

UCSF

Tobacco Control Policy Making: United States

Title

A Public Health Analysis of the Proposed Resolution of [the 1997 United States] Tobacco Litigation

Permalink

<https://escholarship.org/uc/item/5qc0x23w>

Authors

Fox, Brion J., J.D.

Lightwood, James M., Ph.D.

Glantz, Stanton A., Ph.D.

Publication Date

1998-02-01

A Public Health Analysis of the Proposed Resolution of Tobacco Litigation

Brion J. Fox, J.D.
James M. Lightwood, Ph.D.
Stanton A. Glantz, Ph.D.

Institute for Health Policy Studies
School of Medicine
University of California San Francisco
San Francisco, CA 94109



February 1998

Supported in part by National Cancer Institute Grant CA-61021 and the University of California Tobacco Related Diseases Research Program Grant 6FT-0105. Opinions expressed reflect the views of the authors and do not necessarily represent the sponsoring agency or the Institute for Health Policy Studies. This report is available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/ustl/>.

This report is the latest in a series of reports that analyze tobacco industry campaign contributions, lobbying, and other political activity in California and other states. The previous reports are:

M. Begay and S. Glantz. *Political Expenditures by the Tobacco Industry in California State Politics* UCSF IHPS Monograph Series, 1991.

M. Begay and S. Glantz. *Political Expenditures by the Tobacco Industry in California State Politics from 1976 to 1991*. UCSF IHPS Monograph Series, 1991.

B. Samuels and S. Glantz. *Tobacco Control Activities and the Tobacco Industry's Response in California Communities, 1990-1991*. UCSF IHPS Monograph Series, 1991.

M.E. Begay and S.A. Glantz. *Undoing Proposition 99: Political Expenditures by the Tobacco Industry in California Politics in 1991*. UCSF IHPS, 1992.

S.A. Glantz and L.R.A. Smith. *The effect of ordinances requiring smokefree restaurants on restaurant sales in California*. UCSF IHPS Monograph Series, 1992.

M.E. Begay, M. Traynor, S. A. Glantz. *Extinguishing Proposition 99: Political Expenditures by the Tobacco Industry in California Politics in 1991-1992*. UCSF IHPS, 1992.

M.E. Begay, M. Traynor, S.A. Glantz. *Tobacco Industry Political Expenditures in California State Politics, January-June, 1993*. UCSF IHPS, 1993.

M.E. Begay, M. Traynor, S.A. Glantz. *Tobacco Industry Political Expenditures in California in the 1991-1992 Election*. UCSF IHPS, 1993.

M.E. Begay, M. Traynor, S.A. Glantz. *The Twilight of Proposition 99: Preauthorization of Tobacco Education Programs and Tobacco Industry Political Expenditures in 1993*. UCSF IHPS, 1994.

H. Macdonald and S. Glantz. *Analysis of the Smoking and Tobacco Products, Statewide Regulation Initiative Statute*. UCSF IHPS, 1994.

H. Macdonald, M. Traynor, S. Glantz. *California's Proposition : An Analysis of the Tobacco Industry's Political Advertising Campaign*. UCSF IHPS, 1994.

S. Aguinaga, H. Macdonald, M. Traynor, M. Begay, S. Glantz. *Undermining Popular Government: Tobacco Industry Political Expenditures in California 1993-1994*. UCSF IHPS, 1995. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/tobexp>)

M. Begay, and S. Glantz. *Question 1: Tobacco Education Outlays From the 1994 Fiscal Year to the 1996 Fiscal Year* UCSF IHPS 1995. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/q1>)

F. Monardi, E. Balbach, S. Aguinaga, S. Glantz. *Shifting Allegiances: Tobacco Industry Political Expenditures in California, January 1995 - March 1996*. UCSF IHPS 1996 (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/sa>)

F. Monardi, A. O'Neill, and S. Glantz. *Tobacco Industry Political Activity in Colorado 1979 - 1995*. UCSF IHPS 1996. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/co>)

F. Monardi, and S. Glantz. *Tobacco Industry Political Activity in Washington 1983 - 1996*. UCSF IHPS 1996. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/wa>)

F. Monardi, and S. Glantz. *Tobacco Industry Political Activity and Tobacco Control Policy Making in New Jersey 1982 - 1995*. UCSF IHPS 1997. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/nj>)

E. Balbach, F. Monardi, B. Fox, S. Glantz. *Holding Government Accountable: Tobacco Policy Making in California, 1995-1997*. UCSF IHPS 1997. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/ca9596/>)

S. Aguinaga-Bialous and Stanton A. Glantz. *Tobacco Control in Arizona 1973-1997*. UCSF IHPS 1997. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/az/>)

F. Monardi, and S. Glantz. *Tobacco Industry Political Activity and Tobacco Control Policy Making in Pennsylvania 1979 - 1996*. UCSF IHPS 1997. (Available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/pa>)

TABLE OF CONTENTS

Introduction and Summary	7
The Funding Provisions of the Deal Are Inadequate	7
The Taxpayers will Absorb a Substantial Fraction of the Nominal Costs to the Industry	8
The Industry Will be Protected from Litigation	8
Eliminating Litigation Will Eliminate a Valuable Public Health Tool	8
The Deal Requires Congress to Preempt Laws in Every State	8
Regulatory Controls are Unnecessary and Insufficient	9
The Lookback Provision Is Inadequate	9
The Deal Preserves the Oligopoly Structure of the Industry	10
The Deal does not Provide for Full Disclosure of Tobacco Industry Wrongdoing	10
There are No Barriers Other than a Lack of Political Will to Adopting the Beneficial Provisions of the Deal	10
The Deal is Silent on International Issues	10
The Deal is Based on Several Premises that are no Longer True	10
Political Issues	12
Preemption of State Authority	15
Limitations on State Authority to Regulate Tobacco	15
Preemption of Consumer Protection, Fraud, Anti-Trust, and Other Laws	15
Implicit Expansion of Preemption	16
General Enforcement	17
The Tobacco Companies and Bankruptcy	19
What is bankruptcy?	19
What are the types of bankruptcy?	19
Bankruptcy as a result of mass tort litigation.	20
Why would the tobacco companies file for bankruptcy?	21
Why would the tobacco companies not file for bankruptcy?	21
The Reorganization Plan Must Present a Feasible Solution	21
Not All Lawsuits Will Be Stayed	22
The Corporate Uncertainties	23
Who wins and who loses with bankruptcy?	23
International Issues	25
Current United States Efforts to Control Tobacco have World-Wide Significance	25
The Deal Fails to Effectively Address the United States Tobacco Problem	26
The Deal Will Result in Increased International Tobacco Sales	26
The Deal Will Encourage Overseas Corporate Expansion	26
The Deal Affects the Legal Rights of non-United States Entities	27
The Deal Could Prevent Full Disclosure of Tobacco Industry Documents	27
The Deal Could Stymie Future Efforts by the United States to Influence International Tobacco Control	27
Funding the Deal	29

Effects of the Passthrough Provision	33
The Lookback Provision	34
The Level of Surcharge is Too Low	34
The Surcharge Level is Frozen	34
The Rebate for Good Behavior Could Eliminate the Effect of the Lookback	35
Daily Smoking Prevalence is the Wrong Measure	35
Protecting the Oligopoly	37
Disclosure of Tobacco Ingredients	40
FDA Advertising and Marketing Restrictions	42
Youth Access and Licensing	44
Youth Access	44
Licensing	44
FDA Controls on Nicotine and Other Tobacco Constituents	46
Special Treatment for Tobacco	46
Procedural Barriers to Effective FDA Regulation of Tobacco	47
Secondhand Tobacco Smoke	50
Incentives to Create a Safer Product	52
Elimination of Liability for the Tobacco Industry	54
Added Protections Against Most Civil Liability for the Tobacco Industry	56
The Deal Creates High Barriers to Litigation Against the Tobacco Industry	56
The Deal Creates Additional Procedural Advantages for the Tobacco Industry	58
The Deal Removes Incentives for the Tobacco Companies to Act More Responsibly	58
Access to Tobacco Industry Information	60
Reformation of the Tobacco Industry	62
State Settlements	64
Technical Appendices	A-1
APPENDIX A: ECONOMIC IMPACTS OF THE TOBACCO PAYMENTS	A-3
Funds and Budgets	A-3
After Tax Cost of The Deal	A-9
Financial Analysis Using the Federal Trade Commission Model	A-11
Analysis of the Lookback Provision	A-15
Sensitivity Analysis	A-19
Conclusions	A-19
References	A-21

APPENDIX B: ECONOMIC ANALYSIS OF THE LOOKBACK PROVISION	A-22
Introduction	A-22
Idea of Lookback Provision and Assumptions of Analysis	A-22
Base Case	A-24
Sensitivity Analysis of the Penalty	A-25
Price	A-26
Discussion	A-27
Conclusion	A-30
References	A-30
APPENDIX C: THE POLITICAL ENVIRONMENT	A-31
Historical Tobacco Industry Influence over the Political Process	A-31
Current tobacco industry influence in Congress	A-32
State vs. Local Authority	A-32
References	A-33
APPENDIX D: PUBLIC HEALTH BENEFITS OF THE DEAL	A-34
Codification of FDA Regulatory Authority	A-34
Jurisdiction	A-34
FDA Authority	A-35
Performance Standards	A-36
FDA ability to require tobacco products to meet performance standards	A-36
Restrictions placed on FDA authority to regulate performance standards	A-37
Good Manufacturing Practices	A-37
Disclosure of Hazardous Constituents of Cigarettes	A-38
Increased Advertising and Marketing Restrictions	A-38
Improved Cigarette Warning Labels	A-38
Increased Measures to Limit Youth Access to Tobacco	A-38
Licensing of Retail Tobacco Product Sellers	A-39
Mechanisms to Encourage Innovation Into Safer Products	A-39
Funding for National Anti-tobacco Counter Advertising	A-40
National Standards Regarding Environmental Tobacco Smoke	A-40
References	A-40
APPENDIX E: SUPPORTING LEGAL RESEARCH AND ANALYSIS	A-42
History of tobacco civil liability	A-42
Product Liability	A-42
Nicotine Dependence Lawsuits	A-42
Health Care Reimbursement Suits	A-43
Pressures for Settlement	A-43
Litigation as a Public Health Tool	A-45
Industry Admission of Wrongdoing	A-45
References	A-45
APPENDIX F: TEXT OF JUNE 20, 1997 PROPOSED RESOLUTION OF TOBACCO ISSUES (“THE DEAL”)	A-47

Introduction and Summary

The proposed tobacco settlement agreement, as negotiated by some state attorneys general and the tobacco industry that was made public on June 20, 1997 (Appendix F), raises a complex array of public health, public policy, legal and economic issues. It was intended to be a blueprint for national tobacco control legislation that would end the most important litigation current and potential against the tobacco industry. As with most complex legislation, the deal, after it was announced, underwent a great deal of scrutiny and criticism. Many public health and policy groups analyzed the deal in whole or in part in order to provide guidance for those who wished to distill the essential elements and implications of the deal. While many have pronounced the original deal “dead” as a result of this criticism, it remains the fundamental framework around which most proposals for federal legislation on tobacco has been based. As a result, a careful analysis of the terms and implications of the original June 20 deal remains a worthwhile effort.

This report seeks to provide policy makers and advocates with a context and analysis of the most important aspects of the deal through a series of briefing papers, which can be read independently or collectively. Each paper addresses one aspect of the deal. The papers are organized according to general topics: political issues related to the deal, financial and tax aspects of the deal, regulatory implications of the deal, and civil liability controls in the deal. For those who desire a more technical approach to the issues, we have included five technical appendices to provide additional support regarding the economic analysis of the deal, the economic analysis of the lookback provision, the political analysis of the deal, and the public health analysis of the deal, the legal analysis of the deal. To the extent that the deal is reflected in any legislative proposals that emerge, this analysis will be relevant to that legislation.

In the months leading up to the publication of the deal, many commentators discussed the relative merits of entering into a negotiated resolution of the tobacco litigation. The advocates of the deal pointed to the ability to obtain specific relief, the advantages of having a national tobacco policy, and the elimination of the risks to continuing the litigation. Critics of the deal-making process were concerned that making a deal would: guarantee tobacco industry profitability; require Congressional action, which in turn would provide weak proposals because of the influence the tobacco lobby in national politics; preempt stronger state and local regulatory efforts to control tobacco; and preclude broad based public health efforts to control tobacco in the future.

Many commentators have described the deal as one in which the tobacco industry accepts strong restrictions in exchange for some limitation of liability. Our analysis reaches just the opposite conclusion: A close reading of the deal reveals that the benefits to the tobacco industry are concrete and substantial whereas the public health benefits are less clear.

The Funding Provisions of the Deal Are Inadequate

The money in the deal is large in absolute terms but small when compared to the damage done by tobacco products. Even if one takes the more limited view of the deal that its purpose is only to reimburse the states for future Medicaid expenses plus fund the specified public health programs, the payments are not high enough to cover these limited costs. If the deal is designed to reimburse society for all damage done by tobacco, it provides less than 10 cents on the dollar.

The financial portions of the deal are structured in such a manner that they will guarantee industry profits.

The Taxpayers will Absorb a Substantial Fraction of the Nominal Costs to the Industry

All payments by the tobacco industry, including those made “in lieu of” punitive damages, are tax deductible, which results in a decrease in the impact of the deal on the industry and a cost shifting to American taxpayers. Taxpayers will absorb 30-40% of the cost of the deal, which will need to be recovered through increased taxes or spending cuts. The tax subsidy provided to the tobacco industry by the deal, amounting to about \$4 billion a year, dwarfs both the current tobacco price support program and the funds that the deal makes available for public health programs.

The Industry Will be Protected from Litigation

The civil liability protections will strongly protect the tobacco industry. The deal eliminates large-scale suits that are most threatening to the industry and only allows individual cases, which the industry has been successful in defeating. In addition, the deal changes the rules of evidence and civil procedure in ways that will make it more difficult for people with cancer, heart disease, and other smoking-induced problems to win their individual cases. The deal provides the industry financial security by capping exposure. These limitations on litigation will effectively preclude injured smokers from receiving just compensation and perhaps limit future criminal and civil enforcement actions against the tobacco companies. Moreover, the caps eliminate the incentives the civil justice system to improve corporate behavior, by reducing the threat that the tobacco companies will be held fully accountable for their actions. Under the terms of the deal, the industry will avoid about \$150-\$200 billion in liability at a cost of \$6-\$7 billion.

Eliminating Litigation Will Eliminate a Valuable Public Health Tool

The current litigation against the tobacco industry has a discernible benefit to the public health community which will be eliminated should the litigation cease. For example, the litigation provides a ready means to educate the public about the dangers of smoking and misbehavior of the tobacco industry. Without the prosecution of the current lawsuits, a valuable health education opportunity will be lost. In addition, the litigation which the deal seeks to resolve is based upon the enforcement of laws which serve public health interests, such as consumer protection and anti-trust laws. The deal restricts use of these laws in against the tobacco industry. Losing both a timely health education opportunity and the right to fully utilize consumer protection and related laws against the tobacco industry limits the public health tools to combat death and disease related to tobacco.

The public health community has an interest in preserving the right to litigation to obtain social justice. The deal compromises the rights of individuals and institutions to sue the tobacco industry without fair compensation. Similarly, the public health community has an interest in fairly allocating the damages related to a particular harm. Societal resources which are currently being expended to remedy the harms related to tobacco could be re-allocated to serve other public health interests. The litigation provides a valuable tool to force the tobacco companies to pay for the damages related to tobacco, leaving societal resources to address other public health problems. The absence of litigation will remove one tool the public health community can use to force the tobacco companies to internalize the costs of the damage tobacco does.

The Deal Requires Congress to Preempt Laws in Every State

The essential principle behind the deal was the willingness of the Attorneys General, private lawyers, and health officials who negotiated the deal to support substantial limitations on liability of the tobacco industry for its past and future behavior. The deal not only “legislatively settles” the Medicaid lawsuits brought by the Attorneys General, but also effectively ends most other forms of litigation against the tobacco industry. Since most of this litigation is being brought under state (as opposed to federal) consumer protection, fraud, anti-trust, and other laws, granting the tobacco industry the immunity it seeks will require Congress to preempt these laws in every state and the District of Columbia.

In addition to preempting these laws, the deal preempts existing state authority to require ingredient disclosure and may increase the strength of tobacco industry claims that local and state restrictions on tobacco industry marketing practices are illegal.

