additionally, FDA would have the authority to mandate the introduction of less hazardous tobacco products that are technologically feasible.

---

[3] 61 Federal Register 44396 (August 28, 1996).

- Tobacco product manufacturers would be subjected to good manufacturing practice standards in a manner similar to the oversight exercised by FDA over other drug and device manufacturers.

- FDA would be permitted to adopt "performance standards" that could require the modification of tobacco products to reduce the harm they cause, including (subject to restrictions discussed below) modifications in nicotine content.

These additional forms of regulation could be asserted by FDA on its own authority if its jurisdiction to promulgate the 1996 regulations is upheld by the courts. However, the settlement probably accelerates the timing of these additional forms of regulation.

- If there were no settlement, FDA might wait until all appeals are exhausted before moving to adopt any of the additional regulations contemplated by the settlement. These appeals might not be resolved for several years.

- FDA might also lack funding to take on some of these additional forms of regulation -- something which the settlement provides. Congress has not been eager to increase substantially the funds available to FDA to regulate tobacco products.

(3) **Limitations on FDA's Jurisdiction.**

Ideally, any legislation confirming FDA jurisdiction to regulate tobacco products would permit the agency to adopt any form of regulation consistent with the public interest. This approach may not be possible within the context of a settlement. However, even if it is necessary to recognize some limitations on FDA authority – at least for a period of time -- those limitations should not include substantive and procedural barriers that have no plausible public health justification and that are likely to frustrate FDA efforts to reduce the adverse public health effects of tobacco use.

Set forth below are several areas in which the proposed settlement imposes unacceptable limitations on FDA authority or where the language is sufficiently ambiguous to require clarification to assure that unacceptable limitations are not created through interpretation.

(a) Except as Expressly Stated, FDA's Authority Over Tobacco Products Should Be No Different From Its General Authority Over Drugs and Devices.

The general approach to FDA authority in the proposed settlement appears to be one of "enumerated powers." The settlement lists and describes a number of categories of FDA authority over tobacco products, including advertising and marketing, youth access, reduced risk products, performance standards, manufacturing oversight, access to company information, and non-tobacco ingredients.

- There is a danger that such an approach will lead to the inference that if a specific power is not granted to FDA, it is by implication denied.

- For example, if FDA is not specifically given authority to regulate flavoring ingredients, can FDA regulate flavorings that have strong appeal to youths (such as cherry flavoring in smokeless tobacco) under its authority to regulate non-tobacco ingredients shown to be "harmful"?

- Similarly, FDA may want to acquire information about, or require companies to perform safety assessments concerning, ingredients contained in substances derived from tobacco, as well as ingredients added to tobacco. It is not clear that the settlement as drafted would permit this (I.F.).

A better approach would be to grant FDA full authority over tobacco products as "drugs" and "devices" under the Food, Drug and Cosmetic Act, subject to express exceptions.

- The burden should be on the tobacco companies to spell out with specificity the ways in which FDA authority to regulate tobacco products as drugs or devices will be limited.

- The burden should not be on government regulators and the public health community to imagine every conceivable issue that might arise in the future, and to devise specific statutory language conferring authority on FDA to tackle the problem.

Any legislation implementing the settlement should therefore include a constructional principle stating that, except as otherwise expressly indicated, FDA has all power and authority to regulate all tobacco products as drugs and devices under the Food, Drug and Cosmetics Act.

(b) Restrictions on the FDA's Promulgation of "Performance Standards."

The most serious and unacceptable limitations on FDA authority are substantive and procedural barriers placed on FDA's authority to issue performance standards requiring the modification of tobacco products to reduce the harm they cause.

The parties to the settlement appear to have reached an understanding to the effect that, for twelve years, FDA may not order a fundamental alteration of traditional tobacco products (for example, by mandating the elimination of nicotine).

- For the first 12 years, FDA "shall be permitted to adopt performance standards that require the modification of existing tobacco products, including the gradual reduction, but not the elimination, of nicotine yields, and the possible elimination of other constituents or other harmful components of the tobacco product" (I.E.5.A.).

- After the first 12 years, FDA may "require the alteration of tobacco products then being marketed, including the elimination of nicotine and the elimination of other constituents or other demonstrated harmful components of the tobacco product" (I.E.5.B.).

Although undesirable, this moratorium is undoubtedly the result of compromise. It may be critical to providing some predictability to the tobacco industry about the future course of FDA regulation.

However, the language that reflects the 12 year moratorium includes a number of troubling ambiguities which should be clarified in a satisfactory fashion.

- The proposed settlement says that FDA may not prohibit "the sale to adults of traditional tobacco products" (I.E.5.). Yet it also says that an FDA order requiring a fundamental alteration (such as the elimination of nicotine) after the 12 year moratorium "shall not be deemed to violate the prohibition on the sale of traditional tobacco products to adults" (I.E.5.B.n.1.). This is confusing and a potential source of mischief. The legislation should clarify that only during the first twelve years after implementation of the settlement is FDA prohibited from banning "the sale to adults of traditional tobacco products."

- In order to require the modification of tobacco products during the first 12 years or direct a fundamental alteration in tobacco products after 12 years, the FDA must find that its regulation "will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard." Such a finding could be virtually impossible to make with

respect to any substance for which there is a strong public demand. The legislation should clarify that demand for contraband is one factor to be considered by FDA as matter of protecting the public health, but is not an absolute precondition to any regulation.

- A footnote in the proposed settlement (I.E.5.B.n.2.) could give rise to a negative inference that FDA's authority to modify tobacco products during the 12-year moratorium does not extend to ordering reductions in nicotine content on the ground that nicotine is addictive (as opposed to finding that it has direct adverse health effects). Any such inference should be disclaimed. Rather, it should be made clear that FDA may order modifications in nicotine content (short of a total elimination) during the moratorium for any reasons that it deems necessary to promote the public health.

Equally troubling are a number of procedural barriers to the regulation of tobacco products that do not generally apply to FDA regulation of drugs and devices.

- FDA rules requiring either the modification or the fundamental alteration of tobacco products are subject to highly cumbersome formal rulemaking proceedings -- as opposed to the informal rulemaking ordinarily used in FDA regulations pursuant to §701(a) of the Act. Informal rulemaking procedures should apply.

- FDA rules requiring either the modification or the fundamental alteration of tobacco products are subject to *unusually* stringent standards of judicial review. With respect to any action to modify tobacco products, FDA must sustain its findings by "substantial evidence" (as opposed to the usual and somewhat more lenient "arbitrary and capricious" standard). With respect to any action to require fundamental alterations in tobacco products, FDA must sustain its findings by a "preponderance of the evidence" (the standard a plaintiff must satisfy in an ordinary civil trial). The "arbitrary and capricious" standard of review should govern.

- Reviewing courts are instructed to defer to FDA's findings only to the extent that they fall within the agency's "field of expertise." The FDA is not ordinarily required to demonstrate that any particular finding is within its expertise. No demonstration of particular FDA expertise should be required.

- The proposed settlement says that any performance standard requiring a modification of existing tobacco products "shall be subject to the current procedures of the Regulatory Reform Act of 1996 to provide time and a process for Congress to intervene should it so choose" (I.E.5.A.). This appears to be a reference to Section 251 of the Small Business Regulatory Enforcement Fairness

Act of 1996, Pub. L. No. 104-121, which provides that any "major rule" must be submitted to Congress for sixty days to allow Congress to consider enacting a joint resolution of disapproval. Apparently the settlement would mandate that this procedure be followed even if it would not be independently required by the terms of the 1996 Act, or if the 1996 Act were repealed or invalidated. This provision should be deleted.

There is no evident justification for the foregoing procedural limitations other than to erect additional barriers to any FDA regulation of tobacco products -- barriers not generally placed in the way of FDA regulation of drugs and devices. Given the moratorium on any FDA action requiring the fundamental alteration of tobacco products, we see no legitimate justification for these procedural hurdles.

(c) The Definition of "Tobacco Product."

The proposed settlement gives FDA authority over "tobacco products." This term is said to have the same definition as contained in the FDA's 1996 regulations. The settlement also apparently covers "Roll Your Own, Little Cigars, Fine Cut, etc." (I.E.1.).

- Because the FDA in its 1996 regulations elected not to regulate pipe tobacco and cigars, an argument could be made that the regime established by the proposed settlement excludes pipe tobacco and cigars.

- FDA authority to investigate and regulate pipe tobacco, cigars, and all other tobacco products and nicotine delivery devices should be made explicit. Cigar smoking, including such smoking by young persons, is on the rise. This trend may accelerate, especially if the price of cigarettes rises significantly because of the pass through of Annual Payments required by the settlement. Moreover, future forms of tobacco use, e.g., variants on "smokeless cigarettes," cannot be foreseen.

More generally, there is reason to believe that the market for traditional tobacco products containing nicotine and nicotine delivery devices such as inhalers may soon converge. It would be desirable to have all nicotine delivery devices subject to a single integrated regulatory scheme.

- All tobacco products should be subject to a single, comprehensive, regulatory scheme.

- Any legislation enacted as a result of the settlement should be drafted so that eventually all nicotine delivery devices -- whether based on tobacco or not -- are subject to a single, comprehensive, regulatory regime.

II. Advertising and Marketing Restrictions.

The proposed settlement includes restrictions on marketing and advertising that extend beyond the FDA's 1996 regulation.

- FDA's 1996 rules restrict tobacco advertising to FDA approved media; restrict advertising to black text on white background in publications likely to reach minors; ban tobacco billboards within 1000 feet of schools and playgrounds; require tobacco products and advertisements to include the label "nicotine delivery device;" ban the use of promotional merchandise; ban offers of gifts; and ban sponsorship of concerts and sporting events.

- The proposed settlement would incorporate requirements at least this restrictive in the legislation.

- In addition, the settlement would ban all use of human images and cartoon characters in any advertising; ban all billboard advertising; prohibit tobacco advertising on the Internet; ban indirect payments to movies and music videos to glamorize smoking; require new and more emphatic warning labels ("WARNING: Smoking can kill you", etc.); and require that warning labels comprise 25% of front panels of packages.

(1) First Amendment Issues.

One issue raised by these advertising restrictions is whether they will survive judicial challenge based on the First Amendment.

- We believe that the courts would ultimately uphold the FDA's 1996 advertising regulations, given the record compiled by FDA showing a compelling public health rationale for reducing underage smoking, and the fact that FDA's regulations are limited to media likely to be seen by minors.

- Because the provisions of the proposed settlement go beyond the FDA regulations, they would likely encounter a more vigorous First Amendment challenge.

- We do not suggest that these provisions cannot be defended with equal vigor, nor do we believe that they would be struck down. But the probability of sustaining them would be somewhat lower than is the case with respect to the FDA regulations.

- In order to maximize the chances that all advertising restrictions will be upheld, any legislation resulting from the proposed settlement should include express

findings and statements of purpose that emphasize the importance of reducing smoking among adults as well as minors. Such findings and statements of purpose would make it easier to justify the extension of advertising regulation to adult media.

One advantage of the proposed settlement is that it creates a mechanism for increasing the chances that the agreement's advertising regulations will endure regardless of the outcome of First Amendment challenges. The settlement provides that the parties will enter into consent decrees, in which they will "expressly waive any claim that the provisions of the consent decrees or the agreement violate the federal or state constitutions" (III.B.bullet 5.). In addition, "[t]he consent decrees will also state that if a provision of the Act covered by the decrees is subsequently declared unconstitutional, the provision remains an enforceable term of the consent decrees" (id.).

- In other words, the signatories to the proposed settlement -- including, of course, the major tobacco manufacturers -- will be bound to observe the advertising restrictions by judicial decrees as well as by statutory regulation.

- If the statutory law is invalidated on constitutional grounds, the signatories would continue to be required to abide by those restrictions.

There is some danger that this "waiver of rights" provision might be struck down under what is called the "unconstitutional conditions" doctrine.

- But the parties to the consent decrees are sophisticated and clearly understand their rights; the government has an important interest in obtaining a waiver; and the speech involved is commercial speech that can be subjected to a greater degree of government regulation. The unconstitutional conditions doctrine should therefore not cause the waiver of rights provision to be invalidated.

- The waiver of rights feature of the settlement substantially increases the probability that important advertising restrictions can be put into place in the near future.

(2) Tombstone-Only Advertising in All Publications.

Although the proposed settlement would ban image advertising in publications that reach a substantial portion of juvenile readers (15% or more), it would continue to permit color graphics, landscapes, and other evocative images in publications that serve a predominantly adult audience.

- Such image advertising serves no purpose other than to make tobacco products more attractive and hence to stimulate demand for their use.

- To the extent that image advertising affects overall levels of smoking, it represents a serious public health concern, whether the target of the advertising is adults or adolescents.

- Also, of course, some image advertising in publications primarily read by adults will also reach adolescents and children.

- Perhaps most importantly, the presence of image advertising in publications helps to reinforce a social attitude that smoking is acceptable. This attitude helps to perpetuate smoking by adults and increases its allure for teens.

Therefore, the Task Force recommends that the tombstone-only restriction on tobacco product advertising be extended to all publications, including those that have a predominantly adult audience.

(3) Advertising Restrictions As A Five Year Trial Period.

The AMA House of Delegates has previously adopted a resolution advocating the complete prohibition of tobacco product advertising.[4] We do not regard the proposed settlement as inconsistent with this resolution, or as precluding its eventual realization.

- The proposed settlement provides that the advertising restrictions it imposes "shall be allowed to operate" for five years. Thereafter, "the FDA would be authorized to review and revise the rules under applicable Agency procedures" (I.introduction.).

- It appears, therefore, that FDA is free to revisit the advertising restrictions after 5 years and, if it deems it appropriate, to adopt tougher restrictions, such as a complete ban on tobacco advertising.

On this understanding, we believe that allowing the restrictions of the proposed settlement to take effect for a five year trial period -- especially if supplemented by requiring tombstone advertising in all print media -- is an acceptable first step in dealing with tobacco advertising.

---

[4] AMA Policy No. 500.980, AMA Policy Compendium (1997 ed.).

- Other nations are moving rapidly to adopt limits on tobacco advertising more restrictive than those contained in either FDA's regulations or the proposed settlement. During the five year period in which the settlement provisions are in effect, additional information can be gathered about the effectiveness of these regulations. These studies will provide additional experience and knowledge on which to base further FDA action.

- It is also important to note that the proposed settlement calls for the expenditure of $500 million per year on counter-advertising. Again, it will be useful to study the effect of this major commitment of resources to counter-advertising, in order to determine whether additional counter-advertising might prove to be a promising strategy for FDA to pursue in the future.

(4) **Miscellaneous Clarifications.**

There are a few other areas in which clarification or elaboration of the advertising regime that will be in place for the next five years is warranted.

- The proposed settlement provides that "[c]urrent federal law providing for national conformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health is preserved" (V.B.2.). This should be clarified by the adoption of an explicit preemption and savings clause that supersedes existing preemption provisions of the Federal Cigarette Labeling and Advertising Act. Federal regulations should preempt state advertising regulation only in media that are distributed in interstate commerce. States should remain free to adopt more stringent regulations of local print advertising, point of sales advertising, promotional allowances, sampling distribution, and coupons.

- States should also be free to tax tobacco companies to fund counter-advertising beyond the levels provided for in the proposed settlement (as under the current California program).

- The prohibition on sponsorship should also be clarified to preclude tobacco company sponsorship of any computer software, Internet, or video products that utilize human or animal images or cartoon characters associated with smoking or that glamorize use of tobacco.

III. Restrictions on Youth Access.

The proposed settlement includes restrictions on access to tobacco products by minors that go considerably beyond the FDA's 1996 regulation.

- FDA's 1996 rules adopt a national minimum age for purchase of 18; require retailers to verify age by photographic ID; prohibit vending machines in places frequented by persons under 18; and ban sampling of tobacco products.

- The proposed settlement would incorporate requirements at least this restrictive in legislation.

- In addition, the settlement would require that all sales of tobacco take place through face-to-face transactions (no vending machines).

- Another important new provision regarding access is a national-licensing scheme for retail tobacco product sellers.

- Finally, the proposed settlement includes a number of provisions designed to encourage greater state efforts to enforce laws regarding sales of tobacco products to minors.

In general the licensing and state enforcement provisions appear to represent a substantial advance beyond the program adopted by FDA in August 1996.

The access provisions should be drafted to avoid the constitutional problems that led the Supreme Court recently to invalidate portions of the Brady Bill.[5]

- With proper drafting, it would appear that virtually all of the access regulations can be implemented as conditions attached to federal grants given to states.

- Further consideration should therefore be given to the mechanics of the flow of funds from the tobacco companies to the states, in order to assure that the grants to the states properly qualify as "federal funds" and thus that the conditions imposed on receipt of those funds satisfy constitutional requirements.

In addition, the enforcement provisions of the access regulations should be strengthened. The civil sanctions set forth in Appendix II, in particular, provide for very modest civil fines and suspension periods for selling tobacco products to minors. A retailer's license is to be permanently revoked only "for the tenth offense within any two year period."

- These wholly inadequate civil sanctions can aptly be described as "ten strikes and you're out."

---

[5] Printz v. United States, 65 U.S.L.W. 4731 (June 27,1997).

- Moreover, the civil sanctions are set forth as a federal maximum which the states "shall not exceed."

- Given that the proposed settlement expressly retains authority in the states to impose state criminal sanctions on retailers who sell to minors, there is no sound rationale for preemptive federal standards limiting states to nothing but the most modest civil sanctions.

- In formulating any legislation to implement the settlement, Congress should change this federally-imposed schedule of civil sanctions from a maximum to a minimum.

More generally, it is important to preserve the role of state and local governments in developing and enforcing access restrictions.

- In addition to being allowed to adopt civil penalties for violation of licensing requirements that go beyond the federal *minimum*, states should be allowed to experiment with additional enforcement tools, such as citizen suits and the use of consumer protection statutes.

- States should also be allowed to make it a criminal or civil offense for any person, not just a retailer, to sell cigarettes to a minor.

In addition, all too often federal PXs and commissaries serve as major sources of supply of cheap and readily accessible cigarettes to local communities.

- State and local access restrictions should be extended by statute to federal enclaves and federal facilities, including military bases and hospitals. The manner in which these state and local rules would be enforced at federal facilities should be determined by Executive Order.

- In addition, we recommend that a federal use tax -- equal to federal, state and local excise and sales taxes otherwise applicable in the area -- be imposed on tobacco products sold at federal enclaves and facilities. Consideration could be given to dedicating the proceeds of this tax for the benefit of federal service personnel and employees at these federal facilities.

IV. Economic Incentives – Smokers.

Economists and other public health policy analysts believe that one of the most effective measures for discouraging the initiation of youth smoking and reducing the prevalence of smoking by adults is to increase tobacco product prices. Higher prices

discourage initial use, reduce smoking by current smokers, and increase the rate at which such smokers quit.

- The effect of price on consumption is especially pronounced for underage smokers, who have less disposable income and are less likely to be already addicted.

- Each price increase of 10% is expected to lead to a decline of 4% in the number of cigarettes sold in the short run, and a 10% decline in the number of new smokers.

The proposed settlement contains a program for increasing the price of tobacco products, although it is not separately described as such. Three provisions in the proposed settlement work together to create this program.

- The proposed settlement states: "In order to promote maximum reduction in youth smoking, the statute would provide for the Annual Payments to be reflected in the prices manufacturers charge for tobacco products" (VI.B.7.). We refer to this provision as the "automatic pass through."

- Appendix IV states: "In order to achieve the goals of this Agreement and the Act relating to tobacco use by children and adolescents, the tobacco product manufacturers may, notwithstanding the provisions of the Sherman Act, the Clayton Act, or any other federal or state antitrust law, act unilaterally, or may jointly confer, coordinate or act in concert, for this limited purpose. Manufacturers must obtain prior approval from the Department of Justice of any plan or process for taking action pursuant to this section; however, no approval shall be required of specific actions taken in accordance with an approved plan" (App. IV.C.2.).

- The final piece of the picture is provided by the annual Volume Adjustment provision. If in any given year the volume of domestic sales exceeds the level of 1996 domestic sales, the annual payment for that year is increased in proportion to the increase over 1996 sales. On the other hand, if there is a decrease in volume sales over the 1996 base year, manufacturers are entitled to a proportionate reduction of the annual payment obligation (provided, however, that sales to non-adults are excluded for purposes of calculating a decrease in volumes).

Taken together, these three provisions indicate that the Annual Payments obligation will move up and down in relation to sales volume, and that the tobacco companies will meet

together periodically to develop a common plan for passing these volume-adjusted Annual Payments through to customers in the form of higher retail prices.

- Like a sales tax, the price increases resulting from the automatic pass through will presumably be uniform throughout the industry and uniform with respect to each unit of product.

- Like a sales tax, the price increases will provide funding for worthy public projects, except now the allocation of the funds would be determined by settlement agreement rather than by Congress.

(1) Interpreting the Pass Through.

The magnitude of the price increases generated by the automatic pass through depends critically on how the imprecise language of the automatic pass through provision is interpreted.

- Most readers of this language assume that the way the tobacco companies would "reflect" Annual Payments in prices would be simply to add the additional cost associated with the Annual Payments to the unit retail price of tobacco products. We refer to this assumption as the "constant cost" interpretation. Under this reading, overall prices would rise by an amount equal to the Annual Payments, and, since consumption probably would decline as a result of the higher prices, net income realized by the tobacco companies from domestic sales would likely decline.

- Conceivably, however, the language could be read to permit the tobacco companies to "reflect" Annual Payments in prices in a manner that would prevent the loss of net income as a result of declines in volume of sales caused by price increases. We refer to this reading as the "constant income" interpretation. Under this interpretation, prices would have to be raised by an amount even higher than the Annual Payments, in order to offset the lower volume of sales. Because the tobacco companies would enjoy higher profits per unit sold, their net income would remain constant notwithstanding lower sales volumes.

- A variation of the constant income interpretation is introduced by virtue of the exemption from the antitrust laws afforded the tobacco companies in order to take action in furtherance of the settlement's goals.[6] We refer to this variation as the "profit maximization" construction. Under this approach, the tobacco

[6] As noted above, the manufacturers will be required to obtain Justice Department approval of any plan for concerted action pursuant to the exemption.

companies, relying upon the exemption from the antitrust laws, would collectively set prices in excess of that which is necessary to pass through Annual Payments or preserve net income, ostensibly for the purpose of further discouraging consumption. Given the oligopolistic structure of the industry and the relative inelasticity of demand for cigarettes, this approach could significantly enhance the profitability associated with domestic sales, although it probably would also pose the most significant deterrent to consumption.