Regulatory Controls are Unnecessary and Insufficient

The details of the regulatory provisions in the deal favor the tobacco industry. Rather than recognizing that there are many agencies with jurisdiction over tobacco, the deal concentrates almost exclusively on the federal Food and Drug Administration (FDA). The deal also ignores the fact that most progress in tobacco use has been made at the local and state level.

The FDA currently has jurisdiction over tobacco products and is executing its regulatory authority pursuant to its jurisdiction. The few provisions in the deal which are not currently a part of FDA regulations could become so even without the deal, or like the current advertising restrictions, be regulated by another agency. Furthermore, the expectations regarding the benefits attendant with many of the regulatory changes should be small. Even with the advertising restrictions in place, the tobacco industry will still find successful ways to market their products, and tobacco imagery will be ubiquitous. Similarly, the proposed regulations regarding tobacco warnings and restrictions on youth access add little new authority. The deal would essentially codify the law as it currently exists, except that it would also place limitations on future FDA authority. Although the codification of FDA authority may be desirable, the deal would add intensive rollback FDA authority by requiring the FDA to meet additional regulatory hurdles before it can regulate tobacco constituents and restricting how and when it can regulate nicotine. These hurdles will preclude much of the potential for true regulatory reform.

Similarly, the secondhand tobacco smoke provisions in the deal represent a rollback of the current ability of the Department of Labor to regulate broadly. The secondhand smoke provisions within the deal accept industry claims that smokefree workplace laws would harm the hospitality industry, which is not true.

The Lookback Provision Is Inadequate

There are provisions in the deal designed to penalize the industry for not meeting specific targeted reductions in youth smoking. The lookback provision is a good example of how the technical details of the deal have important impacts that are not evident. The lookback provision ties goals in reducing teen smoking to the percentage of teens who are *daily* smokers. While 75% of smokers have their first cigarette by age 14, 75% do not become daily smokers until they reach age 18 (the cutoff for calculating the lookback penalty). Epidemiological evidence indicates that nicotine is as addictive as cocaine heroin and opiates. Symptoms of addiction begin before the onset of daily smoking. Limiting the measure of youth smoking to daily smokers will allow the tobacco industry to comply with the lookback provision by simply marketing in a way that leads children to begin smoking two years older than they do now; it will continue to recruit new adult smokers by addicting them as youths. By increasing the age of initiation by two years, the transition of most smokers to daily smoking in new smokers will occur after their eighteenth birthday.

In addition, the penalty is too small to provide an effective economic incentive for the industry to reduce youth smoking; if the industry were to simply continue its current recruiting of teens, the after-tax cost of the lookback provision would be about a nickel a pack. Furthermore, the penalties are pooled among the industry, which decreases the pressure any one company will have to reform its behavior.

The Deal Preserves the Oligopoly Structure of the Industry

Throughout the deal there are a number of provisions which increase barriers to market entry and

preserve the current profit structure. These provisions will encourage anti-competitive behavior and eliminate any incentive to innovate toward safer products. Furthermore, by closing the market, new companies will find it more difficult to compete. This situation will further guarantee excess profits for the existing companies.

The Deal does not Provide for Full Disclosure of Tobacco Industry Wrongdoing

One of the most important aspects of the current litigation is the ongoing disclosure of industry wrongdoing. The document disclosure provisions of the deal are weak and would permit the industry to continue to withhold privileged documents, which many believe are the most damaging to the industry. The deal may not be necessary to secure disclosure of these documents, because the Congress has subpoenaed and disclosed some tobacco industry documents, and more are emerging through litigation. Between further Congressional action and the litigation there is likely to be a continuous release of documents without a need for the deal.

There are No Barriers Other than a Lack of Political Will to Adopting the Beneficial Provisions of the Deal

Tobacco control advocates have successfully enacted legislation that meets many of the goals of the deal at the state and local level without compromise with the tobacco industry. The federal government could do the same. For example, the public health measures of the deal could be enacted and the funds for these programs appropriated out of the general fund or through an increase in the tobacco excise tax. Congress can give the FDA and Department of Labor more direct authority over tobacco products, and it could ensure full funding for their programs. Plaintiffs can enter (and Mississippi, Florida, Texas, San Francisco, and a plaintiffs' class of non-smoking flight attendants have entered) into individual legal settlements with the tobacco industry.

The Deal is Silent on International Issues

The deal ignores the implications that U.S. tobacco control policy has on international tobacco control efforts. The precedents established by the deal are particularly important because litigation against the tobacco industry is beginning in other countries. The limitations on liability in the deal may compromise the ability of other countries to recover the cost of tobacco-induced illness.

The Deal is Based on Several Premises that are no Longer True

The original premise behind the deal was that if the Attorneys General, public health advocates, and the tobacco industry could come to an agreement that all found acceptable, such legislation would be enacted into law rapidly. Some public health advocates argued that such a compromise was necessary and appropriate because the power of the tobacco industry in Congress was such that industry acceptance was necessary in order to get legislation enacted. Legislation was seen as necessary because the tobacco industry had never lost nor settled any health-oriented lawsuits against it. Because of this, rather than risking everything in Court, the Attorneys General and other decided that it was better to gain a partial victory in Congress.

Since then, the terms of the deal have been declared unacceptable by all elements of the public health community, so the original premise of going to Congress with a partnership between public health and tobacco forces no longer holds. The tobacco industry has maintained that the deal should be enacted as negotiated and has dramatically increased its campaign contributions and lobbying activities in order to see the deal enacted. Tobacco executives have testified in Congress that a grant of immunity for the industry is a

condition of industry support for federal tobacco legislation. Public health groups are divided about the wisdom of trading some form of immunity for the tobacco industry in exchange for public policy changes that some believe will reduce tobacco control. Even the forces in the health community who are willing to entertain such a trade, however, have rejected the deal as originally negotiated. As a result, they are now in the position of going into Congress opposed to the tobacco industry, the very situation that the deal was supposed to avoid.

Finally, the belief that the tobacco industry would never settle or lose health-related lawsuits has changed. The industry settled the Mississippi, Florida, and Texas Medicaid suits on favorable public health terms, as well as a case brought by San Francisco over the Joe Camel advertising character and a class action suit on secondhand smoke brought by flight attendants. The industry has also lost several cases brought by individuals. It will be difficult for the industry to return to a no-settlement strategy, particularly in light of documents and other information that have come out of the litigation process and Congressional hearings to date.

Political Issues

The original premise for the deal was that, while public health advocates had rarely been able at the Congressional level to overcome opposition from the tobacco industry for tobacco control legislation, the unprecedented pressure that the state and private lawsuits were placing on the tobacco industry created a unique opportunity for a negotiated settlement in which the tobacco industry was willing to accept (and support in Congress) legislation that it had previously opposed. Under this scenario, the public health community, together with the attorneys general, would go to Congress as partners to secure passage of a legislative package that would include tobacco control measures and protection of the industry from legal liability.

When questioned by skeptics, the deal's primary architects, Mississippi Attorney General Mike Moore and Dick Scruggs (one of the leading private attorneys involved in the negotiations) informed people that they had private assurances from President Clinton and Senate Majority Leader Trent Lott (Scruggs' brother-in-law) that if the attorneys general, public health groups, and tobacco companies could come to an agreement, they would see that the deal went through Congress unchanged (S. Glantz, personal communication.) As a result, the deal was presented as a take it or leave it proposition, with various proponents arguing that it was both necessary to do everything in the deal, and that it was impossible to separate out the individual provisions of the deal.

The tobacco companies have endorsed the deal as it is written. The tobacco industry is increasing its already substantial presence in Congress through increased lobbying efforts and increased campaign contributions [1]. In 1995-1996, Philip Morris was the single largest source of "soft money" contributions to political parties, giving \$2,520,518 to the Republicans and \$496,518 to the Democrats. In total, tobacco interests gave more than \$5 million to the Republicans and nearly \$1 million to the Democrats in soft money contributions. Perhaps in anticipation of the debate on the deal, their 1997 contributions are greatly exceeding that figure [1].

In contrast, no public health organization has embraced the deal as written.* The public health groups have abandoned the original premise of the deal, namely that they will go to Congress in partnership with the tobacco industry. Instead, if the attorneys general and public health groups wish to implement the changes that these organizations have said are necessary, they will need to go to Congress as opponents of the tobacco industry, the very situation that the deal was supposed to avoid. Moreover, President Clinton and many members of Congress have already called for revisions to the deal as written.

While there is a wide belief within the public health community that there is strong public opposition to the tobacco industry, there is no evidence that public health groups can translate this public opinion into a defeat for the tobacco industry in Congress. The tobacco industry remains among the largest sources of campaign contributions to Congress, particularly to the Republican Party, which controls Congress. The industry's power was manifest recently when Congress gave (and President Clinton signed) a tax provision granting the industry a \$50 billion tax credit against the costs of the deal based on the fact that the tobacco excise tax (paid by smokers) was increased by 15¢. When this action was isolated and highlighted, public

*The American Cancer Society, American Heart Association, and American Medical Association (AMA), the three highest profile public health groups that have been supporting the principle of a negotiated settlement with the tobacco industry, have all published extensive critiques of the deal that would require fundamental changes in its structure. The American Lung Association and many tobacco control groups have opposed the deal. The House of Delegates of the AMA has reiterated its earlier policy against immunity for the tobacco industry. The American Public Health Association and several affiliates of the American Heart Association have also opposed immunity.

health advocates were able to force repeal of this provision.

The continued support of some public health groups for the process of a negotiated resolution with the tobacco industry has been based on the assumption that some sort of Congressional action is necessary to advance the public health agenda. This is untrue. Many of the terms of the deal would be better left to percolate through the current system at the state or local level or under existing Federal law without involvement of the Congress or omnibus legislation.

The FDA currently has the authority to regulate tobacco products. It should not be necessary to pass a law to give them authority. Alternatively, if it is deemed good public policy make the FDA jurisdiction explicit, this law can be passed independently of the comprehensive deal. Without the terms of the deal, most of the regulatory provisions in the deal can be implemented by the FDA. Should the FDA lose the authority to do so through court challenges, this could be remedied through a minor repair of the enabling act.

The federal Occupational Safety and Health Administration (OSHA) is developing a rule which would restrict secondhand smoke throughout workplaces across the country [2]. The deal is not required for OSHA action.

Mississippi entered into a settlement of its litigation against the tobacco companies. Under the terms of this settlement it recovered more of its damages than it would likely recover under the terms of the deal (*In re Mike Moore, Attorney General ex rel, State of Mississippi*, State of Mississippi Tobacco Litigation in the Chancery Court of Jackson County, Mississippi, Cause No. 94-1429, Memorandum of Understanding July 2, 1997) Florida won a settlement for not only money, but also for several public health provisions, including banning billboards and several other forms of tobacco advertising and funding for an anti-tobacco education campaign (*Florida v. American Tobacco Co.*, Case No. 95-1466 AH, Court of the Fifteenth Judicial Circuit, Palm Beach Florida, Settlement Agreement 8/25/97). The fact that the Mississippi settlement included a most favored nation clause meant that the public health provisions in Florida also apply to Mississippi. Texas reached a settlement that contained additional public health provisions (*Texas v. American Tobacco Co.*, Case No. 5-96CV-91, USDC E.D.Texas (Texarkana Division) Comprehensive Settlement Agreement and Release 1/16/98). The industry also settled a private class action brought on behalf of flight attendants (Broin) (*Norma R. Broin v. Philip Morris*, Case No. 91-49738, Circuit Court of the Eleventh Judicial Circuit, Dade County Florida, Settlement Agreement, 10/9/97). and a case against the Joe Camel advertising campaign (*Janet C. Mangini v. R.J. Reynolds Tobacco Co. et al.*, Case No. 939359, Superior Court of the State of California County of San Francisco, Settlement and Consolidation Agreement, 9/8/97). These settlements represent a major shift in the historic industry strategy of never settling a case.

The primary effect of the deal on tobacco consumption is likely to be through the price increase associated with a provision in the deal which requires the tobacco companies to passthrough all of their costs. As constructed, this situation essentially taxes smokers to pay for the tobacco industry's legal liability. If increasing the price of tobacco products is the desired outcome, it would be simpler and more just to simply increase the tobacco tax.

References

1. Abramson J, Meier B. Tobacco Braced for Costly Fight. *The New York Times*. New York City. December 15, 1997: .
2. US Occupational Safety and Health Administration. Indoor Air Quality (Proposed Rule). *Federal Register*. 1994;59:15968-16039.

Preemption of State Authority

Tobacco control advocates embrace the principle that decentralized efforts at tobacco control work best, and any elements of the deal which would preempt stronger local controls on the tobacco industry would be unacceptable [1]. While most discussion of preemption has centered on preemption of state and local tobacco control laws, the deal also requires extensive preemption of state consumer protection, anti-trust, fraud, and other laws in order to provide the tobacco industry the protection from legal liability that it seeks. Indeed, because most of the lawsuits that are pending against the tobacco industry have been brought under state laws, the issues of preemption and immunity are inextricably intertwined. The deal preempts or complicates both state and local action for tobacco control as well as enforcement of state consumer protection, anti-trust, and other laws in a way that will benefit the tobacco industry.

Limitations on State Authority to Regulate Tobacco

Subparagraph B of Title V of the deal addresses state and local regulatory controls over tobacco products. Subparagraph B(1) identifies that the regulatory controls within the deal establish a base minimum for tobacco control efforts and preserves state and local flexibility to regulate tobacco products more strictly. Subparagraph B(2), however, provides limits for state and local control over items such as national warning labels and national performance standards for tobacco products.

Subsection B(1) of Title V of the deal is fine in principle but is ineffective. In order for it to have any effect it will need to be embraced in the drafting the legislation. Laws will need to be drafted to give the states and localities specific authority to regulate in various areas. The only areas in which the deal clearly grants authority to states and localities appears to be for taxes, youth access, and clean indoor air laws.

For youth access the federal licensing scheme adopted under the deal, the table of penalties appears to preclude much of the ability of states and localities to create a stronger enforcement mechanism. The licensing penalties are phrased in such a manner it does not provide States the ability to develop stronger solutions. Similarly, in order to adopt a non-preemptive federal program on secondhand smoke through the Occupational Safety and Health Act, 29 U.S.C. § 651 et seq. will have to be amended.

Ultimately the deal provides for what appears to be a comprehensive scheme to be adopted by the federal government which will replace all existing laws. This combined with the limitation on enforcing the terms of this deal contained within Title III means that states and localities will have little room to develop their own regulatory structure.

The continued preemption of local efforts to control labeling and advertising, and further preempting state regulation of tobacco manufacturing practices, and product content will eliminate a great deal of local control. Only through a formal application for an exception to the FDA can a State exceed these public standards established by the FDA. As a result, all of the power will vest in a single agency. Should that agency be captured by political or industry influences, there will be no mechanism to affect tobacco company behavior to create safer products. This is a dramatic shift of authority away from the States and into a single agency, and leaves no protections for the public health.

Preemption of Consumer Protection, Fraud, Anti-Trust, and Other Laws

The terms of the deal may explicitly preempt many state enforcement activities. For example, the deal restricts state enforcement actions, specifically that they “could not impose obligations or requirements beyond those imposed by the legislation.” (Title III.A) This could be viewed as preempting either the enforcement of specific laws, such as anti-trust or consumer protection laws, or restricting possible

enforcement actions. For example, it may preclude the disgorgement of profits, treble damage penalties or certain civil fines. All that the industry would need to prove is that the state action was related to the deal and sought to impose an obligation greater than that provided for under the deal and the law could be preempted.

Through the preemption of state consumer protection and other laws, the industry will gain additional immunity from civil lawsuits. Since most of the litigation against the tobacco industry is being brought under state, not federal, law, Congress will have to preempt these state laws in order to give the tobacco industry immunity, however limited. For example, many of the medical care reimbursement lawsuits are based upon tobacco industry violations of state consumer protection and antitrust laws. Similarly, many of the lawsuits which are seeking changes in industry behavior are based upon criminal fraud statutes or state racketeering laws. If Congress preempted the enforcement of these laws, they would be granting the industry freedom from state or private enforcement of these laws in the courts.

Similarly, a preemption of the state laws could provide the tobacco industry protection from state criminal laws. For example, the comprehensive efforts to eliminate certain tobacco trade groups, and provide for certain joint activities, could be used as a defense by the tobacco companies to state enforcement of its antitrust laws.