It is unclear whether the profit maximization approach is within the contemplation of the parties to the proposed settlement.

- To avoid the serious inequities that the profit maximization approach would create, the statutory language should be drafted to make clear that the antitrust exemption will not permit the tobacco companies to act in concert in order to achieve profit maximization.

- Whether legislatively to impose the constant cost or the constant income interpretation is a more difficult issue.

- From a public health perspective, the constant income interpretation would have one desirable consequence: It would raise tobacco prices even higher than they would rise under the constant cost interpretation, resulting in further reduction in consumption and lower rates of initiation.

- However, these benefits would come at the expense of completely insulating tobacco company shareholder value from the direct and indirect costs associated with the settlement.

- We take no position on this issue, other than to note that adoption of the constant income interpretation would provide an additional justification for modifying the Look Back surcharge (discussed below) in ways that would impose powerful economic incentives on tobacco companies.

(2) Tax Deductibility.

Another important variable is tax treatment. The proposed settlement provides that Annual Payments and Look Back surcharges are to be deemed ordinary and necessary business expenses in the year incurred and hence will be fully tax deductible (VI.D.).

As a general matter, we believe that the payment obligations imposed by the proposed settlement should treated for tax purposes the way analogous obligations are treated under the law. Under this standard, the proper tax treatment of the Annual Payments is debatable.

- On the one hand, the Annual Payments could be regarded as payments made in the settlement of litigation, which are usually regarded as tax deductible. Or they could be regarded as a kind of excise tax, which also may be deducted as an ordinary and necessary business expense.[7]

- On the other hand, the Annual Payments could be regarded as akin to a civil fine or penalty imposed by law in order to deter tobacco companies from engaging in conduct that violates public policy.[8]

- We take no position on how Congress should resolve the tax treatment of the Annual Payments, except to note that the resolution of this issue will have an impact on the magnitude of the price increases that flow from the settlement.

(3) **Public Health Benefits of Price Increases.**

Unlike many of the other benefits of the proposed settlement, the public health benefits of a price increase are susceptible to quantitative estimation.

- The proposed settlement, with its existing schedule of Annual Payments and automatic pass through, should result in an increase in the price of cigarettes of $0.62 per pack to an estimated average of $2.67.[9]

- Given consensus estimates about the price elasticity of demand, this translates into an estimated 10% decline in tobacco consumption and an estimated 23% decline in youth consumption.[10]

---

[7] See 26 CFR 1.164-2(f).

[8] See 26 U.S.C. §162(f).

[9] This is the increase in year five under the settlement when the Annual Payments equal $15 billion. See Exhibit A attached to this Report. Increases in price in years one to four would be lower. The current average price of cigarettes is $2.05 per pack. See Economic Research Service, U.S. Dept. of Agriculture, Tobacco, TBS-278, Tables 1,33 (Washington D.C., May 5, 1997).

[10] We have assumed an overall price-elasticity of demand of -.4 and a price elasticity of adolescent demand of -1.0, in line with most economists' estimates. See, e.g., J. Harris, A Working Model for Predicting the Consumption and Revenue Impacts of Large Increases in the US. Federal Cigarette Excise Tax, National Bureau of Economic Research Working Paper No. 4803 (Cambridge, MA: National Bureau of Economic Research, July 1994); G.S. Becker, M. Grossman, and K. Murphy, An Empirical Analysis of Cigarette Addiction,

(continued...)

Significant additional benefits would be realized by even higher price increases. Congress should therefore take additional steps, either as part of legislation implementing the settlement or in independent legislation, to push retail tobacco prices to even higher levels.

- Exactly how high prices should be set in the short run entails a weighing of competing factors.

- Economists have estimated that price would have to rise to slightly more than $4.00 per pack before the revenue losses associated with declining sales would overtake the increase in profits due to higher prices.[11]

At a minimum, an immediate price increase in the magnitude of $1.00 per pack should be considered.

- Such an increase would generate measurable additional benefits beyond the $0.62 per pack increase that would result from the proposed settlement.

- We estimate that a $1.00 per pack increase would translate into a 15% reduction in overall consumption, and a 33% reduction in adolescent consumption.

There are at least three ways to achieve an additional price increase to the level of approximately $1.00 per pack.

- One would be to increase the federal excise tax on cigarettes. The Kennedy-Hatch Child Health Insurance and Lower Deficit Act that nearly passed the Senate earlier this year called for a $0.43 increase in the cigarette excise tax. Adopting such a provision in conjunction with legislation implementing the proposed settlement would generate a price increase approximately in the $1.00 per pack range.

---

[10] (...continued)
National Bureau of Economic Research Working Paper No. 3222 (Cambridge, MA: National Bureau of Economic Research, March 1993); T.E. Keeler, T. Hu, P.G. Barnett, and W.G. Manning, "Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Timeseries Evidence," 118 Journal of Health Economics 12 (1993).

[11] Jeffrey E. Harris, "American Cigarette Manufacturers' Ability to Pay Damages: Overview and Rough Calculation," 5 Tobacco Control 292-294 (1997).

- Alternatively, the Annual Payment obligations under the proposed settlement, which are subject to the automatic pass through, could be increased by $9 billion per year above the proposed level of $15 billion per year to $24 billion per year.

- A third option would be to make the Annual Payments nondeductible for income tax purposes but then permit tobacco companies to engage in collective price setting to offset the impact of nondeductibility.[12]

V. Economic Incentives -- Tobacco Companies.

The proposed settlement includes an important provision designed to provide financial incentives to tobacco manufacturers to achieve the overriding goal of reducing underage smoking. This provision is the so-called "Look Back" surcharge. The proposed settlement's attention to the issue of financial incentives for tobacco companies represents an important breakthrough. However, the structure of incentives adopted for manufacturers is fundamentally flawed. Indeed, the public health benefits of the Look Back surcharge program, as currently formulated, would be negligible or negative.

It is absolutely essential that the Look Back program achieve its stated goals if the proposed settlement is to serve the public interest. Given that the settlement eliminates the risk of significant civil liability to tobacco companies, and given that FDA's jurisdiction over tobacco products is curtailed for the period of the 12-year moratorium, the only guarantee that the settlement will produce real, permanent, and major reductions in consumption and youth initiation has to come from the Look Back program.

In brief summary, the proposed Look Back surcharge program contains the following elements (II.; App.V.).

- Targets are set for reductions in underage smoking: 30% of current underage smokers by years 5-6, 50% by years 7-9, and 60% by year 10 and thereafter. More modest targets are set for smokeless tobacco: 25%, 35% and 45%.

- Tobacco manufacturers will be assessed a surcharge for each percentage point by which the industry as a whole fails to meet these targets. The surcharge is set at $80 million per percentage point for the whole industry, to be prorated

---

[12] If payments are nondeductible, but tobacco companies could engage in collective action to negate this effect, then presumably they would be permitted to raise prices so that the after tax increase in their margin equals 62 cents. Assuming a marginal corporate income tax rate of 35%, the price increase would be 62/(1-.35) = 95 cents. This would result in an increase to $3.00 per pack.

among manufacturers in accordance with their overall market share. The $80 million figure is said to represent the present value of the profit the industry would earn over the life of 1% of underage smokers.

- Total annual surcharge liability is, however, capped at $2 billion.

- In addition, individual tobacco companies may apply to FDA for an "abatement" of up to 75% of their share of the surcharge, upon a showing that they have acted in good faith and in full compliance with all requirements of the act.

- The surcharge "will be reduced to prevent double counting of persons whose smoking had already resulted in the imposition of a surcharge in previous years."

- Although the proposed settlement is not explicit about this, it appears to be contemplated that surcharge payments, like other Annual Payments, would be subject to the automatic pass through.

- The surcharge, like the Annual Payments, is fully tax deductible (VI.D.).

The proposed Look Back surcharge contains a number of unacceptable features. Cumulatively, these defects mean that tobacco manufacturers will have very little incentive under the program to reduce underage smoking. Indeed, it is conceivable that the program in its proposed form could create an incentive for tobacco companies to increase their share of the underage market. Six different features of the Look Back surcharge must be changed if this program is to perform an effective role in the overall settlement. Moreover, FDA must play a role in establishing and implementing a Look Back surcharge program.

(1) Automatic Pass Through and Tax Deductibility of the Surcharge.

If the Look Back surcharge is to function as an incentive for manufacturers (as opposed to smokers), it must not be subject to the automatic pass through. If surcharge payments are simply passed through to consumers, then the surcharge will constitute nothing more than an additional increment in Annual Payments liability that shows up as a small increase in consumer prices (estimated to be approximately $0.08 per pack of cigarettes if manufacturers are subject to the full $2 billion annual surcharge). This would have some (very modest) additional effect in depressing consumption of tobacco products. But the dollar-for-dollar shift in liability from manufacturers to consumers would eliminate any incentive for manufacturers to change their behavior.

The Look Back surcharge therefore should not be subject to the automatic pass through rule.

- The legislation implementing the settlement should also make clear that tobacco companies will not be allowed to act in concert to agree upon a pass through of the surcharge to consumers.

- Tobacco companies may still be able to recover some of the costs associated with Look Back surcharge payments. But they will be able to do so only insofar as competitive conditions in the market would permit them to raise prices independently of whatever actions are taken by their competitors.[13]

Further, the Look Back surcharges should not be tax deductible. Rather, the tax treatment of the payment obligations under the proposed settlement should be based on the way in which closely analogous obligations are treated under current tax law.

- The Look Back surcharge is most closely analogous to a civil fine or penalty imposed under federal law in order to deter companies from engaging in conduct that violates public policy.

- Under the Internal Revenue Code, no tax deduction is allowed for civil fines or similar penalties, such as treble damages for antitrust violations.[14]

- Moreover, manufacturers should not be permitted to act in concert to raise prices to offset the effect of the denial of tax deductibility.

- The denial of tax deductibility, like the elimination of the automatic pass through, is necessary in order to bring the full deterrent impact of these payments home to the companies.

---

[13] Legislation that would go further and prohibit any attempt on the part of tobacco companies to pass through Look Back surcharges would probably be futile unless the FDA is prepared to engage in comprehensive oversight of all tobacco company pricing decisions in order to determine that they are justified by costs other than surcharge payments.

[14] See 26 U.S.C. §§ 162(f), 162(g). These Code provisions are a codification of Tank Truck Rentals, Inc. v. Commissioner, 356 U.S. 30, 36 (1958), which reasoned that a trucking company should not be allowed to deduct fines incurred for operating trucks in excess of state weight limits because this would "frustrate state policy in severe and direct fashion by reducing the 'sting' of the penalty."

(2) **Collective Responsibility for the Surcharge.**

The Look Back surcharge in the proposed settlement is based on a principle of collective responsibility. The annual penalty is calculated on the basis of the collective performance of the industry each year in reducing underage smoking, with the penalty then apportioned among companies according to their share of the total market (adult as well as minors).

This collective responsibility feature establishes a "tragedy of the commons" in which each company, perversely, would have an incentive to increase rather than decrease its share of the underage market. The problem, in a nutshell, is that each company would capture the added profits from increasing its share of the underage market, but the penalties for this behavior would be spread among all companies in the industry.

A simple numerical example illustrates the problem.

- Assume that the tobacco market is served by two companies, Company A and Company B, and that each initially has 50% of both the total and the underage market.

- Assume further that in a certain year Company A adopts a marketing campaign to increase its share of the underage market. It succeeds in capturing an additional 2% of that market, which under the assumptions of the proposed settlement means an additional profit having a discounted present value of $160 million.

- Meanwhile, Company B adjusts its marketing strategy so as to reduce underage consumption of its products. It succeeds in achieving a reduction equal to 2% of the underage market. This translates into a loss having a discounted present value of $160 million.

- Assume further that the industry misses its target for reducing underage smoking in this year by 1%. This translates into a collective Look Back surcharge of $80 million.

- The financial consequences to the two companies are set forth in Table 2. Company A, the bad corporate citizen, gets an additional profit of $160 million offset by a penalty of $41.6 million, for a net gain of $118.4 million. Company B, the good corporate citizen, experiences a loss in profit of $160 million augmented by a penalty of $38.4 million for a total loss of the $198.4 million.

Table 1

	"Bad" Company A	"Good" Company B
Starting Market Share[15]	50%	50%
Market Share Gain/(Loss) during Year 1	2%	(2%)
Market Share at Year 1 End	52%	48%
Surcharge ($80 million) Allocation	(41.6) million	(38.4) million
Gained/(Lost) Profits	160 million	(160) million
Net Change in Position in Consequence of Changed/Market Share and Surcharge Imposition	118.4 million	(198.4) million

The lesson of the existing Look Back surcharge program for tobacco companies could not be more inappropriate: It pays an individual company to be a bad corporate citizen and to try to increase its share of the underage market. A good corporate citizen which succeeds in reducing its share of that market is penalized. Any legislation that incorporates the collective responsibility feature of the proposed Look Back surcharge is therefore unacceptable.

The University of Michigan's National High School Drug Use Survey, whose methodology the proposed settlement adopts for calculating both the base percentage and the annual percentage of underage use, is not designed to measure underage smoking by manufacturing company. Nevertheless, we see no insuperable barrier to developing an accurate national survey of underage use by company.

- For example, the CDC's Teenage Attitudes and Practices Survey (TAPS) has undertaken surveys of youth smoking by brand name.[16]

- Thus, either the University of Michigan survey method could be modified to measure underage use by brand, or a different sampling method could be developed that would survey for underage use by brand.

---

[15] The hypothetical assumes that initially overall market share is equal to underage market share.

[16] Center for Disease Control, "Changes in the Cigarette Brand Performances of Adolescent Smokers - United States, 1988-1993," 93 Morbidity and Mortality Weekly Report 577-581 (August 19, 1994).

- Once underage use by brand is determined, it should be easy to calculate underage use by manufacturing company.

(3) Use of Profits Rather Than Social Costs.

The proposed Look Back surcharge is based on a principle of restitution of profits earned by tobacco companies in selling to the underage market. A more appropriate measure would be based on a principle of internalization of the social costs associated with use of tobacco products.

Requiring tobacco companies to disgorge the profits they earn in introducing minors to tobacco products leaves them at best indifferent to whether or not youth smoking occurs. If the incentives are to work, tobacco companies should be forced to internalize the social costs associated with underage smoking. Only by forcing the tobacco companies to bear the social costs of underage smoking will they have the proper incentive to take all measures which would be socially justified to reduce these costs -- including redesigning their products to increase quit rates or to lower the lifetime health risks associated with using their products.

Social costs also provide a better measure than purely external costs.

- If this were an incentive program to reduce adult smoking, then perhaps an argument could be made that adult smokers are responsible for the costs that they and their families bear. The fact that tobacco products are highly addictive, however, makes it difficult to assume that even adults who start smoking have accurately calculated either the lifetime costs that they and their families will bear, or the "benefits" they derive from smoking.

- The Look Back program is not addressed to adult smoking, however. Rather, it is designed to create an incentive for companies to prevent smoking by adolescents, some of whom are 10 years old or younger.

- Given the immaturity and the limited experience of this cohort, it makes little sense to assume that adolescents have accurately accounted for the long-term consequences of this highly addictive product.

We recommend that the social costs of underage smoking be determined by FDA using the "cost of illness" methodology developed by Dr. Dorothy Rice and utilized by the CDC.[17]

---

[17] D.P. Rice, Estimating the Cost of Illness, Health Economic Series, no. 6, DHEW Publication No. (PHS) 947-6 (Rockville, MD: Department of Health, Education, and Welfare, (continued...)

- This method relies on two factors: the lifetime medical costs attributable to smoking and lost wages due to premature morbidity and mortality.

- This measure of social costs is thus conservative, since it does not attempt to measure the value of lost years of life when wages are no longer being earned, loss of consortium to family members caused by premature deaths, the costs associated with second hand smoke, etc.

FDA should develop the costs of illness measure through rulemaking, and should revise the number periodically in order to reflect new data about medical costs, quit rates, and so forth.

- This process of periodic revision would provide a powerful incentive to companies not only to come up with new ways to prevent youth smoking, but also ways to reduce the lifetime costs of using their products.

- For this reason, the social cost measure will provide indirect benefits to adult smokers as well as to adolescents who never start smoking.

We have attempted to develop a preliminary estimate of the social cost measure under the costs of illness methodology using conservative assumptions.

- To do so, we adjusted the most recent cost of illness estimate published by the CDC[18] for wage and medical inflation.

- We also adopted, to the extent possible, the same assumptions as to discount rate, inflation, etc. as were employed in developing the $80 million life profit figure under the proposed settlement.

- We assumed a period of 50 years between the time a smoker begins smoking and the onset of smoking-related disease. Some might argue that the period is significantly shorter. To the extent that it is, we have chosen to err on the conservative side.

---

[17] (...continued)
1966): D. P. Rice, T.A. Hodson, and A. N. Kopstein, "The Economic Cost of Illness: A Replication and Update," 7 Health Care Financing Review, 61-80 (1985).

[18] Center for Disease Control, "Medical-Care Expenses Attributable to Cigarette Smoking -- United States, 1993," 42 Morbidity and Mortality Weekly Report 469-472 (July 8, 1994).

Following this approach, we estimate that the present value of the lifetime social cost of underage smoking would be within a range from $400 to $450 million for each percentage point by which the industry misses its target.[19]

- This figure is much larger than the expected profits figure, for the simple reason that the social costs of smoking are so staggering in their magnitude.

- This figure thus underscores the great urgency, from a public health perspective, in achieving rapid and permanent reductions in the incidence of underage smoking. Adoption of social costs as the measure of the Look Back surcharge would harness the energy of the industry to achieve those reductions.

As an alternative to the social cost measure, Congress could also consider adopting a measure of the Look Back surcharge based on the lesser of social costs or a multiple of profits.

- For example, the surcharge could be based on the lesser of (i) the lifetime social cost per percentage point above the target, (ii) three times the lifetime profit per percentage point above the target, or (iii) the company's net profit from domestic tobacco sales for the year.

- Although a mixed rule lacks the conceptual clarity of the pure social cost measure, it nevertheless would also provide a strong incentive for tobacco companies to achieve the targets for underage smoking reduction.

---

[19] Following the cost of illness methodology, the CDC has estimated that the medical costs attributable to smoking in 1993 were $50 billion and that the lost wages associated with premature morbidity and mortality totaled $47.2 billion in 1990. Adjusting these figures for wage and medical inflation, the total cost of smoking in 1996 would equal about $115 billion or $4.72 per pack of cigarettes. According to the data used in the settlement to calculate the average profit per underage smoker, an adolescent smoker can be expected to consume 23,129 packs over the course of his or her lifetime. This translates into a lifetime social cost of $109,169 per adolescent smoker. However, this figure must be discounted, since the medical and productivity costs associated with smoking illness tend to occur later in life. If we assume that, on average, these costs are incurred 50 years after initiation, and discount at 4 percent after inflation, then the present value of the social costs of smoking are $15,361 per adolescent smoker. Applying this to the penalty mechanism in the Look Back provisions would increase the penalty per percentage point of underage smoking above target from $80 million to $423 million.

(4) **The $2 Billion Annual Cap.**

The $2 billion cap on annual industry Look Back penalties is unacceptable, especially if the program is reoriented along the lines of a social cost internalization program, as described above.

- Even if the Look Back surcharge payments could not be automatically passed through and were not tax deductible, the $2 billion cap would still represent an arbitrary limit on the capacity of the surcharge program to impose on the companies the full costs of their actions. It would thus undercut their incentives to devise ways of inhibiting underage tobacco use.

- At an estimated social cost rate of between $400 and $450 million per percentage point, the $2 billion cap would impose no additional penalty once the target was missed by 4.0 to 5.0%.

We are not, however, inalterably opposed to a cap under any circumstances. Whether a cap is appropriate, and, if so, in what amount, depends on how other elements in economic picture are resolved.

- However, any cap should take the form of the "lesser of" alternative to the pure social cost measure of the surcharge (discussed at the end of point (c) above).

- Such a cap would provide assurance that no company would face insolvency because of its failure to meet the underage smoking targets, but would also preserve a very powerful deterrent.

(5) **Rewards for Companies that Exceed the Targets.**

The Look Back program should contain a system of rewards for companies that exceed the stated targets. Those rewards, however, should be based on achieving actual results, not persuading regulators that the company has acted in good faith and full compliance with the law.

- The incentive system should be directed at stimulating companies to do whatever it takes to lower underage smoking, whether those steps are required by existing regulations or not.

- For example, it may be that in order to discourage youth smoking, companies should stop producing certain brands, or should modify flavoring ingredients, or should stop selling in certain types of retail outlets, or should launch their own counter-advertising campaign. None of these steps is mandated by the proposed

settlement. However, each is something each tobacco company can do on its own initiative in order to reduce teen tobacco use of its products.

- The abatement provision in the proposed settlement, in contrast, creates an incentive for companies to foster the appearance of "corporate compliance" and to make elaborate presentations to regulators about corporate good faith. We believe that corporate compliance programs can be valuable, but would urge that any incentive system be based on real results, not rhetoric.

In lieu of an abatement based on compliance with regulations and good faith, we recommend that provision be made for a system of monetary credits for companies that exceed the stated targets for reductions in underage smoking.

Such a system of monetary credits, like the surcharge, should be based on costs -- in this case the costs to the tobacco manufacturing company of exceeding the legislated targets.

- That cost is the foregone profit that the tobacco company would earn by attracting additional underage smokers to its products. This figure is stated to have a present value of $80 million for the industry per percentage point of the underaged market served. (The actual number for each company should be determined by FDA through rulemaking.)

- Thus, while the penalty for failing to reach the target should be based on the costs to society (estimated to the $400 to $450 million per percentage point for the industry), the credit for exceeding the target should be based on the costs to the company (estimated to be $80 million per percentage point for the industry).

A system of credits should also be designed in such a way as to minimize any reduction in Annual Payments.

- Thus, we believe that any credits earned by tobacco companies should be offset first against surcharge payments that have been made by other companies.

- Only if total credits for any year exceed total surcharge payments should credits result in a reduction in Annual Payment obligations.[20]

---

[20] Another way to avoid having credits reduce Annual Payments would be to establish the Look Back program as a system of transferable allocations. Each year, each tobacco company could be assigned an allocation based on its baseline share of the underage market and the targeted reduction in underage use for that year. Companies that exceed this target would have extra allocation units left over, which could then be transferred to companies that fall short of

(continued...)