Implicit Expansion of Preemption

There are additional risks to adopting a comprehensive regulatory scheme at the federal level in that it may be used by the tobacco companies as a shield to state action. First, it can be used to dampen enthusiasm for change by arguing that the federal policies are sufficient and that states and localities do not need to go any further. Second, the tobacco companies will be able to argue that even though a particular provision for regulatory control may not be preempted, the comprehensive scheme embraced by the federal government results in a de facto preemption. This argument can be used while lobbying or challenging actions in court.

Another way in which the deal limits state authority is by providing for penalties for failing to meet youth access requirements. These provisions require that states forfeit money received under the deal for failing to meet compliance rates on retailer sales. This is a misplaced program and a mechanism to weaken state oversight over tobacco control. There is at best a loose connection between youth access laws and youth consumption [2]. This being the case, a state could find itself penalized for having relatively weak enforcement of the access laws, even if it has a lower youth prevalence because it chose to use its resources to adopt a more effective programs. Thus, if a state wished to win back its money, it could be forced to reallocate resources away from more effective youth programs into compliance checks.

References

1. Siegel M, Carol J, Jordan J, Hobart R, Schoenmarklin S, DuMelle F, Fisher P. Preemption in Tobacco Control: Review of an Emerging Public Health Problem. *JAMA*. 1997;278:858-863.
2. Rigotti NA, DiFranza JR, Chang Y, Tisdale T, Kemp B, Singer DE. The Effect of Enforcing Tobacco-Sales Laws on Adolescent Access to Tobacco and Smoking Behavior. *New England Journal of Medicine*. 1997;337:1044-1051.

General Enforcement

As with any law there needs to be an effective enforcement mechanism to ensure compliance. Subparagraph A of Title III of the deal provides for dual enforcement authority in the Federal Government and in the States, subjecting the tobacco companies to a maximum amount of scrutiny. There are also requirements that the Companies enter into an “enforceable national tobacco protocol” (“Protocol”), which would provide contractual rights to the states and the federal government to enforce certain provisions of the deal, and consent decrees with the settling states. The deal would be subject to the penalties of the statutes which will be enacted or amended as part of the deal, including the federal Food Drug and Cosmetic Act, 21 U.S.C. § 301 et seq, which governs the FDA. States would not be able to go beyond the scope of penalties established within the legislation. Although seemingly broadly stated, the enforcement provisions of the law are a retrenchment of current state and federal authority.

The tobacco companies are now subject to multi-jurisdictional attacks to enforce the laws of the different states and the federal government. For example, the current lawsuits represent an enforcement of antitrust laws, racketeering laws, and consumer protection laws. Suits are being pursued by states, cities, counties, the federal government and private citizens. (Other countries are also beginning to file legal actions against the tobacco industry, some of which involve US courts.) The enforcement scheme in the deal would preempt all of these enforcement mechanism for any matters covered by the law that implements the deal or the associated Protocol. The proposed law and the Protocol are sufficiently broad, that they would cover most if not all of industry behavior leaving little to be regulated by alternative jurisdictions. Moreover, the deal would not provide for citizen enforcement of the laws or the Protocol.

The states would also be effectively prohibited from enforcing their own laws in their own courts. With the grant of federal jurisdiction, states would have their actions (perhaps unconstitutionally) removed to federal courts. There would also be a weakening of the vast array of penalties currently available and replaced with the civil penalties contained within the new legislation. States would not be able to choose which of the statutes would be best to enforce any particular action, such as a state antitrust or racketeering law, but would be restricted to filing an action under the terms of this statute.

It is not clear what result the new law would have on the enforcement of state or federal criminal laws. It is possible that this scheme would be intended to replace the patchwork quilt of criminal law liabilities to which the tobacco companies are subject. Yet to provide any form of criminal immunity would be inappropriate in this context because there are no admissions of liability, no prior disclosure of information, and no criminal penalties.

As for the Protocol, it is not clear what effect this document would have. Because a Protocol has not been drafted, or is at least unavailable for review, it is unclear how effective and appropriate that this document would be. One can easily picture a document that is illusory or otherwise unenforceable. Its implications could also be far broader than intended actually acting as a barrier to future regulation, by binding of the States and Federal government as well as the tobacco companies. To present the Protocol as an important enforcement tool without providing its text, means that the that the authors of the deal are asking people to make important policy decisions without providing crucial information.

As for the states, they have the ability to enforce the deal in name only. The Consent Decrees set out in Subparagraph B of Title III of the deal do not provide any additional protections against Congressional action and are themselves faulty. First, the Congress will be able to change the rights and obligations of the states and the tobacco industry which would make the consent decrees either irrelevant or unenforceable.

Second, the Consent Decrees as constituted are weak. No Consent Decree has been drafted for

review, but it is clear that there are substantial restrictions on the enforcement of the Consent Decrees. For example, the States can only seek injunctive relief to enforce them, and cannot seek sanctions even for intentional violations of the Consent Decrees by the tobacco industry. This limitation on authority is dramatic and unnecessary. In addition, there is a requirement that the Consent Decrees be interpreted in a manner consistent with the other federal laws and the other consent decrees. This could result in a least common denominator problem, where the tobacco industry seeks courts that will provide a weak interpretation (“forum shops”) of the Consent Decrees and forces that interpretation upon other jurisdictions. Finally, the Consent Decrees appear to duplicate the Protocol, and it is not clear which would take priority.

Third, the Consent Decrees would not cover many of the more important public health measures, such as design modification of tobacco products, the youth look-back provisions, the testing of toxic constituents, and FDA regulation over good manufacturing practices. And even those terms which are covered will only be as good as the underlying terms of the deal, which are relatively weak. Thus, by entering into the Consent Decrees, the States may be preempting themselves from enforcing other State laws against the tobacco companies.

Finally, the enforcement mechanisms vested in the regulatory agencies are insufficient. For example, simply granting the FDA with the authority to regulate the industry will not be sufficient to ensure effective regulation. Protections should be established to protect the FDA’s autonomy from influence from either political forces and the industry. Even assuming that the money provided in Title VII(a)(2) for the enforcement of FDA programs is protected from the vagaries of the legislative process (which it will not be) there are substantial ways in which the FDA can be undermined. First, restrictions could be placed on the FDA’s actions, such as limiting for what programs the FDA could use its money. Second it would be subject to intense political scrutiny. The office of the Commissioner could be a highly politically charged office which would be only as strong as the political process allowed. Third, the industry could work through official and unofficial channels to influence agency behavior. The deal is insufficient to shield the FDA from these influences.

The Tobacco Companies and Bankruptcy

An issue that has haunted the debate over the tobacco deal is bankruptcy. Today, the mass of litigation against the tobacco industry has raised the possibility that one or more of the tobacco companies may declare bankruptcy because of verdicts against them or because of the continued threat of litigation. Indeed, some supporters of the deal have argued that the deal is necessary because it would ensure the industry's continued financial viability and avoid a tobacco bankruptcy. Although there is little doubt that bankruptcy would change the dynamics currently at play, and could make it more difficult for current and potential creditors to be paid, it is unlikely that these changes would favor the tobacco industry over the broader public health agenda. The industry would probably not be able to use bankruptcy to continue business as usual and bankruptcy would probably not permit the industry to stop litigation growing out of the government's police powers. While there are great uncertainties associated with bankruptcy, these uncertainties probably impose greater risks for the tobacco industry than for the public health. In short, a bankruptcy by one or more of the tobacco companies should be approached cautiously, but it should not be feared and is not a reason to enter into an otherwise insufficient and possibly damaging deal.

What is bankruptcy?

The bankruptcy laws set out a series of procedures by which persons (including both individuals and corporations) can obtain support from the federal courts in managing their creditors. The motivation behind the bankruptcy laws is twofold. First, it is to assure equitable distribution to the creditors. If, for example, a business did not have sufficient assets to pay all of its creditors, bankruptcy would protect the creditors so that no single creditor would have access to the assets at the expense of the other creditors. Second, the bankruptcy laws provide a "fresh start" for the debtor. Once a debtor has satisfied its debts through bankruptcy then it will be able to start anew. The debtor corporation is given time to design a reorganization plan that will not only resolve current problems, but will avoid problems in the future. One of the advantages of entering into bankruptcy is that it buys time for the debtor. Instead of a debtor being subject to the continuing crush of collection actions and litigation, a bankruptcy will automatically stay (put a hold on) all such actions. This arrangement provides breathing room for the debtor, the creditors, and the bankruptcy court to fully evaluate the situation.

What are the types of bankruptcy?

There are many ways to enter into a bankruptcy. The two most common forms of voluntary bankruptcy, the process by which a debtor actively seeks protection from its creditors, are Chapter 7 and Chapter 11. Each of these procedures is initiated with the filing of a petition with a Bankruptcy Court. Bankruptcy Courts are a part of the Federal Judicial System and are constituted in order to supervise and administer bankruptcy proceedings. Under a Chapter 7 bankruptcy, the result is a liquidation of assets. The assets of the corporation are sold with the proceeds of the sale given to the creditors and the corporation ceases to operate. Creditors are paid in the order of their "priority," based on a ranking of the debts as established under the bankruptcy code. Under a Chapter 7 bankruptcy a corporate debtor does not receive a discharge of whatever debt remains unpaid after the liquidation process. Hence, contrary to the general policy of providing debtors with fresh starts, Chapter 7 denies that benefit to corporate debtors.

Under a Chapter 11 bankruptcy, the debtor in consultation with the Court and its creditors, develops a "reorganization plan" by which it meets its credit obligations in a manner acceptable to all parties of interest and emerges in a form that will increase the chances of the debtor succeeding in the long run. The goal of a Chapter 11 bankruptcy is to have a reorganized company that is able to satisfy past and future credit obligations. To accomplish this goal, the Bankruptcy Court, in conjunction with the company and the creditors, reviews and confirms a plan for reorganization which will protect the interests of the company and

the creditors. The creditors' interests are represented by a "Creditor's Committee." There can be more than one such committee and the Courts attempt to appoint them in such a manner that all creditors' interests are represented.

Some of the reasons a creditor would accept a Chapter 11 bankruptcy plan by a debtor, as opposed to forcing a debtor into a Chapter 7 bankruptcy, would be if the corporation were worth more as a viable concern than if it were dissolved. Thus, if the company were reorganized, it would better be able to protect the creditors' interests. For example, if a company had \$1 million in assets but could enter into a contract by which it would be able to receive a net income of \$10 million over the next year, the creditors would be better served by allowing the company to keep its assets and enter into the contract. They would then have a larger pool from which to draw their relief.

Bankruptcy as a result of mass tort litigation.

It is conceivable that the tobacco companies could be forced into a Chapter 7 bankruptcy by litigation, should they find themselves subject to large verdicts. Since the current tobacco companies present a barrier to improved public health, the dissolution of the current corporations could only be seen as a benefit for the public health. The problem with a Chapter 7 bankruptcy is that it would allow the brand names and cigarette manufacturing equipment to be sold to a new corporation. If that new corporation were, for some reason, not subject to the same liability exposure of the current corporations, it may be able to continue the production of tobacco products. This risk is unlikely to be realized, simply because future tobacco companies would likely be subject to the same, or similar liability, as those companies sent into Chapter 7 bankruptcy.

It is also possible that as a result of the litigation the tobacco companies could file for reorganization under Chapter 11 of the bankruptcy code. They could do this prior to having any verdicts against them, because under Chapter 11 there is no requirement that the debtor presently be insolvent. The primary creditors would be the plaintiffs filing suit against the companies, and potential plaintiffs could be considered parties in interest to the bankruptcy. The companies' bankruptcy would be the result of many adverse verdicts as well as the cost of defense, exceeding the assets likely to be available.

There are three historical examples where a company that faced mass tort litigation sought protection from the bankruptcy courts: asbestos manufacturers, the manufacturer of the dalkon shield intrauterine device, and a manufacturer of silicon breast implants. In the largest of the asbestos bankruptcies, Johns-Manville Corp. (*In re Johns-Manville Corp.*, 36 B.R. 743 (Bankr. S.D.N.Y. 1984)) filed under Chapter 11 even though it was a viable billion dollar corporation. The problem was twofold: the predicted liability of the asbestos litigation, which likely exposed it to up to \$5 billion worth of adverse verdicts, and the cost of defending those suits. The Court allowed the bankruptcy to continue and included as represented creditors "future claimants." Dow Corning (breast implants) stressed the cost of defense was exorbitant and a significant reason that it sought bankruptcy protection.

The tobacco companies currently face crippling litigation, with the estimated cost of tobacco-induced illness running around \$100 billion per year in liability for medical costs and lost wages (excluding punitive damages and attorneys' fees) [Bartlett, 1994 #2]. Based on the three historical precedents, there is a reasonable likelihood that they could petition for bankruptcy protection. Although there is a "good faith" requirement within the bankruptcy laws, i.e. the companies seeking reorganization actually need it and are not seeking simply to avoid debt or litigation, the historical precedents and the magnitude of the claims against the tobacco companies suggest that this requirement would not present a high barrier to a claim for bankruptcy. Because of the solvent nature of the tobacco companies, however, they would likely need to argue that it was the verdicts and threat of verdicts that create the need for protection, rather than simply the

cost of defense.

Why would the tobacco companies file for bankruptcy?

Because the goal of a Chapter 11 bankruptcy is to allow the debtor to continue as a viable concern, the companies may consider bankruptcy if they could improve their chances for corporate survival. In particular, the tobacco companies seem to be seeking predictability. For example, creating a situation in which their liabilities and costs would be manageable and predictable is one of their main motivations for engaging in settlement discussions and supporting the national deal. If the national deal fails, they may consider whether they can gain predictability through the bankruptcy courts.

In the Johns-Manville bankruptcy, the asbestos company sought protection less from debts that had been incurred than for debts that might have been incurred through the litigation process. The court gave them that protection by holding future claimants as parties in interest, and creating a special fund for their claims. The tobacco industry would like the same protections. If the relief provided by a bankruptcy court to the tobacco companies includes current and future litigants, then the tobacco companies may have the predictability they seek. At the least, the automatic stay of the lawsuits would stop or dramatically slow the pace of the current litigation, which will have value to the tobacco companies, even if it only provides slightly improved predictability. An additional value could be a reduction in the constant negative public exposure that the companies have been receiving as a result of ongoing litigation.

Why would the tobacco companies not file for bankruptcy?

The tobacco companies are unlikely to file for bankruptcy unless or until they start getting hit with large verdicts because bankruptcy itself presents an unpredictable set of circumstances which will subject the tobacco companies to great risk. In order for a reorganization plan to be acceptable, the plan must be feasible. In other words, the plan must present an alternative which will relieve the company of its debts and not likely result in the company suffering the same financial constraints that sent it to bankruptcy in the first place. Given the large amount of potential liability associated with tobacco products, it is not clear that a plan would be "feasible" if the company continued to sell tobacco products. Although it is impossible to determine the exact outcome of any bankruptcy, we can explore some of the arguments that can be made on behalf of the various creditors.

The Reorganization Plan Must Present a Feasible Solution

The most damaging exposure that the tobacco companies face is that a reorganization plan that would protect them from future liability must treat claimants, current and future, as parties in interest who must be satisfied. The total damages caused by the tobacco industry each year have been conservatively estimated to be \$100 billion [Bartlett, 1994 #2]. If the Bankruptcy Court were to approve a plan that established a trust fund which reimbursed the plaintiffs at 50 cents on the dollar the tobacco companies would have to finance \$50 billion per annum. This figure, which does not include punitive damages, is beyond the theoretical profits of the tobacco companies and could as a result force the tobacco companies into a Chapter 7 bankruptcy [Harris, 1996 #11]. Furthermore, the damage estimates given above do not include possible liability from international sales of tobacco products or for claims based on harm which has not yet been incurred or related to tobacco use. These additional costs will increase the total exposure for the tobacco companies and make the development of a feasible plan to eliminate the risk of liability less likely.

Moreover, the risks would likely rest with the tobacco industry. In the Johns-Manville bankruptcy there was a trust fund established for future claimants, but this fund was later found to be woefully underfunded. Efforts to later repair the fund were largely unsuccessful. With the nature of tobacco litigation

threatening higher damages and more uncertainty than the asbestos litigation, a court is likely to be more conservative about how it approaches a tobacco industry bankruptcy so it can better protect claimants.