(6) Future Targets and Targets for Smokeless Tobacco.

We do not quarrel with the proposed settlement targets of 30%, 50%, and 60% reduction over the first ten years of the program.[21]

- These targets should be well within the reach of the tobacco companies.
- For example, our economic calculations suggest that if the price of a pack of cigarettes rises by $1.00, the economic disincentive to youth consumption may by itself allow the companies to reach the initial 30% target in year five.

But the targets should not be frozen at 60% for all years following year 10.

- Freezing the targets at 60% would mean that smoking by approximately 1.2 million adolescents (not accounting for population growth) is contemplated to continue indefinitely.
- Any legislation adopted should set an express goal of additional reduction in underage smoking over some reasonable interval of time.
- FDA should be authorized to adopt further incremental increases in targets for reductions underage smoking after year 10, with an ultimate goal of eliminating all but an incidental levels of underage smoking by year 20.

We also see no justification for setting targets for underage use of smokeless tobacco at substantially lower levels than the targets for underage use of cigarettes.

- Maintaining different targets for different tobacco products could result in underage use *shifting* from one nicotine delivery device to another.
- Smokeless tobacco products should therefore be subject to the same reduction targets, and the same general structure of incentives, as are cigarettes.

---

[20] (...continued)
their target. Under such a system, the credit for exceeding the target would come in the form of a payment from another tobacco company, leaving the Annual Payments obligation untouched.

[21] These targets are not dissimilar to those endorsed by the Koop-Kessler Advisory Committee, supra at 5 n.3.

- To the extent that the lifetime social costs of using smokeless tobacco differ from the lifetime social costs of smoking, the surcharge payments for smokeless tobacco companies would be adjusted accordingly.

(7) **The Role of the FDA.**

In general we believe it is unwise for legislation adopting the Look Back surcharge to specify in great detail the methods of surveying for underage use.

- For example, it seems unwise to lock in by legislation the University of Michigan "Monitoring the Future" survey methodology. Better survey methods may be developed in the future that render this obsolete.

- Similarly, it seems inappropriate to specify whether youth smoking and reductions should be measured by daily smoking or monthly smoking. There are too many complications here to resolve by legislation. Moreover, a consensus that one method is better than another or that yet a third method is preferable may emerge over time.

- Furthermore, we believe that questions about whether targets should be expressed as percentages of the youth market or in terms of absolute number of underaged smokers should be left to agency determination.

- We agree with the proposed settlement that double counting of underage youths should be avoided. Again, however, this is the kind of technical problem that is best left to FDA resolution through rulemaking.

Rather than legislate the details of methodology, the legislation should resolve the major principles that would govern the Look Back program, and should leave the details to implementation of FDA through rulemaking. The major principles should be:

- There should be no automatic pass through of the surcharges in tobacco prices.

- The surcharge should not be tax deductible.

- The surcharge should be based on the discounted total lifetime social costs of underage smoking.

- The surcharge should not be subject to any cap, except perhaps for a cap equal to multiple percentage points of profit or each company's total net profits from domestic tobacco operations for the year.

- There should be no abatement for corporate compliance or good faith, although credits should be given to firms that exceed the targets.

- The targets should continue to progress after year ten and smokeless tobacco should be subject to the same targets as cigarettes.

VI. Funding of Public Health Programs.

The proposed settlement also provides for significant funding for various public health initiatives related to tobacco. Programs funded by the settlement include:

- A Presidential Commission to direct tobacco-related medical research.

- Programs directed by HHS to reduce smoking.

- Payment of FDA's enforcement costs under the agreement.

- State and local government community control efforts modeled after the ASSIST program.

- Research and development into methods for discouraging the use of tobacco.

- A public education program to discourage and de-glamorize tobacco products.

- Tobacco cessation programs.

- Compensarion for events and teams that lose tobacco sponsorship.

The funds made available for these purposes range from $4.5 billion to $7.5 billion per year over the first ten years of the settlement. (A spread sheet showing the proposed allocation of Annual Payments over the first ten years is attached as Exhibit A to this Report).

- In addition, approximately $64 billion over the first ten years is not allocated by the settlement. Presumably, substantial portions of these funds are allocated to state governments for tobacco related health expenditures.

- Given the severe budget constraints that prevail in Washington and in most states, the generation of substantial sums of money for tobacco related research and education programs is clearly an important plus of the proposed settlement.

The monies allocated to these various programs vary widely. Moreover, there is no indication in the proposed settlement as to how the amounts were selected. Five of the grant programs are described as being "recommended by the Attorneys General for consideration by

the President and the Congress." This description suggests that the allocation of funds is open to adjustment.

We recommend four modifications in the allocation of funding under the proposed settlement.

- Funds should be allocated to a program to provide transitional relief to tobacco farmers who experience financial dislocation because of declining markets for tobacco leaf. One possibility would be a public program to purchase tobacco farmland or tobacco crop allotments from farmers who wish to exit the tobacco market.

- As discussed more fully below, funds should be allocated to international organizations devoted to achieving reductions in tobacco consumption worldwide.

- Funds should be allocated to support smoking cessation programs in health care settings. Studies suggest that intervention in the form of counseling by knowledgeable professionals may be cost-effective in assisting smokers to quit.[22]

- Funds should be allocated to support comprehensive school health education from pre-kindergarten to grade 12 in all U.S. school districts, designed in part to emphasize the dangers and the addictive potential of tobacco use.

More important than the initial allocation of funds, however, is the need to develop a governance mechanism for overseeing the expenditure of monies and to make changes in the allocation of funding over time.

- Ideally, of course, the funds would be allocated where they would do the most good.

- A thoughtful allocation requires a mechanism for selecting appropriate grant recipients, evaluating their performance, auditing the expenditure of monies, and so forth.

---

[22] See Agency for Health Care Policy and Research, Smoking Cessation, Clinical Practice Guideline No. 18, U.S. Dept. of Health and Human Services AH CPR Pub. No. 96-0692 (April 1996); K. Fiscella and P. Franks, "Cost-Effectiveness of Transdermal Nicotine Patch as an Adjunct to Physicians' Smoking Cessation Counseling," 275 JAMA 1247-1251 (1996).

- Moreover, there should be a method for changing the allocation of funds over time, as experience and follow up studies show that greater benefits can be obtained from expenditures in some areas than in others.

The best entity to perform the functions of oversight and adjustment would be the U.S. Department of Health and Human Services (HHS).

- An executive branch department such as HHS, which is subject to Presidential and Congressional oversight and yet insulated from direct political influence, would strike a good balance.

- At the same time, a public-private partnership should be established by which HHS will consult with one or more private foundations or advisory boards in establishing its oversight function and in making major decisions about reallocation of resources.

- Decisions about administration of grants, evaluation of grant recipients, and changes in funding allocations (after an initial interval of, say, five years) should be informed, to the extent possible, by public health considerations rather than by interest group politics.

VII. Civil Liability.

Although the provisions of the proposed settlement regarding resolution of pending litigation and reducing the potential liability of tobacco companies from future litigation are complex, the public health implications of these provisions largely reduce to one overriding consideration: These provisions effectively eliminate the most significant deterrent effects from civil liability, and hence any future incentive for the industry to enter into further agreements expanding the regulatory regime that applies to tobacco. Once the settlement is approved, the tobacco companies will likely have no reason to return to the bargaining table.

(1) Limitations on Liability.

Perhaps the most important liability provisions are those that ban attorney general suits, class actions, joinder of multiple plaintiffs, consolidations, or actions by third party payors based on theories other than subrogation of individual claims.

- In the future, individual plaintiffs will have to go it alone against the tobacco companies.

- In the past, tobacco companies have been highly successful in defending against individual plaintiff suits. A major factor was their ability to concentrate heavy legal firepower defending these suits, often wearing down plaintiffs before trial. When the rare case went to trial, tobacco companies were able to persuade the jury that the individual plaintiff knew about the health risks of smoking and voluntarily accepted the risks of smoking. Until very recently, tobacco companies prevailed in each and every one of these trials.

- What forced the companies to the bargaining table was the emergence in recent years of class actions and attorney general suits. Class actions, in particular, focused attention on what the tobacco companies knew about their products, rather than on what individual smokers knew about the dangers of the products they chose to use.

- The proposed settlement, by requiring that all future suits be individual suits, allows the tobacco companies to return to a proven, successful litigation strategy.

The ban on class actions or other types of joinder is reinforced by the proposed settlement's limits on individual recoveries.

- A plaintiff's attorney will ordinarily take on a personal injury or products liability case only if it presents the prospect of a significant financial recovery.

- The proposed settlement eliminates punitive damages (for pre-settlement conduct), which would be a source of a large recovery in an individual suit.

- In addition, recovery is capped at $1 million per plaintiff if the annual industry cap (equal to 33% of the Base Amount) is exceeded.

- It appears that the proposed settlement extinguishes causes of action based on wrongful addiction or dependence.

- Finally, the proposed settlement preserves unchanged "applicable case law" under the Federal Cigarette Labeling and Advertising Act. This proviso presumably includes the Supreme Court's Cipollone decision,[23] which held that most causes of action based on failure to warn are preempted.

---

[23] Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

- Given these serious constraints on recoveries, individual plaintiffs may face difficulties finding experienced attorneys to bring suits against tobacco companies.

As a final protection against significant liability, the proposed settlement puts an annual cap on total industry liability from all civil judgments equal to 33% of the Base Amount.

- This means total industry liability is capped at between $2 billion and $5 billion per year.

- Moreover, 80% of any settlements or judgments for any company may be credited against its Annual Payment obligations.

- The net effect is that the maximum additional industry financial exposure to civil liability (beyond the regularly scheduled Annual Payments) is from $400 million to $1 billion per year.

- This figure is not materially different from the estimated $600 million per year that the industry currently is spending on litigation in defense costs.[24]

Taken together, these changes eliminates the most significant threats of future civil liability.

(2) The Impact of Limitations on Liability.

One consequence of the limitations on liability is that future plaintiffs will have a substantially more difficult time obtaining at least some of the compensation they might have obtained (most likely as a members of class actions) under pre-settlement law.

- Some organizations will place significant weight on this factor. Consumer groups, public interest lawyers, and attorneys for smokers not currently in litigation probably will regard the reduced likelihood of compensation as a serious disadvantage of the proposed settlement.

- One difficulty with placing too much weight on lost compensation, however, is that up to now no private plaintiff has ever collected from a tobacco company.

- Consequently, the "loss" is a loss relative to a projected future state of litigation in which class actions, third party payor claims, etc. eventually start to produce recoveries or significant settlements from tobacco companies. Often losses of

---

[24] "How Badly is Liggett Getting Burned?," Business Week, July 7, 1997.

this sort -- foregone opportunities -- are considered less troubling than deprivation of existing assets.

- In addition, some persons may question whether tobacco plaintiffs are entitled to compensation, given the widespread knowledge that smoking is dangerous.

From a public health perspective, we believe the consequence that deserves greater weight is the de facto elimination of any deterrent effect from civil liability. This will erase a powerful incentive for the tobacco companies to desist from socially harmful practices.