A second argument that the tobacco companies could face is that a reorganization plan should require the tobacco industry to fundamentally change the way in which it does business in order to eliminate future liability. A court and creditors could argue that tobacco is inherently dangerous and that no change in corporate behavior can eliminate future liability. Therefore, an order requiring the tobacco companies to cease production of the hazardous product which created the liability in the first place is a possibility. (In each of the three historical examples, asbestos, the dalkon shield, and silicon breast implants, the debtor ceased or seriously restricted the manufacture of the product which resulted in the litigation.) Even if a much narrower view of the litigation is taken, that it was the tobacco industry's specific market behavior which caused the liability exposure, the reorganization plan could require a fundamental change in behavior which would eliminate such exposure. Some of the actions which could be demanded of the companies are that they: fully disclose all research regarding the health hazards of tobacco, that they create and market safer products, cease all marketing and distribution which recruits new smokers or encourages current smokers to continue smoking, provide full disclosure of all additives, and provide clear and complete warnings. Furthermore, because the tobacco companies face risks from international litigation, a reorganization plan could require that whatever actions the tobacco companies take, they do so worldwide to prevent liability in other countries. In sum, creditors could argue that unless the tobacco companies take extraordinary measures, they could not say they were taking the necessary steps to limit future liability and that any reorganization without provisions for such measure would be unsuccessful. It is possible that a bankruptcy would require much greater changes in industry behavior than the proposed national deal.

Not All Lawsuits Will Be Stayed

The tobacco industry is also unlikely to have complete certainty under a bankruptcy because not all lawsuits will be automatically stayed. Although the general rule is that a debtor is protected from collection claims and lawsuits while it is in bankruptcy, there are exceptions which may prove especially damaging to the tobacco companies. For example, one of the exceptions to the automatic stay is in a situation where a governmental body -- such as the Attorneys General or local authorities -- uses its police power or enforces a regulation (11 USCS § 362(b)(4)). The claims for injunctive relief under the state lawsuits, such as those including advertising and marketing restrictions, and those requesting the dissolution of the Tobacco Institute and the Council for Tobacco Research, would probably not be stayed. Similarly, the state claims for monetary relief couched in terms of enforcing the consumers' protection, antitrust, and other laws would also probably not be stayed (although the state or local entity would not be able to sue to collect the monetary part of the judgment outside the bankruptcy proceeding). There are also provisions within the Bankruptcy Code which give the courts the ability to eliminate a stay if a party's interests would not otherwise be protected in the bankruptcy. With the wide range of lawsuits against the tobacco companies, many presenting novel legal theories, it is conceivable that a plaintiff class could be found to be in a unique position such that the bankruptcy court would allow the case to proceed. It is not difficult, for example, to imagine that the courts would not stay private lawsuits which sought to eliminate "Joe Camel," such as the one settled in California in September, 1997. (See *Janet C. Mangini v. R.J. Reynolds Tobacco Co. et al.*, Case No. 939359, Superior Court of the State of California County of San Francisco, Settlement and Consolidation Agreement, 9/8/97).

The Corporate Uncertainties

There are also uncertainties related to bankruptcy that affect the corporation itself. For example, entering into bankruptcy because of the threat of liability will probably be seen as a tacit admission of the dangers of tobacco products. If so, this tacit admission will affect the marketing of their products both domestically and internationally, and will reduce the inherent value of the company.

In addition, if a single tobacco company declares bankruptcy it faces the risk of being saddled with the bulk of the liability while leaving the remaining companies to defend the lawsuits in court. It could also risk alienation from the other tobacco companies by breaking ranks and leaving them to defend the lawsuits. Up until now, with the exception of Liggett, the tobacco companies have maintained a solid block. For one to splinter off would risk corporate alienation. (The possibility that the tobacco companies would file bankruptcies at the same time is even less likely. Besides the problems with respect to coordination and administration, the simultaneous filings of multiple bankruptcies could violate the antitrust laws.)

Ultimately, bankruptcy could affect the financial viability of the companies themselves, as well as the value of the parent companies. In a bankruptcy, shareholders will have a lower priority than creditors holding a judgment against the company. Therefore, the value of the stock will be affected considerably as the assets decrease. Because the tobacco companies represent a profitable business for their corporate parents, it is likely that the stock value of the parent corporations would suffer, as would the ability to obtain future financing. The likelihood that the companies' stock would drop substantially represents probably the strongest disincentive to declaring bankruptcy.

Who wins and who loses with bankruptcy?

Although it is impossible to predict the exact winners and losers with bankruptcy, it is likely that the tobacco companies would face greater risks than the public health community.

One of the concerns about litigating the companies into bankruptcy is that it would reward only those entities who sued it first. For example, if one or more states or other plaintiffs obtain large verdicts against the industry and it is forced to dissolve, the remaining states and other potential plaintiffs will not obtain financial compensation for their Medicaid claims and future plaintiffs will not have anyone to sue. This "first in time" concern is relevant from a policy perspective, but may be irrelevant from a public health perspective. If the companies cease to do business as usual, there may be a net increase in the number of lives saved even if the monetary damages recovered are divided inequitably.

Another concern about bankruptcy is that the better represented and more sophisticated creditors will likely fare better under a reorganization plan. Thus individuals who are more disenfranchised, such as individual plaintiffs, are likely to struggle in their attempts to influence the reorganization plan. Again, the public health advantages of the bankruptcy may make these concerns less relevant. But even so, we should look at the current system to see whether the bankruptcy presents a worse alternative. Both the civil liability system and the political process (necessarily a part of having Congress enact the deal) are notorious for favoring those with resources. Often these interests are protected at the expense of the disenfranchised. With the oversight of the bankruptcy Court, bankruptcy is unlikely to prove less equitable than the current system, and may actually produce a more equitable outcome.

A third concern is that bankruptcy would allow the tobacco companies to continue in business profitably. Although there is a chance that the tobacco companies could reorganize in a manner that they end up conducting business as usual, that risk is not unique to bankruptcy. The same result could occur with continued litigation should the industry prove successful. The deal would guarantee the future profitability of the tobacco companies while simultaneously restricting many public health measures.

Some also feel that the negotiated deal to settle all of the litigation is necessary because it would ensure that the debts incurred under the deal have priority and that the agreements made by the tobacco companies to support the public health measures would not be discharged by a Bankruptcy Court. These promises are insignificant. First, provisions do not protect against a Chapter 7 bankruptcy. Second, the money provided for under the deal represents a dramatic underfunding of the damages incurred as a result of

tobacco that claimants are likely to recover a higher proportion of the actual damages under a Chapter 11 bankruptcy than under the deal.

Some public health advocates are also concerned that in a bankruptcy, the tobacco companies would be able to manipulate the system in their favor. The fear is that the tobacco companies and the shareholders would somehow corrupt the system and work together to defraud creditors. This outcome is unlikely. It is more likely that the creditors and the Bankruptcy Court would be cognizant of efforts at corporate self-protection and would guard against it. This is likely because of widespread beliefs that the corporate officers have placed the industry at risk by concealing the dangers of tobacco. In addition, congressional action in general, and the deal in particular, provide a number of corporate advantages for the tobacco industry which it could not obtain in the course of a bankruptcy. For example, a Bankruptcy Court could not weaken the FDA jurisdiction over tobacco or the regulations it issued, preempt state and local laws, or change the tax code in ways favorable to the tobacco industry. A bankruptcy might better protect the public health than the deal by allowing other public health measures to go forward concurrently.

The attorneys representing the various plaintiff groups could be worse off if the industry goes into bankruptcy. Under a bankruptcy, the Court is able to control the flow of recovery to plaintiff attorneys. This situation may result in much lower fees than the attorneys would receive under either the litigation system or the deal. Because private attorneys have occupied a visible role in both the prosecution of cases against the tobacco industry and the negotiation of the deal, the effect of fee reimbursement could be a significant motivating factor for those encouraging the deal over bankruptcy. From a public health perspective, however, the relative difference between the fees is not enough to outweigh the likely advantages. While it is important to reward the attorneys who have at great effort and risk prosecuted these cases, once they have been reasonably compensated, their rights to additional funds should not be superior to their clients nor the public health.

International Issues

The tobacco industry is probably willing to enter into a deal with public health forces in the United States so it can remove the financial uncertainties associated with litigation and clear the way for international expansion. The fastest growing segment of the American companies' profit base is the foreign markets. As Eastern Europe and Asia open their markets wider to foreign cigarettes, these manufacturers are expected to participate more in those markets at great profitability. Delegates that the Tenth World Conference on Tobacco and Health (in Beijing, August 1997) reflected an international consensus that any national tobacco control policy, including in the United States, should take steps to assist international tobacco control efforts. The deal, however, fails to address international issues in any manner.

Current United States Efforts to Control Tobacco have World-Wide Significance

The ongoing litigation and tobacco control efforts in the United States assist the international tobacco control efforts in the same way they benefit the public health. The discovery of documents and tobacco industry behavior can assist countries in their efforts to control tobacco. By watching the U.S. experience in the prosecution of the lawsuits countries can learn ways to hold tobacco companies responsible for the damages caused by tobacco in those countries. Since the deal was announced, several other countries have indicated interest in filing suits to recover tobacco-induced costs; some of these actions would involve US courts and would be precluded by the deal. Finally, other countries can work with U.S. tobacco control advocates and policy makers to form a coordinated response to international tobacco issues. The United States cannot pretend that its actions have no significance on international events.

There has been one standard developed by an international body which can assist the United States as it reviews the proposed deal. At the Tenth World Conference on Tobacco or Health the following resolution was adopted:

The Conference recommends governments consider the international implications of tobacco control policies or settlements with the tobacco industry, to ensure that:

- i. such measures do not contribute to an increase in the worldwide epidemic of tobacco-related death and disease;
- ii. the legal rights of those not party to any agreement or policy are fully protected;
- iii. such measures do not inhibit full public scrutiny of the past, present and future activities of the tobacco industry and;
- iv. that the tobacco industry pay the costs of damage caused by tobacco.

This resolution embraces a model that looks beyond the impact a lawsuit or settlement has on its participants. The United States is at the forefront of private and public lawsuits against the tobacco companies setting important precedents both domestically and internationally. If these lawsuits are eliminated, international tobacco control efforts will be hindered. Similarly, because the United States is the home to many of the world's most dominant tobacco companies, and the second largest number of smokers, any regulatory measures taken could have a ripple effect internationally.

The Deal Fails to Effectively Address the United States Tobacco Problem

If the deal effectively addressed the domestic tobacco problem, it could be argued that the omission

of international issues in the deal had limited relevance. The deal could be said to both present the maximum solution which could be adopted by the United States and simultaneously act as a model for other countries. The deal, however, fails to present a reasonable public health solution for the United States.

First, the deal is greatly underfunded compared both to what the tobacco companies can afford to pay and compared to the damages caused to the United States by tobacco products. This is directly contrary to item four of the World Conference resolution: that the tobacco companies be held liable for the full measure of damages caused by tobacco.

Because of the deal's financial inadequacy, the deal will have limited effect on the profitability of the tobacco companies. With their profits protected, the tobacco companies will be able to accelerate the marketing of their products both domestically and internationally. The fact the deal "resolves" many of the contentious issues within the United States, such as litigation and regulation, will also free the industry from distractions to selling their wares elsewhere.

Second, the public health measures in the deal are inadequate. The measures can be seen as neither good enough for the rest of the world to model after nor sufficiently strong that they would explain the need to omit international issues from the terms of the deal.

The Deal Will Result in Increased International Tobacco Sales

Although the deal is insufficient, it may make the United States market less hospitable market than those of other countries. This situation will encourage worldwide expansion. The drafters of the deal could have avoided this problem by expanding the application of the marketing restrictions to all foreign markets. For example, under the deal, the new warnings only need to be applied to packs of cigarettes sold in the United States. They do not need to be on packs manufactured in the United States and sold overseas, or on United States brands manufactured and sold overseas. In fact, the deal specifically restricts FDA controls to "products sold in U.S. commerce." Similarly, any FDA requirements regarding advertising, ingredient disclosure, less hazardous products, and lower nicotine products will only apply to the United States.

Increased inequity between the market controls in different jurisdictions will increase the incentive for the tobacco industries to expand into less restrictive markets. This result of the deal, combined with guaranteed tobacco industry profitability, specifically contravenes point one of the World Conference resolution because the deal would likely contribute to the increase sale of cigarettes around the world.

The Deal Will Encourage Overseas Corporate Expansion

The deal will encourage American tobacco companies to establish overseas corporations. The only entities that are subject to the terms of the deal are those that sell into the United States market. Therefore, if the American tobacco companies were to move offshore, or to create foreign subsidiaries while eliminating United States sales, they would be immune from the terms of the deal. It can be argued, therefore, that one effect of the deal would be to force the United States problem out of the country while ignoring what happens to the rest of the world. By pursuing the litigation, United States plaintiffs are seeking compensation for damages, not to establish international tobacco control policy. Nevertheless, under the deal, the United States government would be making the conscious choice to encourage overseas expansion while limiting the tobacco companies' domestic liability. The tobacco companies would be out of the United States market and therefore not subject to market and civil liability controls, and the government would abdicate its regulatory authority.

The Deal Affects the Legal Rights of non-United States Entities

The litigation protections for the tobacco industry provided by the deal will almost certainly preclude the filing of lawsuits by foreign governments in United States courts. Although cases by foreign governments in United States courts may prove to be difficult, if not impossible, to maintain for procedural reasons, the elimination of the possibility of these suits is unnecessary. Should a government otherwise meet the appropriate requirements of United States courts, it should not be precluded from proceeding because of the deal. The deal, however, eliminates all suits by governmental entities, all class actions, and severely restricts actions for civil liability related to tobacco and health. As a result, all original cases from foreign governments would be precluded.

Lawsuits by private entities in United States courts would similarly be restricted. If allowed to proceed, they would likely be subject to the same restrictions on civil liability faced by United States citizens. The problem with this is twofold. First, the civil liability fund is based upon the number of possible United States litigants. Should this fund be additionally taxed by needing to satisfy claimants worldwide, all litigants will suffer the risk of insufficient compensation for damages. Second, United States citizens are theoretically sacrificing some of their rights because they are able to benefit from other aspects of the deal. Non-United States persons will not be similarly benefitted.

Besides the restrictions placed on original suits, it is possible that provisions of the deal could be used as a defense by the tobacco companies against efforts to domesticate foreign judgments. Given that many of the assets of the American tobacco companies remain in the United States, plaintiffs who are successful in other countries may still need to pursue assets in the United States. The deal, could act as a barrier to these efforts to reach assets in the United States.

In sum, the deal could foreclose the possibility of foreign governments recovering against the tobacco companies, and could place serious restrictions on private suits. At best, foreign judgments are likely be subject to the litigation caps accounted for in the deal, limiting their overall effectiveness. Thus, the deal fails to meet the second provision of the World Conference resolution because it limits the legal rights of those not participating in the settlement.

The Deal Could Prevent Full Disclosure of Tobacco Industry Documents

The deal also fails to meet the third requirement of the World Conference resolution because it does not require the complete disclosure of tobacco industry documents and information. The deal instead develops a complicated procedure, which will likely delay if not eliminate the need for complete industry disclosure. Because many of the important tobacco industry documents are contained within the United States, this process may preclude the dissemination of information worldwide.

The Deal Could Stymie Future Efforts by the United States to Influence International Tobacco Control

The deal also eliminates the U.S. ability to develop a coordinated international tobacco control policy. By embracing a dual tiered system which applies one set of standards to the United States and another to international cigarettes the United States loses whatever moral authority it has to influence international tobacco control efforts. It is ignoring the health of non-United States citizens. Furthermore, by restricting the ability of the FDA to affect international sales of tobacco products, the United States would be giving the American tobacco companies assurances that their overseas actions will be protected. In the past, the United States has often taken a two stage regulatory process, first regulating domestically and then regulating overseas sales. For example, pesticides and hazardous consumer products are sometimes outlawed in the United States first, and then the sale or “dumping” of these products overseas is proscribed. The deal apparently legitimizes tobacco use, and seems to preclude the application of the terms of the deal to any

international markets, precluding the possibility of ever taking the second regulatory step.

Funding the Deal

There are three parts to the deal’s funding: an initial lump sum Up Front Payment, an annual Base Payment which extends into perpetuity, and an eight year Public Health Trust Fund. The annual payments will be adjusted for inflation using the consumer price index or 3%, whichever is greater. The Up Front Payment is \$10 billion with no allocation provided for in the deal. This payment is presumably to compensate for past damages and is not accounted for in our analysis. There are also adjustments to annual payments which depend on industry tobacco sales volume. The primary disadvantages with the payment allocation is that it fails to provide enough money to adequately compensate those injured.

The Base Payments are to be divided in the following manner (Table 1): First, is the Civil Liability Fund. This Fund is one third of the Annual Base Payments to be reserved for any individual civil judgments against the tobacco industry. If judgments against the industry exceed the annual fund allotment, then the remainder is paid out of the next annual fund allotment. If the fund is not exhausted each year, a Presidential Commission will determine the use of the funds, which can include public health expenditures, compensation to claimants not otherwise entitled to compensation, or other purposes. Second, other moneys from Base Payment are to be used for public health programs (called the Public Health Funds), which consist of anti-smoking education, smoking cessation programs, community anti-tobacco programs, and replacement funds for lost tobacco company arts and sports sponsorships. Third, is the disposition of the Base Payments. The deal does not specify any use for these funds. Presumably they will be used to offset societal costs of smoking to governmental health programs such as Medicaid and Medicare, and to compensate individuals and entities precluded from suing the industry. Most believe that because the states who sued the industry were among the main negotiators of the deal, that Medicaid programs will have high priority in recovering costs from these unallocated funds.

Table 1. Allocation of Funds (in billions of dollars)					
Year	Public Health Trust Fund	Base Payment	Allocation of Base Payment		
			Civil Liability Fund	Public Health Funds	Unallocated (Presumably Medicaid/Medicare Reimbursement)
1	2.5	6.0	2.000	2.100	1.900
2	2.5	7.0	2.330	2.175	2.500
3	3.5	8.0	2.670	2.200	3.130
4	4.0	10.0	3.330	2.325	4.345
5	5.0	10.0	3.330	2.825	3.875
6	2.5	12.5	4.167	2.825	5.508
7	2.5	12.5	4.167	2.825	5.508
8	2.5	12.5	4.167	2.825	5.508
9	0.0	15.0	5.000	2.825	7.825
10	0.0	15.0	5.000	2.825	7.825
11+	0.0	15.0	5.000	2.825	7.825

Note: There are no adjustments for inflation or changes in tobacco consumption

The civil liability fund is inadequate to cover even the medical costs and lost wages associated with tobacco use. The private sector bears approximately \$70 billion dollars in medical costs and lost wages due to tobacco; these damages are potentially recoverable damages by potential private plaintiffs every year. At its maximum the civil liability fund will only provide \$5 billion, or 7%, of the total amount recoverable. This figure does not include punitive or other consequential damages nor does it include civil fines. These additions will make the civil liability fund even more inadequate.

The unallocated funds will be inadequate to compensate those plaintiffs whose cases are legislatively settled, including all suits brought on behalf of governmental entities, all class actions, all *parens patriae* actions, and all nicotine addiction actions. (It is not clear whether class actions will be settled or decertified as classes. Reading the deal literally, the cases would be settled and the plaintiff classes would be entitled to reimbursement from the settled cases fund.) This arrangement creates a logjam of plaintiffs seeking reimbursement from an inadequate fund.

For example, if we assume that the state governments are the only ones being reimbursed and that all other parties are shut out of the process, including the federal government, territories, cities and counties as well as the private class actions there is insufficient money to reimburse the states for current Medicaid losses. When it is recognized that the amount of money expended by the Federal government on tobacco-related health costs in the Medicare program alone is roughly double that which is expended under the Medicaid program, and that other governmental programs are likely to double that figure again, it is apparent that the money to reimburse plaintiffs is insufficient even before the other resolved actions are considered.

This underfunding is magnified further when it is realized that the wrong inflation adjustment is used to account for the increases in medical expenditures over time. Medical inflation rises at a rate faster than the rate of inflation and is usually measured by a rate known as the medical CPI. If the medical cost inflation continues to grow at the annual rate of the last ten years, less than 80 per cent of the Medicaid costs can be financed out of the annual payments over the first 25 years of the settlement. Similarly, the amount of damages incurred by the other plaintiffs will be reduced.

A volume adjustment clause changes the payments in proportion with changes in tobacco product sales volume. If the volume adjustment results in decreased payments while industry profits increase, a profit penalty will be triggered. The profit penalty offsets the decrease in payments (that is, makes the decrease in payments smaller) by 25 per cent of the increase in profits. The compensation numbers get worse with future decrease in consumption because the adjustment to damage payments related to volume decreases in cigarette sales is too generous. The damages incurred by the states and individuals, however, are unlikely to drop in a similar fashion because the risks of some of the diseases caused by smoking (e.g., cancer) persist for years after cessation. Thus, the tobacco companies would be able to reduce their payments immediately even though health care costs will not drop for twenty years.

Looking specifically at the test case where only Medicaid is reimbursed from the unallocated funds, it is clear that the amount of money is insufficient. We do not assume that medical costs increase at the rate of general inflation. We consider two cases. The first is a low cost case in which real Medicaid costs grow only because of increases in enrollment. We assume enrollment growth continues at the average rate of the most recent ten years (omitting 1990-1995 when legislation greatly expanded eligibility). Enrollment growth is assumed to increase by 1.18 per cent per year. The second is a high cost case which assumes that expenditures also increase at the rate of medical care inflation. This is assumed to continue at the rate of the most recent ten years. During this time medical inflation was 3 per cent per year greater than general inflation. The high cost case results in an annual increase in Medicaid expenditures of a little over 4% above general inflation, for a total nominal increase of about 7% per year. Excluding 1990-1995, nominal Medicaid expenditures have increased at an average rate of about 8% per year over the last ten years.

Table 2. Inadequacy of funds in settlement , assuming Medicaid priority on unallocated funds (Years 1-10) (Percent of costs met by the deal)		
	low medical inflation	high medical inflation
Average Medicaid reimbursement	76%	64%
Average Civil liability reimbursement	8%	7%
Average Medicare reimbursement	0%	0%
City/County reimbursement	0%	0%
Other Federal health reimbursement	0%	0%
Other State health reimbursement	0%	0%
Other governmental reimbursement	0%	0%
Legislatively settled class actions	0%	0%
Legislatively settled addiction actions	0%	0%

The problem of fully funding Medicaid costs increases after the first ten years if the medical inflation rate exceeds general inflation significantly because Medicaid costs will increase faster than the inflation adjustment. Assuming that the level of smoking and the fraction of costs due to tobacco does not change, funds will be adequate if medical inflation matches the CPI. For the low cost case, the undiscounted sum of the budgets for years 11 to 25 is \$230 billion, for the high cost it is \$317 billion. With annual real settlement payments of \$15 billion, this totals \$225 billion over the same period. So 100% of the budgets can be funded in the low cost case but only 71 per cent in the high cost case. Medicaid costs are by far the largest budgeted items after year ten, and these costs alone exhaust the Base Payments less the Civil Liability Fund starting around year 14 of the settlement in the high cost case, and Medicaid alone will exhaust the total \$15 billion annual payment in year 22.

All told, about one third of the Medicaid claims are paid in the first year. This fraction rises gradually to over 100 per cent of the claims in the low cost case, and around 80 per cent in the high cost case by year ten. However, even in the low cost case, excess funding in the later years does not compensate for the initial shortfall (Table 2). The adequacy of the funding of the settlement, assuming current levels of cigarette sales is questionable. The effects of the sales volume adjustment would reduce payments as much 10 to 15 per cent within 10 years and make any shortfalls more severe.

Similarly, if there is a significant market shift to a reduced risk or nicotine free product, which is determined to be not a tobacco product, there would be a decrease in the sale of tobacco products and therefore of funds available under the deal. As a result, the funds available under the deal could drop much more precipitously than the health risks and the costs to the states.

The inadequacy of funds is problematic for two reasons. First, by not fully compensating those injured and preventing those parties from suing in the future, the deal is unjust. Although there is always a risk associated with litigation, and settlements rarely compensate plaintiffs at 100%, the proportion of the damages for which the parties are actually receiving compensation is pennies on the dollar - greatly out of proportion to the litigation risks involved. Second, the failure to fully compensate the governmental agencies will necessitate a continued cost shifting of the damages associated with tobacco related diseases to the taxpayers. The deal will allow the tobacco companies to continue to externalize the true costs of their

products and will maintain the market failure and artificial price structure which guarantees their profitability. Effectively, the deal creates a subsidy in perpetuity for the true costs of tobacco products.

The funding inadequacy problem is also not necessary. Because of the relatively inelastic demand for cigarettes, tobacco companies can elevate their annual profits to an estimated \$30 billion domestically [Harris, 1996 #11]. If the funds from international sales and companies related to the tobacco companies are made available, the available funding is magnified. Therefore, the shortfalls negotiated in the deal are not a result of industry inability to pay and maintain profitability, but instead represent a giveaway to the tobacco industry.

Effects of the Passthrough Provision

The passthrough provision of the deal says that legislation will specify that the annual payments will be "reflected" in the price charged for tobacco products. It does not say whether costs imposed by other provisions of the settlement can be included in the passthrough, or whether future price changes are going to be tightly linked to the annual total payments. It does not say whether before or after tax costs are relevant. There are two main effects of the passthrough. The first is that the resulting price increases will reduce consumption. Most analyses of the settlement assume that the passthrough price increases are one of the principle means of reducing youth smoking. The second effect is on industry pricing structure. Presumably the passthrough will result in some mandated price increases. It would be redundant for the settlement to stipulate that any net costs of the settlement to the industry will be passed on to consumers. Elementary economics indicates the industry would attempt to do this anyway. If the before tax annual payments are mandated to be passed through to the consumers, there would be a mandated price increase. This mandate will remove the problem of how the individual firms in an oligopolistic industry should change their pricing strategy to account for the costs of the settlement, and may reinforce the current market and pricing structure and limit competition.

The effect of the passthrough provision on adult consumption is relatively straightforward. Almost all adult smokers are addicted, so the relatively modest price increases alone will not dramatically change the prevalence of smoking. There is general agreement that the adult price elasticity of demand is about 0.4. This analysis assumes that a one per cent change in the price of cigarettes will change adult consumption by 0.4 per cent.

Depending on the assumptions on what costs are subject to a passthrough, the price per pack of cigarettes will increase from between 20 to 35 per cent on average over the first 10 years of the deal. This price increase will reduce volume of adult sales by an average of 8 to 15 per cent. Total revenue will increase as result of this by 10 to 16 per cent on average. Most of the added revenue will not be kept by the industry, but will be paid to the government. It must be remembered, however, that because of the volume adjustment provisions in the deal, the tobacco companies will reduce their total payments under the deal with this reduction in consumption. This reduction in payments could range as high as 10%, depending on the cost conditions of the industry and the application of the volume adjustment provisions.

The effects of the passthrough provision on youth consumption and uptake is more controversial because estimates of youth price elasticity of demand are uncertain. Some studies indicate that it is 1.0 or even higher, others that it is close to zero. The measurement is difficult because youth smoking is illegal, youth themselves purchase only about one half of the tobacco they consume, and new smokers generally smoke only sporadically. Moreover, how the youth elasticity of demand is relevant to the target reductions of the settlement is unclear. The target reductions are in terms of prevalence of daily smoking. This measure is not directly comparable to consumption. Apparently it is assumed that a given price increase will decrease consumption, the decreased consumption will result in decreased uptake of daily smoking. Assuming a 0.6 price elasticity for youth applied to both youth consumption and youth uptake, a one per cent increase in price will decrease consumption by 0.6 per cent, and also decrease the rate of new youth daily smokers by 0.6 per cent. If this is an accurate assessment of the youth elasticity, the passthrough price increases can have a significant impact on youth consumption, and significantly reduce the surcharges paid under the lookback provision. The lower pass-through price increase would be sufficient to meet 40% of the initial 30% youth daily smoking reduction and about 20% of the final 60% reduction. The higher increase would meet about half of the initial 30% reduction, and about a third of the final 60% target. Whether this effect will materialize depends on what the actual price elasticity for youth smoking is; it could be higher than adults and it could be zero.

The Lookback Provision

The lookback provision attempts to deny tobacco companies any incentive to sell to underage consumers (youth). It sets target reduction levels for tobacco consumption by youth aged 13 to 17. For cigarettes, the initial target reduction is 30% in year 5 and 6 after the beginning of the settlement, 50% in years 7 to 9, and 60% thereafter. The reductions for smokeless tobacco are slightly smaller. The idea of the provision is to remove the incentive to sell to youth by confiscating the value of the lifetime profit stream of any tobacco product sold to youth above the target reduction. The manufacturer is denied not only the profits from current sales, but also any profits that will occur on average in the future. If the incentive works as planned, tobacco companies would avoid selling product to youth above the targeted reduction, because all prospective profits from selling to anyone in that portion of the market will be lost forever.

Current sales to youth is indexed by the prevalence of daily youth smoking measured using the weighted average of age specific prevalence of daily smoking for ages 13 to 17. The base year average is calculated using data up to 1996. The average daily smoking prevalence is calculated in the relevant settlement year, and the two are compared to determine if the target reduction is met. The industry will pay a surcharge of \$80 million for each percentage point that the current prevalence exceeds the targeted reduction set for that year. (\$80 million is the estimated value of the lifetime profit stream for one percentage point of the annual cohort of new youth smokers.) There is a cap of \$2 billion on the surcharge for any year. There is also a rebate provision. Each firm can recover up to 75% of its portion of the surcharge if it can show it acted in compliance with the deal, had taken "all reasonable" measures to reach the target, or deserved a rebate because of "other relevant evidence."

The lookback provision is unlikely to be a significant deterrent to the tobacco industry recruiting youth. The cost of complete noncompliance will be less than 10¢ per pack. It will be trivial if firms receive a large portion of the 75% abatement for good faith effort. The provision uses inappropriate measures of youth consumption which underestimate actual youth consumption, will probably overestimate reductions in consumption, and are liable to manipulation by the tobacco industry.

The Level of Surcharge is Too Low

If youth sales do not decline at all and current sales volume is maintained, the \$2 billion cap will limit the impact of the provision. Since the industry cannot track the sales of individual cigarettes, they will amortize the cost over all current sales. Then noncompliance can be measured as cost per pack. Current sales are 23.7 billion packs per year. The cost of no change in youth daily smoking would only be 8.5¢ per pack before tax and 5.5¢ after tax. If firms receive the full 75% "good faith" rebate the costs will be reduced to 2.1¢ before tax, and 1.4¢ after tax. These costs could easily be absorbed by the tobacco companies as a cost of doing business. If youth demand elasticity is 0.6, then the total sales volume will eventually decline and the cost per pack will eventually increase slightly until the before tax cost is 10¢ per pack.

The Surcharge Level is Frozen

Another potential problem is that the surcharge is fixed for perpetuity. Adjustments are only made for the general level of inflation and changes in the size of the 13 to 17 year old cohort. However, reasonable variations in assumptions can alter the actual value of a new youth smoker by up to 30%. Changing economic conditions, industry marketing, distribution and production costs may change the value of lifetime profits substantially. An increase in the value of the profit stream of a new smoker may not be reflected in any adjustments in the surcharge, and the incentive effect of the lookback will be weakened. An alternative surcharge could be based on a proportion of total revenue from youth sales. This could be adjusted using a moving average of historical financial ratios, and would be more reliable in the long run.

The Rebate for Good Behavior Could Eliminate the Effect of the Lookback

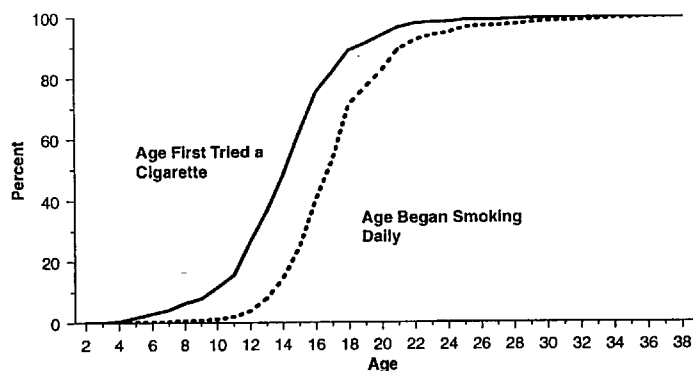
If companies receive a significant portion of the 75% abatement for good faith compliance, then the lookback provision loses all force since the cost of noncompliance becomes trivial. The surcharge is paid out of a common fund, and each firm pays into the fund according to its share of the market. Each firm applies for the rebate individually. The individual companies will have more incentive to attempt to get a rebate than reduce youth smoking. It is also not clear how the industry's "good faith compliance" could be assessed, particularly since the industry is well practiced in promoting smoking while professing to support programs which prohibit sales to minors [1].