- If tobacco companies were to continue to face the threat of significant legal liability, it is difficult to predict their response. That would depend in part on which legal theories (if any) led to recoveries.

- Some of the responses might include more elaborate and emphatic warnings; changes in marketing; changes in products; withdrawing products from the market; raising prices (to cover liability costs); and withdrawing from the market altogether. In other words, the responses might parallel, and conceivably could go beyond, what is required by some of the regulations contained in the proposed settlement.

- In general, fear of civil liability is probably a more powerful stimulus to change in corporate behavior than is regulation. But it is also a highly uncertain stimulus with effects that are very difficult to predict in advance. Further, change through litigation could take years.

- We believe that the dramatic curtailment of the deterrent effect of civil liability for tobacco companies should be counted a major disadvantage of the proposed settlement.

There is another consequence of the effective elimination of the most significant threats of civil liability: It probably eliminates any further incentive on the part of the tobacco companies to cooperate in forging a public regulatory, research, and education program to solve the smoking problem.

- The primary reason the tobacco companies are at the bargaining table is that they apparently have become convinced that they face potentially catastrophic civil liability.

- In particular, it was the emergence of apparently viable class actions and the attorney general suits that made the difference. Suddenly the tobacco companies had to consider the possibility that they could follow the asbestos industry and the silicone breast implant industry into bankruptcy.

- The proposed settlement represents a critical opportunity to achieve fundamental structural changes in the regulatory treatment of tobacco -- and an opportunity that in all likelihood will never be presented again. If the present settlement is approved with the liability limitations in their present form, the tobacco industry is unlikely to be in a similarly vulnerable position in the future. This of course only underscores the importance of making sure the settlement is structured correctly.

VIII. Preserving The Integrity Of The Settlement.

This section briefly discusses some issues that concern the settlement as a whole.

(1) Nonsigning Tobacco Manufacturers.

The proposed settlement recognizes the important question of how nonsigning tobacco companies are to be treated. Of particular concern are foreign or new companies which could enter the market and, if not burdened by the Annual Payment obligations, might capture an increasing share of the market and possibly destabilize the agreement.

- The settlement agreement provides that nonsigning manufacturing companies will be subject to the same regulatory oversight and access restrictions as signing companies.

- It also provides that they will be subject to a "user fee" equal to the portion of the Annual Payments devoted to public health programs and federal and state enforcement of access restrictions that they would have paid if they had signed the agreement (III.C.bullet 2.).

- In addition, nonsigning must pay into an escrow account an amount equal to 150% of the Annual Payments that would be made by a signing company (minus the portion of the Annual Payments earmarked for public health payments and federal and state enforcement efforts). The escrow account is supposedly to satisfy potential judgments against such companies (which do not enjoy the limits on liability). If these companies are not found liable, however, the payments could sit in the escrow account, uncollected and gathering interest for 35 years.

- Thus, in immediate financial terms, the nonsigning companies must pay a substantially greater amount of money in order to participate in the market than the signing companies will pay.

- Finally, the proposed settlement opens up distributors and retailers who handle nonsigning companies to potential civil liability (distributors and retailers who handle signing company products are given full immunity from suits).

The provisions directed at nonsigning companies function as barriers to entry that lock in the current major manufacturing companies as a permanent oligopoly. For two reasons, this is undesirable from a public health perspective.

- One is that nonsigning companies may challenge these barriers on constitutional grounds, or possibly on the ground that they violate international trade agreements (such as GATT or NAFTA). The barriers thus increase the risk of legal challenges and potential invalidation of a key provision of the proposed settlement.

- Moreover, new entry could be desirable insofar as the new entrants seek to market products that have reduced health risks or that provide an effective substitute for the use of tobacco products.

Accordingly, the provisions dealing with nonsigning companies should be structured in such a way as to produce "a level playing field" between signing and nonsigning companies.

- Specifically, the provision establishing an escrow requirement should be amended to require posting of funds equal to 100% of the signing company Annual Payments, not 150%.

- Further, distributors and retailers who deal in the products of nonsigning manufacturing companies should be relieved of liability, as in the case of signing companies.

(2) **Enforcement Of Consent Decrees.**

As discussed above in connection with the advertising restrictions, the proposed settlement contemplates that many of its provisions will be incorporated both in legislation and in consent decrees.

- This is important because the consent decree provisions might survive if the legislation is struck down.

- Also, consent decrees have certain enforcement advantages -- a party can return to the court that entered the decree and get an injunction preventing the enjoined party from violating the decree, or an order holding a violating party in contempt.

The proposed settlement contains provisions indicating that the consent decrees will be entered in state court. This makes sense, given that the attorneys general brought the lawsuits being settled in state court. But it raises certain potential problems.

First, what about those states that do not join the agreement?

- The proposed settlement suggests that a contractual "protocol" will be adopted to handle this situation, but the precise mechanics of how this would work are not spelled out.

- It may be appropriate to condition the states' receipt of funding provided under the settlement upon their agreement to entering into binding consent decrees.

Second, how can the federal government enforce the consent decrees?

- We would prefer that the United States Department of Justice as well as state attorneys general have the power to enforce the consent decrees.

- It is not clear that the proposed settlement would provide for this. If not, a mechanism should be devised that would allow the federal government to become a party to the consent decrees, with full enforcement rights.

(3) Severability.

Whenever complicated regulatory legislation is enacted and constitutional challenges to portions of the legislation are a possibility, it is wise to attend to the "severability" question.

- If a provision of a statute that is struck down is severable, then invalidation of the provision does not affect the remainder of the statute.

- But if a provision of a statute that is struck down is not severable, then invalidation of the provision means the whole statute falls.

A strong severability clause should be included in the legislation, making clear that if any provision is declared invalid, the constitutionality of the balance of the statute is not affected.

(4) Global Extension.

International issues are not covered by the proposed settlement. A truly comprehensive discussion of tobacco control policy would address the rapid growth in tobacco use around the world, with especially alarming increases in developing countries. To some extent, these

concerns can be addressed within the framework of the settlement. In other respects they are best approached through other initiatives.

Steps that can be taken within the framework of the settlement include:

- Allocation of funds from the Public Health Trust or other appropriate sections of the settlement to the World Health Organization (WHO), to be dedicated to the development, adoption, and enforcement of the WHO Framework Tobacco Control Convention, surveillance systems to monitor international morbidity and mortality, and other tobacco control initiatives.

- Allocation of funds from the settlement for federal agency use in international tobacco control efforts.

Other initiatives apart from the settlement by the federal government might include:

- An Executive Order to all appropriate federal agencies to promote actively the adoption of U.S. domestic tobacco control standards as minimum policies throughout the world. Tools for achieving this objective would include export initiatives, Aid for International Development programs, and other communications and information programs. An international summit of health ministers should be convened in 1998 to discuss tobacco control issues, with a follow-up meeting at the World Conference on Tobacco and Health in the year 2000.

- An Executive Order forbidding the U.S. Trade Representative, the Department of Commerce, U.S. embassies, or other government agencies from interfering in any efforts by foreign national governments to curb tobacco use.

- An Executive Order making all U.S. government facilities, worldwide, smoke free.

- Imposition of penalties on U.S. companies that participate in or support international tobacco smuggling, including reintroduction to the U.S. of cigarettes made for export.

The American Medical Association will support the above initiatives in international tobacco use prevention and control, and will work for their implementation with the international medical and public health community, including the World Medical Association.

IX. Recommendations.

The proposed settlement is a promising beginning. It lays out an internally coherent system of regulatory reform, financial incentives, and relief from civil liability. The overall design of the settlement establishes a framework that can be used to achieve real, permanent, and major public health benefits. On the other hand, certain critical changes must be made in portions of the proposed settlement if this goal is to be realized.

(1) Essential Changes.

Two changes in particular are essential if the settlement is to achieve the public health goals we have set out.

The FDA must be given the same authority over tobacco products that it has over other "drugs" and "devices" under the Food, Drug and Cosmetic Act -- with the sole exception of the 12 year moratorium on taking action to implement a prohibition of traditional tobacco products or the elimination of nicotine from tobacco products.

This modification should be implemented through the following revisions to the proposed settlement, or their equivalent:

- There should be a constructional principle indicating that FDA has full authority over all tobacco products and other nicotine delivery devices unless a specific exception is expressly set forth in the legislation.

- The settlement should be clarified by eliminating any language that suggests that FDA authority to regulate tobacco products is limited in ways other than the 12 year moratorium.

- FDA should be permitted to use the same procedures, and its decisions should be subject to the same standard of review, that generally apply under the Food, Drug and Cosmetic Act.

- The definition of "tobacco product" should be clarified to include pipe tobacco, cigars, and any other tobacco product.

The Look Back surcharge program must be redesigned so as to provide significant financial incentives for each tobacco company to achieve the targets for reduction in underage tobacco use set forth in the proposed settlement.

This modification should be implemented through the following revisions to the proposed settlement, or their equivalent:

- The Look Back surcharge payments should not be subject to the automatic pass through and should not be tax deductible.

- The Look Back surcharge payments should be assessed against each individual company based on reductions in underage use achieved by that company. They should not be assessed on the basis of collective industry responsibility.

- The Look Back surcharge payments should be based on the discounted present value of the lifetime social costs of tobacco use, not restitution of profits.

- The $2 billion cap on annual surcharge payments should be eliminated. Any cap should be based on a multiple of company profits from underage use or on total company profits in the domestic market.

- Tobacco companies that exceed the targets should be given a financial credit. There should be no abatement for compliance with regulations and corporate good faith.

(2) **Strongly Recommended Changes.**

In addition to the foregoing essential changes, we strongly recommend the following additional changes in the proposed settlement.

- The price of cigarettes should be targeted to rise by about $1.00 per pack, as opposed to the $0.62 per pack projected under the proposed settlement. This can be accomplished by an increase in the cigarette excise tax, by upward adjustments in the Annual Payments, or by modifications in the tax treatment of existing Annual Payments.

- FDA should have authority progressively to tighten the targets of the Look Back program after the ten year period addressed by the proposed settlement, with an ultimate goal of reducing underage tobacco use to incidental levels.

- The preemptive effect of federal youth access restrictions should be narrowed and clarified so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum.

- The preemptive effect of federal advertising restrictions should be narrowed and clarified so that states and local governments may regulate local advertising and marketing and may impose counter-advertising requirements on tobacco companies.

- The restriction on advertising to tombstone-only format should be extended to all publications.

- A federal agency (such as HHS), in consultation with knowledgeable private entities, should be given overall responsibility for disbursement of the Public Health component of the Annual Payments, including oversight of grant recipients and authority to make adjustments in allocations in future years.

- The provisions regarding nonsigning companies should be modified so as to avoid erecting unnecessary barriers to new entry.

- The Look Back program should have targets for reduction of underage use of smokeless tobacco identical to the targets for reduction in underage smoking.

(3) Recommended Changes.

We have throughout this document recommended a number of other clarifications or refinements in the proposed settlement. These include the following:

- The prohibition on sponsorship should be clarified to preclude tobacco company sponsorship of computer software, Internet, or video programming that glamorizes the use of tobacco.

- The flow of funds from tobacco companies to the states should be structured so that federal standards for state licensing statutes and enforcement programs can be adopted as conditions attached to federal funding.

- States should be expressly permitted to make it a criminal or civil offense for any person, not just a retailer, to sell tobacco products to a minor.