Daily Smoking Prevalence is the Wrong Measure

The settlement language indicates that the goal is to reduce youth smoking. By the age of eighteen, only 75% of adult smokers have started daily smoking.

Figure 1 shows the relationship between age of first use and age when daily smoking began. Note that, while three quarters of new smokers smoke their first cigarette by age 15 (solid line), they do not become daily smokers until age 18 (dotted line). Thus, because the Lookback is structured to base the penalties on the rate of daily smokers under age 18, the deal "gives away" the 25% of addicted smokers who do not become daily smokers until after age 18. Moreover, the tobacco industry could meet the goals in reducing "teen" daily smoking by modifying its marketing strategies to shifting the two curves in Figure 1 to the right (i.e., older ages) by about 2 years.

Figure 1. Cumulative Age of Initiation of Cigarette Smoking*-- United States, 1991



Source: National Household Survey on Drug Abuse
*Among persons 30-39 years old who have ever smoked daily

CDC

Nicotine is as addictive as cocaine, heroin and opiates [2]. Indeed, the physiological mechanisms of these drugs are related. Almost as many frequent but non-daily smokers suffer withdrawal symptoms associated with addiction as daily smokers. Symptoms of addiction begin before the onset of daily smoking. Limiting the measure of youth smoking to daily smokers will allow the tobacco industry to comply with the lookback provision as currently written, but it will continue to recruit new adult smokers by addicting them as youths. All the industry has to do is increase the age of initiation (approximately two years) until most daily smoking in newly addicted smokers occurs after their eighteenth birthday.

References

1. DiFranza JR, Godshall WT. Tobacco industry efforts hindering enforcement of the ban on tobacco sales to minors: actions speak louder than words. *Tobacco Control*. 1996;5:127-131.
2. USDHHS. The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health. 1988.

Protecting the Oligopoly

The tobacco business is an oligopoly [1]. This fact, combined with the addictive nature of tobacco products, leads to a form of market failure in the tobacco market. Consumer prices are not directly related to costs, there is evidence of conspiratorial behavior on the part of the tobacco companies, and there are significant market barriers to entry.

The deal would memorialize many of the current market failures and would erect additional barriers to entry for new or foreign market entrants. Subparagraph C to Title III of the deal tries to address the problem of tobacco companies, new market entrants or foreign market entrants subverting the intent of the deal. It provides mechanisms by which non-participating manufacturers would be subject to the same regulatory authority as the other tobacco companies. These manufacturers would be required to pay “user fees” to account for some of additional moneys paid to the states, and they and their agents would not be exempt from liability.

These non-participating company provisions erect even more barriers to market entry, further protecting the current industry’s oligopoly. The new entrants would be forced to pay a user fee equal to the payments already made, they would have to pay an amount equal to 150% of their share for liability expenses, yet they would not be given civil liability protections and their distributors and retailers would be subject to future liability. Even under the deal, it is not clear that participating manufacturers are responsible for the actions of the retailers. This specific exemption will make it more difficult for a new market entrant to develop a distribution network.

In addition, the restrictions on advertising and marketing within the Agreement will limit the ability of new market entrants to penetrate the market by producing brand recognition [1]. The result may be that market share remain somewhat fixed among the current market participants. At the least, new market entrants will have a difficult time gaining any significant market share.

Ultimately, it may not be bad for the public health to eliminate new market entrants, but there are problems with this policy. First, it preserves the profitability of the current tobacco companies, despite their past behavior. Second, many of the public health benefits which accrue in the deal are based upon trading the tobacco companies relief for past bad acts such as fraud and conspiracy. As a matter of justice, it may not be reasonable to hold new market entrants responsible for these activities. Third, by excluding additional market entrants, the future consumer choice will be limited. One benefit of competition is improved product quality, therefore, by eliminating new market entrants one may be eliminating an opportunity to achieve safer cigarettes.

Other than trying to preserve an oligopoly market structure, it is not clear what is gained by this provision. Many of the issues could be resolved by simply allowing the normal course of regulatory development, and shifting the payment schedule to an excise tax payable by all market participants.

In addition, there are other provisions within the deal which will protect the current tobacco companies’ oligopoly. For example, the provision that requires all costs of the deal to be passed through will simply memorialize the market failure. The passed through costs are sufficiently small, so their effect on demand will be small. In addition, the passthrough results in eliminating the incentive to innovate, perhaps to a safer product, because the cost will be equally shared among all market participants. Finally the passthrough will likely result in anticompetitive behavior. If, on the one hand, the passthrough results in a regulated pricing structure with annual increases, it will be possible to game the market and the result would be mandated price fixing. If on the other hand, the industry is responsible for calculating the passthrough, this could lead to conspiratorial price fixing. In either case, it will be difficult to determine the true price

effect of the passthrough due to market fluctuations, and the inherent market failure. As a result, the passthrough provision will be difficult if not impossible to measure and will encourage anti-competitive behavior.

This maintenance of the current oligopolistic structure may be a reflection of the economic reality of the deal. Because the price effects of the deal are sufficiently small, if the market failures are repaired then the price increases that result from the deal would be greatly reduced in a price war. Thus, in order to gain the public health benefits of the increased consumer price of tobacco products, the excise tax (or deal pass-through) would need to be sufficiently large that they could not be overwhelmed by other market effects. Otherwise, the only solution is to preserve the current oligopoly pricing structure for the tobacco companies.

In addition, despite the possible benefits to allowing the tobacco companies to coordinate youth reduction strategies, the anti-trust exemption granted the companies in Appendix IV for this purpose will invite future conspiratorial behavior on the part of the tobacco companies. The tobacco industry, through its past practices, has given no indication that it is entitled to any protection from the antitrust laws, no matter how small. This formal ability can be embodied within a trade group or other entity which would enable future conspiratorial behavior. Similarly, the joint liability provisions and the industry cap on civil liability damages provide additional opportunities to share information among the tobacco companies, which could lead to anti-competitive behavior.

The document disclosure requirements will also preserve the market failure. The disclosure requirements are incomplete, which will result in a continuation of the information inequities within the market, with the tobacco companies keeping relevant information away from consumers.

Another provision which has the potential to be anti-competitive is section E(4) of Title I of the deal which enables the cross-licensing of reduced risk products among the tobacco companies who are signatories to the deal. This is anti-competitive in that it provides an opportunity for these tobacco companies to conspire in the production and marketing of reduced risk products. The historical actions of the companies indicate that they may have coordinated in the suppression of scientific information and that they may have conspired in their attempts to prevent the production of the safer products [2]. Through coordinated behavior, the market incentives to create safer products are reduced, because such action could be regulated by the group. In addition, other parts of the Agreement will similarly restrict market innovation by requiring that the companies share technical innovation regarding safer products [1]. Through the coordination clause, the companies will be provided a mechanism through which agreements to slow innovation are more likely to occur.

Competition is a mechanism by which innovation is forced. By competing with other market participants a company will be forced to develop better and more affordable products. Such innovation is a vital component to economic growth. This deal removes all incentive to compete among the market participants. The market failures are memorialized by preserving the oligopoly pricing structure and failing to remove the information inequities within the market. In addition, it provides opportunities for further conspiratorial behavior by the tobacco companies. Finally, the deal provides for increased market barriers to prevent new or foreign market entrants to provide economic competition to the tobacco companies. Therefore, those economic incentives which would force innovation are eliminated or greatly limited by the deal.

References

1. U. S. Federal Trade Commission. Competition and the Financial Impact of the Proposed Tobacco Industry Settlement. Washington, DC: October, 1997, 1997.

2. Glantz SA, Barnes DE, Bero L, Hanauer P, Slade J. *The Cigarette Papers*. Berkeley, CA: University of California Press. 1996:219-224.

Disclosure of Tobacco Ingredients

The deal requires the tobacco companies to disclose to the federal government all ingredients added to cigarettes, disclose the pertinent ingredients to the public and prove the safety of all of the additives to cigarettes within a five year period. Section F of Title I to the deal requires manufacturers to provide to the FDA a list of all ingredients added to cigarettes, other than tobacco or water. It would require the manufacturers disclose ingredient information to consumers in a manner similar to what must be reported for food products. Manufacturers would, after five years, be required to submit a safety assessment for each additive. Within a 90 day review period, the FDA would either approve or disapprove an additive as safe. If the FDA takes no action within 90 days, the additive is deemed safe. A similar process would be in place for the introduction of a new additive or a different use of an already accepted additive. This section of the deal is weighted overwhelmingly in favor of the tobacco industry, and will actually slow the process of ingredient disclosure under existing state laws.

The industry has five years during which it can provide information that a product is safe within the “intended conditions of use.” The ambiguity of intended conditions of use versus actual use could be an area of great dispute, and will likely be an area of contention during the mandated FDA rule-making process of the first year. Some of the issues to be addressed will include amount smoked, burn temperatures, oxygenation, and filters. Ultimately the question may come down to whom should the regulations protect? Should they be for the casual smoker, who does not block filter vents, who does not inhale quickly and deeply, and who smokes less than a pack a day, or for the more chronically addicted smoker? The tobacco companies have been arguing that heavy smokers are not using the product as intended, without ever giving an analysis for what a “safe” amount of smoking would be. It is unclear whether the regulations are intended to protect both the heavy and the casual smoker. Past experience has shown that the tobacco companies will take advantage of any opportunity to slow the regulatory process. This provision gives them a sizeable opportunity.

Even if these rules are promulgated in an appropriate manner the FDA will only have 90 days in which to review the data against the applicable standard and approve or disapprove of the additive’s safety. If the FDA does not act, the additive will be approved. This overwhelming inequity -- five years for the industry and 90 days for the FDA -- will limit the effectiveness of FDA review, while the industry will be able to fully garner all of the support it needs. Another way to look at the inequity is that the risk is borne by the consumer. If there is an additive that is harmful, the industry has five years in which to develop a scientific trail to try to create a semblance of safety. If it fails to meet the five year deadline, there is no provision for the additive to automatically be deemed unsafe (although the company would presumably be subject to the Title III Section a \$10,000,000 civil penalty for failing to disclose to the FDA.) If the FDA deems it unsafe after the 90 day period there is no procedure to eliminate it from the tobacco products except in accord with Title I Section E above. Meanwhile, during this entire time this harmful additive has been on the market.

The incentives are backwards from a public health perspective. Good public health practice would give the tobacco industry a much shorter time frame in which to prove that the additives, when used in a reasonably expected manner, are safe, with the understanding that if the tobacco industry fails to meet this time deadline the additive is automatically deemed unsafe. At any time the FDA deems the evidence incomplete or insufficient it can then, 1) require more testing yet allow the additive to remain on the market; or 2) require the industry to remove the additive from the market until such evidence can be produced. Furthermore, at no time should the tobacco companies be immune from liability for the hazardous nature for any of their additives, and FDA rulings that an additive is harmful should be able to be used as evidence in any law suit against the tobacco industry. Besides providing increased safety to the consumers, it places the burden on the industry, which already has (or should have) the scientific data on the safety of its additives.

Second, the definitions of what needs to be listed and tested for the safety of cigarettes is incomplete.

Many, and probably most, of the hazards related to tobacco use arise from the constituents of the tobacco plant itself, e.g. nicotine, nitrosamines. To the extent that hazardous elements of the tobacco products can be discovered and tested for, they too should be included in the testing and safety requirements. (The obvious dilemma is that tobacco is inherently dangerous, therefore no testing can ever prove it to be safe. Nevertheless, this loophole should not protect the industry from using genetically engineered tobacco, or other techniques, which may result in higher exposures to naturally occurring toxic ingredients.) Furthermore, the requirement only extends to the manufacturing process. It should be extended to all processes associated with the production process. For example, pesticides and herbicides added in the growing process should be analyzed at the production stage, as well as any substances which may be added during the curing process. The requirements should also include testing for interaction effects among the constituents.

Third, the public disclosure requirements are inadequate. Linking the regulations to the food requirements may prove to be insufficient given the unique usage of tobacco products as opposed to foodstuffs. Dry weight measures, and percentage of product may prove to be irrelevant measures of certain additives. The burning process of cigarettes also creates unique hazards. When some additives are ingested they may prove to be safe, but those same additives could themselves prove hazardous when burned, or could create by-products which are hazardous. The by-products may also prove to be a function of burn temperature. A strong ingredient disclosure provision would give the FDA, and the states, the flexibility to design a disclosure requirement which can take into account the unique status of tobacco products and provide consumers full disclosure so that they can better understand the risks.

FDA Advertising and Marketing Restrictions

The Food and Drug Administration has assumed regulatory control over tobacco products as a drug delivery device and as a drug (nicotine). One of the first uses of the regulatory authority by the FDA was to pass a series of advertising and marketing restrictions on cigarettes and smokeless tobacco products. The FDA found itself under immediate attack and has been defending its actions against the tobacco industry in Court. Although the FDA won the first round in that it is able to regulate tobacco, the ruling is under appeal. In addition, the Court did not uphold the FDA's ability to regulate advertising.

Section A of Title I of the deal would confirm FDA authority and codify many of the restrictions on advertisement contained in the FDA rule as promulgated, 61 Fed. Reg. 44396 (August 28, 1996). The deal would also expand on the FDA provisions by banning outdoor advertisement, limiting the content of advertisements, banning Internet advertisement, restricting tobacco sponsorships, eliminating product placement, and requiring disclaimers on products identified as "light" or "low tar".

To the extent that tobacco use is encouraged by the pervasiveness of tobacco imagery, many view the advertising restrictions in the deal are an improvement over the status quo. In addition, the First Amendment to the Constitution (and similar free speech protections in State Constitutions) can act as a barrier to restrictions on speech. These protections are irrelevant if the tobacco companies voluntarily accept the speech restrictions.

While the North Carolina opinion disallowed the current FDA advertising restrictions, this is clearly not the final say on this matter. First, that ruling is on appeal and may be overturned. Moreover, regardless of which side prevails at the Court of Appeals, the loser is sure to appeal to the Supreme Court. Second, the Judge in the North Carolina case gave indications as to what measures could be taken to "fix" or otherwise promulgate the regulations so that they will survive a challenge by the tobacco companies. Among the alternatives are ceding authority to the Federal Trade Commission, or regulating advertising under a different portion of the Food Drug and Cosmetic Act.

As for the First Amendment concerns, those are ubiquitous no matter whether the deal is passed. Any Congressional Act or FDA or FTC regulation will be subject to a First Amendment challenge. The deal does not present a serious advantage. Simply because the tobacco companies agreed to the restrictions in the deal does not provide assurances that the restrictions will be enforceable. First, the tobacco companies may prove to be only as good as their word. If they decide to break or bend the terms of the deal, a State or the Federal government would be hard-pressed to enforce the terms of the deal because a federal court would likely defer to enforcing the terms of the First Amendment. Second, even if the deal is enforceable as to the tobacco companies, it will not be enforceable to industries that may prove sympathetic to the tobacco companies' interests. For example, farmers, retailers, and advertisers all may have a vested interest in promoting cigarettes and will not be bound by the terms of the deal and will not be bound by an unconstitutional law. The possible success of such a challenge is unclear. Because advertising is commercial speech, it receives less protection than does political speech, and the governmental interest in protecting youth from being exposed to advertisements is high [1,2]. At least one Constitutional analysis of the proposed regulations concludes that the majority of the regulations will be upheld: "Given the compelling nature of the government's interest in protecting children and adolescents from the dangers of smoking and the narrowly tailored approach that a majority of the advertising restrictions adopt, much of the Settlement would likely withstand judicial scrutiny under the applicable legal standard" [3].

The advertising restrictions are also unlikely to significantly reduce the pervasiveness of tobacco imagery in society. Many countries throughout the world have more restrictive advertising polices than are proposed in the deal and find tobacco imagery pervasive. For example, in other countries we have seen that

the tobacco companies adapt to whatever advertising restrictions are in place to develop advertisements which are just as effective as those outlawed. For example, Marlboro will often use images of the wild west with running horses and deep sunsets to paint a picture that is just as appealing as the “Marlboro man” when it cannot use human figures. Other companies have developed similar advertisement styles; for example, Benson and Hedges anthropomorphizes cigarettes. These attractive advertisements eliminate the need for cartoon characters or human images.