- Federal enclaves and facilities, including military bases and hospitals, should be required to comply with state and local regulations regarding access to tobacco products, and tobacco sales at federal facilities should be subject to federal taxes equal to those that prevail in the local area.

- The antitrust exemption for collective price setting by tobacco companies should be clarified to prohibit companies from raising prices to profit maximizing levels.

- Portions of the Public Health component of the Annual Payments should be allocated to (a) providing transitional relief to displaced tobacco farmers; (b) providing funds to the World Health Organization for the development of a Framework Tobacco Control Convention and other international tobacco control

initiatives, and to federal agencies for use in international tobacco control efforts; (c) providing funds to support tobacco cessation programs in health care settings; and (d) providing funds for mandated comprehensive school health education focusing in part on the dangers of tobacco use.

- Distribution of funds to states should be conditioned on each state, including states that have not sued the tobacco companies, entering into a consent decree embodying the provisions of the settlement.

- The federal government should become a party to the consent decrees, with full enforcement power.

- The legislation implementing the settlement should include a strong severability clause.

If the changes that we have advocated or equivalent changes are adopted by Congress, the Task Force believes that the proposed settlement would be a major turning point in the life-or-death struggle to reduce tobacco use. The American Medical Association pledges to devote its resources toward securing the adoption of these changes. The AMA also stands ready to work in any constructive capacity with the parties to the settlement, members of Congress, and the Administration in order to realize what could be a landmark achievement.

EXHIBIT A

Tobacco Settlement: Payments and Distributions During First Ten Years (Figures in Billions)

	Enactment	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	To
Base Amount		6.000	7.000	8.000	10.000	10.000	12.500	12.500	12.500	15.000	15.000	108.
Public Health Component		2.500	2.500	3.500	4.000	5.000	2.500	2.500	2.500	0.000	0.000	25.0
Total Payments	10.00	8.500	9.500	11.500	14.000	15.000	15.000	15.000	15.000	15.000	15.000	143.
Proposed Uses												
HHS Tobacco Reduction Program		0.125	0.125	0.125	0.225	0.225	0.225	0.225	0.225	0.225	0.225	1.9
FDA Costs & Grants		0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	3.0
State & Local Tobacco Control Efforts		0.075	0.075	0.100	0.125	0.125	0.125	0.125	0.125	0.125	0.125	1.1
Tobacco Research		0.100	0.100	0.100	0.100	0.100	0.100	0.100	0.100	0.100	0.100	1.0
Lost Sponsorship Compensation		0.000	0.075	0.075	0.075	0.075	0.075	0.075	0.075	0.075	0.075	0.6
Public Education Anti-Tobacco Campaign		0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	0.500	5.0
Tobacco Use Cessation Program		1.000	1.000	1.000	1.000	1.500	1.500	1.500	1.500	1.500	1.500	13.0
Public Health Trust Fund		2.500	2.500	3.500	4.000	5.000	2.500	2.500	2.500	0.000	0.000	25.0
Settlement/Litigation Credit		1.584	1.848	2.112	2.640	2.640	3.300	3.300	3.300	3.960	3.960	28.6
Total Proposed Expenditures		6.184	6.523	7.812	8.965	10.465	8.825	8.625	8.625	6.785	6.785	79.3
Unallocated Payments	10.000	2.316	2.977	3.688	5.035	4.535	6.375	6.375	6.375	8.215	8.215	64.1

DPC Draft 8/11/97

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Overall Position	Congress should reject the settlement and legislate a strong tobacco policy. It does not need the industry's help or permission to do this.	Settlement is a landmark effort that would generate far more $ for public health activities than Congress would ever appropriate. Preferable to the uncertainty and delay of litigation.	Settlement is a great start for providing revenues for public health programs. No single piece of federal legislation will solve America's tobacco problem.	Settlement is not perfect but could help to significantly reduce tobacco use.	Settlement as written will not protect the public health. Industry can manipulate gaping loopholes.
Priority Issues	-5 Goals: 1. unhampered FDA regulation of nicotine 2. prohibition of industry efforts to target kids 3. stiff penalties for targeting kids 4. smoke-free public places 5. excise tax to fund education and cessation programs -Increase of at least $2 per pack	-Strengthen FDA jurisdiction -Increase Look Back penalties fivefold -Increase of $1 per pack -Make smokeless tobacco Look Back targets identical to smoking targets -Allow FDA to tighten Look Back targets after 10 years -Expand ad restrictions to allow only black/white "tombstone" ads for all publications -Do not preempt stricter state sanctions on retailers	-Expand authority of FDA -FDA must have all documents relevant to the public health. -Increase settlement payments to produce at least a $2 per pack increase -No tax-deductibility -Increase Look Back penalties	-Complete authority for FDA over tobacco products and nicotine -No immunity for past criminal wrongdoing -Harsher Look Back penalties -Full and open disclosure of all documents that relate to health issues -Prevent industry from escaping obligations and liability through bankruptcy	-No changes or limits on FDA authority -No immunity or limits on industry's liability -Comprehensive ad restrictions that the industry can't get around creatively -Much higher Look Back penalties -Zero tolerance for ETS -Disclosure of documents shielded by attorney-client privilege -A morally acceptable export policy -No tax-deductibility
FDA Regulation	-Make explicit FDA's unlimited authority to regulate and phase out nicotine and remove other ingredients that contribute to the initiation of and dependence on tobacco products -Time limits or moratoriums on FDA activity should be flexible to accommodate advances in science, information, and health policy.	-FDA should have same authority as for drugs and devices. -FDA should be able to use same procedures (notice and comment) and standard of review (arbitrary and capricious) that generally apply under FDCA. -12-year moratorium on complete ban of nicotine; allow interim restrictions.	-Authority for FDA to develop tough performance standards that aim to reduce or eliminate any constituent, including nicotine and that apply from the effective date of the act -No formal rulemaking -Eliminate heightened standards of proof and FDA's black market obligation	-Complete authority over tobacco products and nicotine -Eliminate excessive bureaucracy -More resources -Concerned about formal rulemaking and black market requirements	-No changes to FDA authority - No formal rulemaking requirement -No obligation to prove unlikelihood of black market - Industry should not be allowed to designate any ingredient a confidential trade secret.

Tobacco - settlement - Public health reports

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Look Back	-Adopt stronger targets: 15%-30% from years 1-5, and then 40%-65% from years 5-10. -No cap on penalties for failure -Increase penalties: if industry misses target by 5 points, it should pay 5 times the sanction -Assess compliance and penalties on a company-by-company basis	-No automatic pass through -No tax deductibility -Penalties should be assessed against each individual company based on its own reductions in underage use -Increase penalties from $80 million to $400-$450 million to force industry to internalize social costs of underage use -Eliminate $2 billion cap -Eliminate 75% rebate; add a $80 million credit for each extra percentage point of reduction -Give FDA authority to tighten targets after 10 years	-Increase penalties -Eliminate 75% rebate -Eliminate $2 billion cap -Reduction targets for smokeless tobacco should be the same as for cigarettes, because its use among teenage boys has outpaced their use of cigarettes.	Penalties in the settlement should establish the floor--make them more severe. Amounts should be adjusted annually to reflect the most current data on teen smoking.	-Individual company accountability for reduction -Additional nonfinancial penalties like more ad restrictions -Define "reasonable available measures" in detail, so industry can't get the 75% rebate easily
Document Disclosure	Industry must disclose all documents that: -reveal public relations, advertising, marketing, promotion, and political activities -are improperly shielded by attorney-client privilege -reveal all technical and health/safety data -indicate industry strategies for targeting kids and minorities -show health effects of ETS	No recommendation. Dr. Lonnie Bristow has said that the 3-judge panel procedure is acceptable.	-Streamline 3-judge panel procedure -Industry must show why a document should not be disclosed -FDA must have all information relevant to the public health and the development of reduced risk tobacco products.	Full and open disclosure of all documents that relate to health issues	Streamline/eliminate overly time-consuming, bureaucratic review mechanisms like the document-by-document review of privileged records by industry lawyers.

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
Immunity	Congress does not know enough of the industry's secrets to grant it any immunity. Preserve all avenues of litigation, both civil and criminal.	Immunity to class action suits and punitive damages is a major drawback of the settlement. Class actions draw attention to industry deceit, whereas individual suits focus on plaintiff's personal responsibility. Punitives are the major source of large recovery for plaintiffs--without them, there is no incentive for individual suits. Free of the fear of liability, industry won't change its bad behavior.	No recommendation.	No immunity to either companies or their agents for past criminal wrongdoing. No statement regarding bans on class actions or punitive damages.	-Adamantly opposes any immunity or limits on the industry's future liability -No cap on damages -No ban on class actions -No limits on punitive damages -Requiring public to accommodate corporate wrongdoing sets a dangerous precedent.
Size of Payments/ Price per Pack	-Excise taxes should be dramatically increased and should be indexed to inflation (studies show $2 per pack or more may be appropriate). -Financial punishments should not be considered ordinary business expenses and tax deductible -Demand more money--the industry will boom under the current settlement as it is already targeting 18-24 year-olds.	Increase of at least $1 per pack is necessary-- would result in a 15% reduction in overall consumption and a 33% in youth consumption.	-Payments are too small--either the payments or excise tax should produce a $2 increase in price per pack. -Tax deductibility of payments makes things too easy for industry and decreases federal revenues.	Aggressive enatment of federal and state excise taxes must be maintained.	Tax provisions that make every penny tax-deductible make things too easy for the industry.

ISSUE	Koop-Kessler	AMA	ACS	AHA	ALA
ETS	Ban smoking in: -all work sites -all places of public assembly -outdoor areas where people assemble, like service lines, arenas -schools- inside and outside -all forms of public transportation, including flights going in and out of U.S. -all federal workplaces, including branches of military and VA hospitals	No recommendation. By enacting the Smoke-Free Environment Act of 1993, the settlement would achieve more than would stand alone legislation.	No recommendation. It is good that the provision would not preempt more stringent state or local laws restricting smoking in public places.	No preemption of stronger local and state policies. OSHA standards are the minimum that must be met.	Settlement should protect restaurant, bar, and hospitality workers who are most at risk for passive smoking disease. Advocates zero tolerance for tobacco smoke.
Farmers	-Blue-ribbon panel should recommend short- and long-term strategies to reduce tobacco states' and communities' dependence on the crop. -Industry should finance an economic assistance and development fund to help tobacco farmers and non-farm industry workers find alternatives. -More settlement funds should go to farmers and less to trial lawyers.	Congress should use settlement funds to establish a public program to purchase tobacco farmland or tobacco crop allotments from farmers who want to leave the tobacco market.	No recommendation.	Set aside a portion of excise taxes to provide tobacco-producing communities with economic development assistance and opportunities for crop diversification.	No recommendation.