There are also separate techniques of promotion which are not prohibited by the deal which have proven to be useful tobacco industry tools in other countries. One needs only to look at advertising in the UK or South Africa to see how successful the industry can be. For example, in Australia (where advertising is nearly totally prohibited), the industry is now hosting “Brand X nights” at local bars. The tobacco industry is already beginning similar promotional events in the United States, perhaps in anticipation of advertising restrictions brought on by the deal, the FDA, or state and local restrictions. These events appear to have a strong impact on teens, even though they are not allowed in the bars.

Additional advertising and promotion techniques would also be available under the deal. For example, marketing tools such as direct marketing and establishing distributorship structures which place the responsibility of marketing on intermediary distributors, could prove to be creative avenues to market tobacco products. Similarly, the Internet is an international medium, and placing domestic restrictions on tobacco imagery will have little effect on the availability of reaching tobacco Internet sites. The tobacco companies will also be able to use the packaging of cigarettes as a marketing tool.

Moreover, tobacco imagery is ingrained into our culture. It is not possible to eliminate the romanticized images of smoking from old Hollywood movies. Because of that, any claims that children will be protected from all tobacco imagery will be false. Whatever advantages the advertising restrictions have in the deal, they represent only a partial solution.

Finally, because the deal restricts the FDA’s ability to modify the terms of the advertising restrictions for five years (except under extraordinary circumstances), the deal prevents the federal government from taking any action to address these creative promotional methods. The current situation, with the FDA acting under existing law, in the long run, is at least as likely to accomplish the goals of restricting tobacco advertising as the terms of the deal.

References

1. Food and Drug Administration. Regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents. . *Federal Register*; August 11, 1995:41314-41451.
2. Food and Drug Administration. Proposed rule analysis regarding FDA's jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. . *Federal Register*; August 11, 1995:41453-41787.
3. ACS. Constitutional Issues in Proposed Tobacco Settlement. Washington D.C.: American Cancer Society. 1997.

Youth Access and Licensing

The Food and Drug Administration has assumed regulatory control over tobacco products as a drug delivery device and as a drug (nicotine). This authority has been the subject of much debate and concern. One of the first uses of the regulatory authority by the FDA was to pass a series of regulations to restrict access to cigarettes to adults. The FDA found itself under immediate attack and has been defending its actions against the tobacco industry in Court. Although the FDA won the first round in that it is able to regulate tobacco, the ruling is under appeal.

Youth Access

Sections C and D of Title I of the deal would confirm FDA authority and codify much of the purchase restrictions contained in the FDA rule as promulgated, 61 Fed. Reg. 44396 (August 28, 1996). The deal would also expand on the FDA regulations by requiring states to adopt a licensing scheme for retailers of tobacco products.

Section C of Title I codifies many of the FDA rules intended to restrict youth access to tobacco products. In addition, the deal would go beyond the current FDA rule by banning all vending machine sales and restricting self-service displays of cigarettes to adults only locations. These provisions would clarify the FDA's ability to regulate in this area and would expand on the current FDA regulations. Some believe these provisions are valuable because it is necessary to create supply-side controls for tobacco; others state that, while there is good evidence that such programs are effective in reducing sell rates, there is little evidence that this translates into lower youth tobacco prevalence or consumption.

As with the provisions under Section A of Title I, the deal only embraces the current state of the law. The restrictions put forward are already a part of the FDA program or readily could be. In short, there is no need for the deal to accomplish these objectives.

In addition, these programs have a limited effectiveness. First, evidence suggests that youth access programs may not reduce teen smoking prevalence or consumption [1]. While many of the provisions are a good idea, it is important to remember that teens only buy about half their cigarettes and other tobacco products; they are equally likely to "bum" or steal cigarettes than to purchase them themselves [2]. There is also the theory that such laws actually increase youth desire to smoke. Whether this is under a scarcity theory or "forbidden fruit" analysis, there is some support that smoking may become more attractive as a rebellious activity for some youth with increased enforcement [3]. One only needs to look at the high teenage drug and alcohol rates to understand that supply side laws are not a complete solution to youth consumption.

Licensing

Section D of Title I would mandate minimum standards by which states would institute licensing schemes for tobacco retailers with specific penalties for violations. There would be comparable licensing schemes for entities under federal jurisdiction and Indian lands. By requiring a licensing scheme it is believed that it will be easier to control and supervise those with the direct control over the distribution of cigarettes. By having certain and guaranteed penalties the retailers will know the risks to violating the laws and will be given the necessary inducements to enforce the laws.

The idea for a licensing scheme meets little resistance from public health advocates. Most of the complaints which arise with regard to Section D are specific to the terms of this scheme. First, although the deal identifies that it would promote a national "minimum standard" it is not clear whether this would preempt state licensing schemes which currently exist, or whether it would prevent more strict licensing

schemes. It appears that the civil sanction scheme in particular will be mandatory and not allow for stronger local sanctions. Any preemption of stronger local regulations is inherently suspect. Moreover, the federal sanctions are weak, and may be insufficient to promote responsible behavior in retailers and other distributors.

Finally, the licensing scheme is unlikely to accomplish one of its objectives, that of requiring distributors to comply with the terms of the deal. One of the requirements for obtaining a license would be to comply with the terms of the Act. But there are some terms of the Act to which compliance may not be compelled. For example, if there is a First Amendment right to advertise cigarettes as a legal product, then this right goes to not simply the manufacturers of the products, but also the distributors and retailers. Retailers, who have a large financial interest in promoting cigarette sales, may fill the gap left when cigarette manufacturers reduce their advertising. The First Amendment restrictions which the authors of the deal argue could only be accomplished by the consent of the tobacco manufacturers cannot be thrust upon retailers without their consent. To condition obtaining a license on the forfeiture of a constitutional right may violate the retailers' right to due process under the U.S. Constitution. Thus, the efforts to force compliance through a licensing scheme could fail, and the advantages to the public health of this provision may be exaggerated.

In any event, there is little in the deal beyond current FDA regulations.

References

1. Rigotti NA, DiFranza JR, Chang Y, Tisdale T, Kemp B, Singer DE. The Effect of Enforcing Tobacco-Sales Laws on Adolescent Access to Tobacco and Smoking Behavior. *New England Journal of Medicine*. 1997;337:1044-1051.
2. Cismoski J, Sheridan M. Tobacco acquisition practices of adolescents in two Wisconsin communities. *Wisconsin Medical Journal*. 1994;93:585-591.
3. Glantz SA. Preventing tobacco use--the youth access trap [editorial] [see comments]. *Am J Public Health*. 1996;86:156-8.

FDA Controls on Nicotine and Other Tobacco Constituents

During the past few years, many people have embraced FDA jurisdiction over tobacco as an important regulatory mechanism to reduce the impact of tobacco in society. The deal adopts this model by legislatively vesting in the FDA the authority to regulate tobacco products. Section E to Title I of the deal describes the regulatory regime under which cigarettes and smokeless tobacco products would be governed. Rather than strengthening FDA jurisdiction, the deal restricts FDA regulatory authority over nicotine and other harmful constituents of tobacco.

By rewriting the Food Drug and Cosmetic Act to specifically deal with tobacco products, special protections would be given to the tobacco industry which are not shared by other drug or medical device companies. These special protections would ultimately limit the FDA's ability to adequately regulate tobacco products. Jurisdiction over cigarettes has been granted to the FDA by a Federal Judge in North Carolina and the regulatory process is moving forward. Although there is a risk that the decision may be overturned, this is no reason to restrict FDA authority.

Special Treatment for Tobacco

Under Section E(1) to Title I of the deal tobacco products are defined as they are in the current FDA rule (See 21 C.F.R. Section 897.3). The disadvantages of this definition are that it specifically is geared towards cigarettes and smokeless tobacco. Presumably under the current scheme, the FDA could develop new regulations to address those other forms of tobacco. Should the narrow definition of tobacco products be codified into law, this could preclude FDA authority over other forms of tobacco (e.g., pipe tobacco, cigars).

Section E(2) of Title I identifies that tobacco will be regulated as both a drug and as a medical device, classified in a new subcategory of Class II medical devices. The current FDA regulations were issued pursuant to the general authority of the FDA to regulate restricted medical devices. The FDA had already assumed jurisdiction over tobacco as both a drug and a medical device. It chose, pursuant to its own authority over combination products which are both drugs and devices, to regulate the product as a device. The FDA has not yet classified tobacco products as a particular form of medical device. Although a Class II classification may prove reasonable because it treats tobacco products as deserving special controls, the ramifications of the classification are not clear.

Section E(3) of Title I identifies that the FDA will be able to require product modification including the regulation of nicotine, and shall be able to establish "Performance Standards" for tobacco products. The authority under this section is intended for medical devices for which the FDA can, pursuant to 21 U.S.C. Section 360d(a)(2)(a), "provide reasonable assurance of its safe and effective performance." Tobacco products cannot be made safe, so this authority is at best ambiguous. Trying to regulate a hazardous product in a scheme that is designed to regulate safe products will create conflicts and ambiguities. How these ambiguities are resolved are vital to the continued effectiveness of the FDA as a regulatory authority.

Section E(5) of Title I outlines the authority of the FDA to regulate the performance standards of tobacco products pursuant to its authority under 21 U.S.C. 360d. The FDA is prohibited from banning traditional tobacco products in their basic form. Sub-subparagraph A of this section holds that for the first twelve years after the deal is in place it will need to make a showing of "substantial evidence" and satisfy other procedural hurdles, before it can adopt performance standards which would modify existing tobacco products (including the reduction of but not the elimination of nicotine). The findings the FDA will need to make are that the proposed regulation: a) will result in the significant reduction of health risks to consumers; b) is technologically feasible; and c) will not result in the creation of a significant market for contraband. Sub-Subparagraph A also requires the appointment of a Scientific Advisory Committee to look at the effects

of nicotine levels. Sub-Subparagraph B establishes the regulatory standards for the time after the initial 12-year period. It keeps the same required findings of fact and establishes that the review standard for the findings would be governed by a “preponderance of the evidence” standard. It adds further procedural rights to the tobacco companies to challenge FDA actions and provides a 2-year phase-in period for the elimination of nicotine.

Procedural Barriers to Effective FDA Regulation of Tobacco

A close reading of this section reveals that the tobacco companies are gaining special treatment by having restrictions placed on the FDA’s authority. First, the FDA cannot prohibit the sale of the cigarette in its basic form. This restriction will prevent the FDA from ever requiring the replacement of current technology with the use of new technological advancements (such as slow burn cigarettes, smokeless cigarettes, low burn temperature cigarettes, and non-tobacco based cigarettes), which could otherwise be considered suitable and safe alternatives for consumers. This language could also be used as a shield by the tobacco industry to challenge a regulation it opposes. The breadth of this clause cannot be exaggerated. It is sufficiently broad that the drafters of the agreement felt it necessary to clarify in Sub-Subparagraph B that the elimination of nicotine or other harmful constituent of tobacco will not violate this clause. This ambiguity can only serve to restrict FDA authority. It also implies that, during the initial twelve year period, an effort to ban a harmful constituents of tobacco which would result in a reduction of consumer use would violate this provision.

Moreover, the intent behind the provision is misplaced. The tobacco companies are supporting the impression that prohibition is a likely outcome of unfettered agency control over tobacco. This is not correct. At this time, no major health group supports the concept of prohibition. It is axiomatic that our culture is not prepared at this time to surrender its addiction to tobacco. Society, however, is not static. It is conceivable that within a generation there may be adequate market substitutes such that smokers and society would welcome a prohibition on the use of some of the hazardous products currently on the market. To prohibit the FDA from meeting such a challenge is unnecessarily restrictive and will prevent regulatory actions which benefit consumers.

Second, the implication that the additional language will ensure effective FDA regulation of tobacco products is inaccurate. The agreement does not mandate that the FDA act in any particular manner, it simply reiterates that the FDA has a given authority. This discretionary power will inevitably subject the position of FDA Commissioner to intense political scrutiny. By politicizing the office, it could weaken or immobilize the agency. Although this may not be unique under this regulatory scheme, there are no protections against, and no requirements for, any particular agency actions.

Third, the procedural barriers placed on the Agency are extraordinary. Most of Section E(5) of the deal contains additional barriers which will at best slow agency action and worst stop agency action. For example, the appointment of a Scientific Commission to analyze the addictiveness of nicotine is a redundant activity that can only slow the process. Similarly, the mandated delays in the FDA procedures to allow for Congressional action, the mandatory phase in period for nicotine removal and the burdensome administrative and judicial review procedures will provide the tobacco industry opportunities to harass the Agency and prohibit the effective regulation of the industry.

Fourth, the deal would also change the standards for judicial review of agency action to give special treatment to the tobacco industry. Federal Courts are highly deferential to Agency expertise. If an action is adequately supported by evidence in the record and not arbitrary or capricious, the action will be upheld. Under the deal the Agency will have to use greatly heightened standards of proof. In the first 12 years this will be “substantial evidence.” After the 12 year period the standard will be raised to “preponderance of the

evidence” which is over and above what is necessary in other regulatory contexts and will prove to be a hindrance to agency action. These heightened burdens will make it more difficult for the Agency to take action to protect consumers.

Fifth, the specific restriction on nicotine reduction ties the FDA’s hands dramatically. Under the best scenario, the FDA would not be able to remove nicotine from tobacco for more than 14 years. This is sufficient time for the tobacco industry to addict another generation of smokers. Moreover, there is no provision to allow the FDA to regulate more quickly to account for changes in technologies, such as nicotine analogues or nicotine replacement therapies. This is a bold guarantee of continued profitability for the tobacco industry and an unreasonable retrenchment of current FDA authority. It is also based upon an assumption that the gradual reduction of nicotine will benefit smokers. It is likely that smokers will compensate for nicotine reductions by inhaling more deeply, covering cigarette vent holes or smoking more frequently. As a result, a gradual reduction of nicotine could result in an increase in health risks, at least over the short term. If it is true that the gradual reduction of nicotine will make it easier to eliminate nicotine entirely, then this will be a tradeoff of short term health losses for long term gains. Because the Agreement requires the FDA to account for significant reduction of risks (in particular for nicotine reducing the drug dependency by reducing numbers of smokers and frequency of smokers) this may be an unobtainable short term goal for a moderate reduction in nicotine.

Sixth, the additional findings the FDA will need to make before it can eliminate harmful constituents from tobacco products are burdensome and unreasonable, and each of the three findings is counter to the interests of the public health. The findings, that any performance standard “a) will result in the significant reduction of health risks to consumers, b) is technologically feasible and c) will not result in the creation of a significant market for contraband.” Taking them seriatim: (a) To find that a specific action will result in a significant reduction in health risks may prove difficult. A specific toxic agent may prove to be harmful, but it may not be possible to identify the specific health improvement that arises from the removal of a single constituent. Moreover, to prove the reduction in health risks is “significant” could require extensive epidemiological testing, and even then it may prove difficult to separate out from the other effects of tobacco usage. Then there is the definition of the term “significant”. Would a drop in morbidity of .5%, approximately 2000 lives/year, be significant? To protect the public health, a constituent once deemed harmful should be eliminated from the product until the tobacco industry can prove it does not negatively affect the health of consumers. (There is also the problem that if the constituent is a significant part of the tobacco leaf, this FDA action may violate the restriction that it cannot prohibit tobacco products in their basic form.) In the second twelve years, in order to reduce nicotine levels, the FDA will also need to evaluate the reduction in consumption and moderated use patterns as a result of a non-addictive product. Such research would be highly speculative at best. (b) To prove that a modification is technologically feasible may also prove to be difficult. There is no base of feasibility against which to compare a particular action. It is feasible to stop making the product but would an additional processing step that increases production costs by 10% be deemed feasible? If not, does that give the tobacco industry impunity to sell a known hazardous substance to protect profit margins? (c) Finally, it will be nearly impossible for the FDA to prove that a given action will not result in a demand for contraband. This demand could be due to increased price of the safer product, it could be due to brand affiliation; or it could be due to some other factor. Because the agreement does not extend to overseas markets, the tobacco companies will be able to market their wares near U.S. borders which could enable smuggling. To prove the negative, that an action by the FDA will not increase demand, is a faulty logical construct to begin with. It is made worse when the incentives are in the hands of the tobacco industry to maintain a black market product. The result is that a small market penetration of illegal products could result in a health benefit being denied to millions of smokers.