Tobacco - settlement - public health reqmts

AMA RECOMMENDATIONS
PROPOSED TOBACCO SETTLEMENT

FDA	LOOK BACK	TOBACCO PRICING	FUNDS DISBURSEMENT	PREEMPTION	ADVERTISING/ PROMOTION
• Same authority over tobacco products that it has over other "drugs" and "devices" • Same regulatory process applies as with other drugs/devices • 12-year moratorium on complete ban of nicotine; interim nicotine restrictions allowed	• Provides significant financial incentives for each tobacco company to achieve cuts in youth smoking • Penalties based on lifetime social cost of tobacco use* • Penalties not tax deductible • No annual cap • No abatement; rewards for companies to exceed target • Assessments against individual companies	• Increase price of cigarettes by $1 per pack -- Increase tax, or -- Increase annual industry payment, or -- Modify tax deductibility of annual payment	• A governmental agency should have responsibility for the public health aspect of funding, including asset allocation and expenditures	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• Only black/white "tombstone" advertising should be permitted • State and local governments should be permitted to regulate advertising and marketing

ORGANIZATIONAL COMPARISONS

PROVISION	AMA	ACS	ALA	AHA	ACPM	AAP
TOBACCO PRICING	• Increase price of cigarettes by $1 per pack -- Increase tax, or -- Increase annual industry payment, or -- Modify tax deductibility of annual payment	• Raise federal excise tax to $2 per pack/raise smokeless tobacco tax proportionally	• Increase excise taxes	• Increase excise taxes	NO POSITION	NO POSITION
FUNDS DISBURSEMENT	• A governmental agency should have responsibility for the public health aspect of funding, including asset allocation and expenditures	NO POSITION	NO POSITION	• Funds should be handled by organizations independent of tobacco industry influence	NO POSITION	NO POSITION
PREEMPTION	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws	• No preemption of sales, marketing, tobacco use laws or clean indoor air restrictions	NO POSITION	NO POSITION
ADVERTISING/ PROMOTION	• Only black/white "tombstone" advertising should be permitted • State and local governments should be permitted to regulate advertising and marketing	NO POSITION	• Comprehensive advertising and marketing restrictions • Black/white depiction of product package only	• NO POSITION	• Total ban on all tobacco product advertising and promotion	• Total ban on all tobacco product advertising and promotion

AMA = American Medical Association

ACS = American Cancer Society

ALA = American Lung Association

AHA = American Heart Association

ACPM = American College of Preventive Medicine

AAP = American Academy of Pediatrics

ORGANIZATIONAL COMPARISONS

PROVISION	AMA	ACS	ALA	AHA	ACPM	AAP
FDA	• Same authority over tobacco products that it has over other "drugs" and "devices" • Same regulatory process applies as with other drugs/devices • 12-year moratorium on complete ban of nicotine; interim nicotine restrictions allowed	• Maintain FDA authority over tobacco • No increased regulatory burdens • Delete 12-year provision	• No changes to FDA authority • No increased regulatory burdens • Delete 12-year provision	• Complete authority over tobacco products, including nicotine regulation	• Authority to regulate the manufacture, sale, labeling, distribution, and marketing of tobacco products	• Authority to modify nicotine and other cigarette ingredients without increased regulatory burden
LOOK BACK	• Provides significant financial incentives for each tobacco company to achieve cuts in youth smoking • Penalties based on lifetime social cost of tobacco use* • Penalties not tax deductible • No annual cap • No rewards for companies that exceed target • Assessments against individual companies	• Provide economic incentives to ensure industry compliance • No annual cap or rebate • Assessments against individual companies	• Increased financial penalty • Consider non-financial penalties • Assessments against individual companies	• Current penalties as a "floor" for future action	• Strengthen financial penalties • Consider non-financial sanctions • Begin penalties in year 2 • Not tax deductible	• Strengthen penalties/enforcement • Company specific penalties • Begin penalties in year 2

ORGANIZATIONAL COMPARISONS

FDA

AMERICAN MEDICAL ASSOCIATION

The FDA must be given the same authority over tobacco products that it has over other "drugs" and "devices" under the Food, Drug and Cosmetics Act, with the sole exception of the 12-year moratorium on the prohibition of traditional tobacco products or the elimination of nicotine from tobacco products.

- There should be a constructional principle indicating that FDA has full authority over all tobacco products and other nicotine delivery devices unless a specific exception is expressly set forth in the legislation.
- The settlement should be clarified by eliminating any language that suggests that FDA authority to regulate tobacco products is limited in ways other than the 12-year moratorium.
- FDA should be permitted to use the same procedures, and its decisions should be subject to the same standard of review that generally apply under the Food, Drug and Cosmetic Act.
- The definition of "tobacco product" should be clarified to include pipe tobacco, cigars, and any other tobacco product.

AMERICAN CANCER SOCIETY

The FDA procedural hurdles are wholly unjustified. The ACS recommends:

- Authorize FDA to develop performance standards designed to reduce or eliminate any constituent, including nicotine;
- Delete 12-year provision and apply a single standard that applies from the effective date of the Act;
- Eliminate proposed heightened standard of proof and allow traditional administrative law to apply;
- Delete requirements that FDA demonstrate that modifications in tobacco products will not result in significant contraband; and
- Include regulation of cigars and pipe tobacco

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

No changes to the FDA's current authority or limits on future authority are acceptable. FDA's hands should not be tied with increased regulatory "hoops and ladders." Nicotine is the reason people become addicted to cigarettes and it must be cut as soon as practicable.

- Delete 12-year provision

AMERICAN HEART ASSOCIATION

FDA must be guaranteed complete authority over tobacco products, including nicotine, and must be provided appropriate resources to carry out its regulatory role.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

The FDA must have the authority to regulate the manufacture, sale, labeling, distribution, and marketing of tobacco products.

AMERICAN ACADEMY OF PEDIATRICS

FDA should be able to modify the amount of nicotine and other harmful ingredients in tobacco products without being exposed to complicated regulatory, judicial, and legislative maneuvers.

ORGANIZATIONAL COMPARISONS

LOOK BACK

AMERICAN MEDICAL ASSOCIATION

The Look Back surcharge program must be given real teeth. If the tobacco industry is to be relieved of any significant civil liability and if FDA jurisdiction is to be subject to a 12-year moratorium on nicotine elimination, it is essential that financial incentives be put in place that will guarantee significant reductions in underage smoking and smokeless tobacco.

- Look Back surcharge payments should not be subject to the automatic pass through and should not be tax deductible.
- Look Back surcharge payments should be assessed against each individual company based on reductions in underage use achieved by that company. They should not be assessed on the basis of collective industry responsibility.
- Look Back surcharge payments should be based on the discounted present value of the lifetime social costs of tobacco use, not restitution of profits.
- The $2-Billion cap on annual surcharge payments should be eliminated. Any cap should be based on company profits from underage use or on total company profits in the domestic market.

Credit for compliance with regulations and corporate good faith should be replaced by rewards for companies that exceed the targets in any given year.

AMERICAN CANCER SOCIETY

There is no economic incentive to ensure the industry will meet the targets. The ACS recommends:

- Raise the targets for smokeless tobacco to same level as cigarettes;
- Impose a surcharge on each tobacco company based on brand-specific youth consumption;
- Eliminate the rebate provision to avoid undermining the intent and effectiveness of the look-back provision;
- Add language to explicitly authorize state and local governments to use minors in compliance checks;
- Require sales data, by brand, in order to evaluate performance by individual companies; and
- Eliminate the $2 billion cap.

Raise the federal tobacco excise tax to $2 per pack of cigarettes with a proportional increase on smokeless tobacco products.

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

The penalty is not strong enough and should be made company-specific, so no company would be tempted to do less than its share. Nonfinancial actions also should be taken, including "plain packaging" and a ban on al advertising by the offending company.

AMERICAN HEART ASSOCIATION

The penalties outlined in the settlement should serve as a floor for Congress in determining how much the industry should pay if youth smoking does not decrease by specified amounts.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

The industry must be held accountable for meeting targets for youth reduction in tobacco use, starting in year 2 and increasing every year thereafter. Strong financial penalties and/or other regulatory sanctions must guarantee the accountability of the industry's compliance to such objectives.

AMERICAN ACADEMY OF PEDIATRICS

The penalties/enforcement measures for reducing children's tobacco use are not sufficient. The academy supports the recommendation by the Advisory Committee on Tobacco Policy and Public Health.

ORGANIZATIONAL COMPARISONS

TOBACCO PRICING

AMERICAN MEDICAL ASSOCIATION

The price of cigarettes should be targeted to rise by $1 per pack, as opposed to the $.62 per pack projected under the proposed settlement. This can be accomplished by an increase in the cigarette excise tax, by upward adjustments in the Annual Payments, or by modifications in the tax treatment of existing annual payments.

AMERICAN CANCER SOCIETY

Raise the federal tobacco excise tax to $2 per pack of cigarettes with a proportional increase on smokeless tobacco products.

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

Increase excise taxes

AMERICAN HEART ASSOCIATION

The settlement should not preclude the use of tax policy to further decrease consumption of tobacco products, particularly among the nation's youth. Aggressive enactment of federal and state tobacco excise taxes must be maintained

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

NO POSITION

AMERICAN ACADEMY OF PEDIATRICS

NO POSITION

ORGANIZATIONAL COMPARISONS

FUNDS DISBURSEMENT

AMERICAN MEDICAL ASSOCIATION	AMERICAN CANCER SOCIETY	AMERICAN LUNG ASSOCIATION AMERICAN THORACIC SOCIETY
A federal agency (such as HHS) should be given overall responsibility for disbursement of the Public Health component of the Annual Payments, including oversight of grant recipients and authority to make adjustments in allocations in future years.	NO POSITION	NO POSITION

AMERICAN HEART ASSOCIATION	AMERICAN COLLEGE OF PREVENTIVE MEDICINE	AMERICAN ACADEMY OF PEDIATRICS
Funds should be handled by organizations independent of tobacco industry influence.	NO POSITION	NO POSITION

ORGANIZATIONAL COMPARISONS

PREEMPTION

AMERICAN MEDICAL ASSOCIATION

The preemptive effect of federal youth access restrictions should be narrowed and clarified so that states and local governments may impose civil sanctions on tobacco retailers beyond the federal minimum.

AMERICAN CANCER SOCIETY

States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

States and localities should be authorized to enact laws that are more stringent than federal tobacco control laws

AMERICAN HEART ASSOCIATION

Settlement must not preempt the initiation, adoption and/or enforcement of state or local laws that are more comprehensive/severe in reducing sales, marketing, and use of tobacco products, and restricting smoking in public places.

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

NO POSITION

AMERICAN ACADEMY OF PEDIATRICS

NO POSITION

ORGANIZATIONAL COMPARISONS

ADVERTISING/PROMOTION

AMERICAN MEDICAL ASSOCIATION

The preemptive effect of federal advertising restrictions should be narrowed and clarified so that states and local governments may regulate local advertising and marketing and may impose counter-advertising requirements on tobacco companies.

Only black and white "tombstone" advertising should be permitted.

AMERICAN CANCER SOCIETY

NO POSITION

AMERICAN LUNG ASSOCIATION
AMERICAN THORACIC SOCIETY

Advertising must be more comprehensively restricted because tobacco companies will find creative ways to get around piecemeal restrictions to market their products, as has been done in other countries trying this approach. Restriction examples include: publications with more than 15% youth readers; no ads, marketing or promotion campaigns; other publications black/white depiction of product and package only; and an end to payments to entertainment/sports figures to smoke in "public" or in the course of their professions.

AMERICAN HEART ASSOCIATION

NO POSITION

AMERICAN COLLEGE OF PREVENTIVE MEDICINE

Advertising and promotion restrictions must be increased to provide for a total advertising ban covering all tobacco products.

AMERICAN ACADEMY OF PEDIATRICS

Supports a ban on all tobacco product advertising.