Overall, the deal reduces the FDA’s ability to regulate tobacco products below the status quo. These details of the deal provide an example of how the tobacco industry negotiated a deal which appeared to meet

public health needs while, in fact, protecting the tobacco industry.

Secondhand Tobacco Smoke

The adverse health effects due to exposure to environmental tobacco smoke are well documented [1-4], resulting in approximately 53,000 deaths a year and extensive morbidity, including a significant amount of childhood disease. By restricting smoking in public places this deal seeks to reduce this morbidity and mortality. Title IV to the deal presents a national program to reduce exposure to environmental tobacco smoke by restricting smoking in workplaces. OSHA would be directed to issue a rule restricting smoking to areas which are ventilated outside and maintained at a negative pressure to adjoining areas. However, the hospitality industries (restaurants, bars, hotels, etc.) Would exempt from the secondhand smoke provisions, despite the fact that hospitality workers have the highest exposures to secondhand smoke [5].

The greatest strides towards clean indoor air have occurred at the local and, occasionally, the state level. Although the deal states that it will not preempt stricter measures, care must be taken to carefully craft the appropriate legislation such that the legislative acts or future OSHA regulation will not prohibit stricter controls. The Occupational Safety and Health Act has been interpreted by the Supreme Court as strongly preemptive act [6] and would probably have to be carefully amended to avoid preempting existing and future local flexibility. In addition, there is the concern that many localities and states, which might have otherwise passed stronger, more effective legislation, will fail to act on the misguided impression that the federal standard is sufficient. Finally, it appears that the deal would preempt OSHA from adopting stricter regulations in the future by adopting either stricter controls or limiting or eliminating the hospitality exemption. This restriction on Agency authority would limit its future flexibility and impair its ability to improve the public health.

The deal supports the tobacco industry's claims that restricting smoking in the hospitality industry is not feasible. There is no legitimate reason to exclude these industries. The most common argument for allowing this form of exception is that otherwise the hospitality industries would suffer economically without such an exception. This is incorrect. Research has shown repeatedly that in communities which pass strict clean indoor air legislation the restaurants do not suffer economically from the change [7-15].

Second, it is not necessary to enter into a deal in order to reduce exposure to secondhand tobacco smoke. OSHA is currently reviewing and preparing to issue final regulations governing environmental tobacco smoke [16]. Although it is true that no regulations have been promulgated to date, there is no reason, other than political will, that the process could not proceed quickly. OSHA has completed its public hearing and the next step is issuance of a final rule. In addition, with the science having become so clearly established [1-4], the regulatory environment is ripe for passing more restrictions on environmental exposures. In addition, the proposed OSHA regulations are more restrictive than the terms of the deal. For example the OSHA deal requires smoking areas to be enclosed, and it does not include the hospitality exemption contained within the deal. If anything is done at the Federal level, it could be actions which embrace the current OSHA regulatory process and eliminate the preemption.

States and localities have been the focus of much of the clean indoor air efforts with great success [17]. There are some in the tobacco control community who see value in keeping this debate local. First, experience suggests that the states and localities will pass stricter laws. Second, there is an advantage obtained by the process of educating a community and community leaders about the benefits of restricting environmental tobacco smoke, which would be lost with the passage of federal legislation.

References

1. USDHHS. The Health Consequences of Involuntary Smoking. A Report of the Surgeon General. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control.

- 1986.
2. National Research Council Committee on Passive Smoking. *Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects*. Washington, DC: National Academy Press. 1986.
 3. US Environmental Protection Agency. Respiratory health effects of passive smoking: Lung cancer and other disorders. US Environmental Protection Agency. 1992.
 4. Office of Environmental Health Hazard Assessment. Health Effects of Exposure to Environmental Tobacco Smoke. Sacramento, CA: California Environmental Protection Agency. September, 1997, 1997.
 5. Gerlach KK, Shopland DR, Hartman AM, Gibson JT, Pechacek TF. Workplace smoking policies in the United States: Results from a national survey of over 100,000 workers. *Tobacco Control*. 1997; 6:199-206.
 6. Glantz S. Back to Basics: Getting smoke free workplaces back on track. *Tobacco Control*. 1997;6:164-167.
 7. Bartosch W, Pope G. The Economic Impact of Brookline's Restaurant Smoking Ban. Waltham, MA: Health Economics Research, Inc. November 13, 1995.
 8. California Department of Health Services. The Economic Impact of Smoking Restrictions on Restaurants in California. (Press Packet) Sacramento, CA: California Department of Health Services. December 11, 1995, 1995.
 9. Glantz S, Smith LR. The effect of ordinances requiring smoke-free restaurants on restaurant sales. *Am. J. Pub. Health*. 1994;84:1081-1085.
 10. Glantz SA, Smith LR. The effect of ordinances requiring smokefree restaurants and bars on revenues: A follow up. *American Journal of Public Health*. 1997;87:1687-1693.
 11. Hwang P, Toblas S, Kohout S, Harris M, Satterwhite D, Simpson D, Winn L, Foehner J, Pedro L. Assessment of the impact of a 100% smoke-free ordinance on restaurant sales -- West Lake Hill, Texas, 1992-1994. *MMWR*. 1995;44:370-372.
 12. Maroney N, Sherwood D, Stubblebin WC. The Impact of Tobacco Control Ordinances on Restaurant Revenues in California. Claremont, CA: The Claremont Institute for Economic Policy Studies; The Claremont Graduate School. January, 1994, 1994.
 13. Pope G, Bartosch W. Effect of local smoke-free restaurant policies on restaurant revenue in Massachusetts. Waltham, MA: Center for Health Economics Research (conducted for Massachusetts Department of Public Health). April 22, 1997.
 14. Sciacca JP, Ratliff MI. Prohibiting smoking in restaurants: Effects on restaurant sales. *Am. J. Health Promo*. 1997;(in press).
 15. Taylor Consulting Group. The San Luis Obispo Smoking Ordinance: A Study of the Economic Impacts of San Luis Obispo Restaurants and Bars. San Luis Obispo, CA: Taylor Consulting Group (under contract to the City of San Luis Obispo). January, 1993, 1993.
 16. US Occupational Safety and Health Administration. Indoor Air Quality (Proposed Rule). *Federal Register*. 1994;59:15968-16039.
 17. Glantz S. Achieving a smokefree society. *Circulation*. 1987;76:746-752.

Incentives to Create a Safer Product

One of the leading motivations behind the deal is to provide incentives for the industry to develop safer products. This is one of the theoretical bases of the civil litigation system, i.e. by exposing manufacturers of hazardous products to liability, the manufacturers are induced to create a safer product. Because the deal eliminates the risk of civil liability for the tobacco industry this incentive must come from other areas. Section E(4) of Title I creates incentives for the introduction of less hazardous products to the market by requiring the disclosure and cross-licensing of such technology by cigarette manufacturers. The FDA is given the authority to require that such products be brought to market.

During the 1970's both the tobacco industry and the National Cancer Institute devoted considerable resources to making less hazardous cigarettes as a way of dealing with the disease and death that tobacco causes. The logic for this "harm reduction" strategy is simple: If one assumes static consumption rates and technology that reduces the harmfulness of cigarettes by 50%, close to a quarter million lives could be saved each year. Today, there is renewed interest in harm reduction strategies. As evidenced in the deal, some people believe that providing the FDA with the authority to act as repository of the developed technology and as a conduit for that technology to find its way to the market, will improve the likelihood that safer technologies will penetrate the market. It is further believed that once a safer alternative has penetrated the market, that product will have a market advantage spurring competition and creating market incentives to develop additional safer products.

A "safe cigarette" is an oxymoron to many in the public health community. Even a product which was 50% safer would result in a quarter million deaths annually. In addition, the illusion of safety that such products may increase consumption rates or slow cessation rates which would increase the number of annual deaths. In the same manner, filtered cigarettes or "light" cigarettes kept people smoking who would have otherwise would quit [USDHHS, 1989 #46].

In addition, the specific mandates are not likely to spur competition into safer technologies. First, the deal is predicated on the assumption that there is market interest in creating a safer product. Second, due to the market failure extant within the current tobacco industry there is security with maintaining the status quo. Third, many of the barriers to creating and marketing a safer product will still exist. For example, producing a safer product will imply that the existing products are hazardous, which will decrease the attractiveness of the existing product lines and possibly expose the tobacco companies to increased litigation exposure. (One must realize that though the deal would essentially resolve litigation in the United States, it will still be vulnerable to lawsuits and regulatory controls throughout the rest of the world.) Fourth, the deal does not specifically require the disgorgement of all technology currently in existence and being withheld by the tobacco companies, only for that "develop[ed] or acquire[d]." This, and the requirement to disgorge the licensing rights to the FDA should a manufacturer decide against marketing a new product, could stifle research within the industry. (It is unclear how this requirement interacts with the document disclosure requirement of Section E(7). Presumably, if the information could lead to a marketable product it could be considered a trade secret and withheld from disclosure.) Fifth, the deal preserves the market barriers to new market entrants by restricting the cross-licensing requirement of new technologies to those covered by the same obligations. By erecting higher barriers for new market entrants, the deal may slow or prevent the introduction of a safer product from outside the current tobacco companies.

If one were to support the development of safer technologies, one would have to find an alternative mechanism to reform the market by increasing innovations. In order to spur innovation, incentives will need to be provided to surmount the barriers. For example, a requirement that the current form of cigarette would be rendered obsolete in a set time period would spur innovation in replacement technology. Similarly, providing research money, capital market incentives and capital to new market entrants to produce a safer

product could result in market penetration by a safer product and create a competitive atmosphere by which the existing tobacco companies would develop their own safer products.

Elimination of Liability for the Tobacco Industry

The primary motivation for the tobacco industry to enter into the deal is to protect itself from the risks of litigation. The deal provides the tobacco industry this protection in Subparagraph A to Title VIII by eliminating all present Attorney General actions, and similar actions brought on behalf of governmental entities, all other third-party reimbursement claims, all class actions, all parens patriae actions, and all nicotine dependency actions. Furthermore, it would not allow these types of actions in the future. Third party payer suits that were filed prior to June 9, 1997 would not be settled, but would be subject to the limitations which govern civil liability for past conduct that will make these cases impossible to bring.

The negotiated settlement was primarily conducted by and for the states who had filed attorneys general actions and a collection of plaintiff attorneys who represent the class of nicotine addicted smokers. The settled lawsuits will theoretically compensate those groups by providing funds for tobacco cessation programs and reimbursement to the states. Although no allocation or provision directly awards money to the states, this use of the money is implicit throughout the document. The deal settles far more than that, however, and does not account for the funds to be used for those purposes. For example, as a governmental entity the City and County of San Francisco will have its case resolved, but money for such entities is not even implicit under the deal. In addition, any governmental agency who has not yet filed a lawsuit would be precluded from filing. The magnitude of these potential requests for payments is quite large, especially considering that the federal government is responsible for Medicare, yet the deal does not provide adequate funds to cover these payments.

Furthermore, the deal settles all “class actions.” This statement is ambiguous. If it truly settles all of the actions, then the plaintiff classes would be entitled to some recompense. If it merely decertifies the classes and allows the class members to refile individually, then the class members may not be entitled to compensation. Taking the deal as it is written, it appears that the class actions would be settled and the plaintiffs involved or represented by such classes would be precluded from filing future lawsuits.

In addition, the deal will settle nicotine addiction actions. Because many product liability claims include claims of addiction, it is not clear what effect settling these claims will have on the remainder of the these actions.

Thus, the deal resolves and prevents many more cases than can be compensated under the funding scheme established. By eliminating the right to pursue damages, and by failing to fairly compensate those plaintiff classes, the deal raises constitutional issues. Issues of federalism will be implicated by preventing states and localities from suing to recover for damages under their own laws. There are also due process implications to removing a cause of action without providing for some mechanism for reimbursement. Although the Supreme Court has ruled that the Congress has broad discretion in dealing with rights to sue, it has never been faced with a situation in which the Congress has completely eliminated the rights of a class to sue without providing an alternative mechanism for recovery, and in which the damages are so extreme. Furthermore, because the cases are resolved for such a low price, even if constitutionally appropriate, the deal fails from the perspective of public health policy. The costs of tobacco usage will still be externalized from the tobacco companies (to the general public, both directly and through the medical system) with no opportunity for class members or governmental agencies to recover through the civil litigation system.

Another problem with granting such broad liability protections is that it is likely to create unintended consequences such as barring claims far broader than those settled. States could find themselves precluded from filing any form of action against the tobacco companies. In addition the prohibition on filing nicotine addiction claims can be misinterpreted to prevent the pleading or claiming of nicotine addiction in a product liability action. Without fully recognizing what claims would be resolved and without all claims being fully

reimbursed, the tobacco industry is buying itself protection at the expense of many plaintiff classes.

Also not accounted for in the deal is the awarding of attorney fees. Presumably the attorneys who represent the large classes, as well as those assisting the states with the prosecution of their cases, will obtain some compensation from the deal. Because of the size of the deal, it is expected that the attorneys will be rewarded handsomely. As a result, there will be many cases in which the same attorneys who participated in the negotiations which led to the deal will be making large sums of money from it. Furthermore, the fact that the negotiating attorneys will be so richly rewarded highlights the need for health groups to insist that the provisions of any agreement (whether federal or with individual states) be in the public interest.

Added Protections Against Most Civil Liability for the Tobacco Industry

When negotiating the deal, the tobacco industry desired complete protection from all lawsuits while public health advocates wished to protect the right of individuals to sue the tobacco industry. The deal tries to tread a middle ground in which limitations are placed on the right to sue, but plaintiffs would still retain the right to sue the industry. The deal also provides predictability for the tobacco industry and plaintiffs by requiring that funds be set aside from the industry payments to pay for damages in future cases. The magnitude of the funds begins at \$2 billion in year one and rises to \$5 billion in year nine and represents 80% of the total amount available to future claimants. In addition, Subparagraph B to Title VIII of the deal provides a series of restrictions on lawsuits for the recovery of damages due to the past conduct of the tobacco companies. This section:

- eliminates punitive damages;
- eliminates class action lawsuits (and allows for defendants to remove actions to federal court should a state court certify a class);
- codifies the current state of legal decisions;
- provides for the joint sharing of liability of the tobacco companies who entered into the Agreement;
- restricts who can sue to individuals claiming injury or their heirs, third-party payor suits not based upon subrogation theories filed prior to June 9, 1997, and third-party payor claims based upon subrogation theories;
- restricts defendants to manufacturers and the manufacturers' agents;
- prevents the removal of actions to federal court by plaintiffs;
- prohibits evidence of "reduced risk" products to be used at trial;
- adopts the use of state statute of limitation provisions triggering on the injury, discovery, notice or contamination;
- caps damage exposure; and
- prevents third-party payor lawsuits not based upon a subrogation theory.

Subparagraph C of Title VIII to the deal provides that the same restrictions on the lawsuits for past conduct will also govern lawsuits relating to future conduct except for the restriction against punitive damages and the joint liability of the defendant manufacturers who have signed on to the deal. These two changes alone will not significantly change the litigation environment for the tobacco companies.

The protections given to potential plaintiffs are in name only. The deal will increase the barriers to bringing a lawsuit which will make it more difficult for an injured party to bring a suit against the tobacco companies. The deal also provides protections to the tobacco industry such that it will suffer little to no risks from the civil liability system. Finally, the deal does not provide adequate funding for just compensation.

The Deal Creates High Barriers to Litigation Against the Tobacco Industry

The barriers to filing suit against the tobacco industry are extremely high. The industry uses aggressive litigation practices which make suing the tobacco industry time consuming and expensive which, in turn, has made tobacco lawsuits risky and unattractive prospects for lawyers [Rabin, 1993 #68]. Therefore, even for good cases it is difficult for a plaintiff to find legal representation. This trend has changed in recent years for a variety of reasons. First, discovery of egregious behavior on the part of the tobacco companies could subject them to high damages. Second, new legal theories which appear to be more promising such as those which limit the tobacco industry's use of the assumption of risk defense have been developed. Third, the development of class action lawsuits, which spread the risk and increase the likelihood of higher damages has increased the appeal for plaintiff attorneys to file actions.

Through this deal the barriers to litigation are raised. This will make it more risky to prosecute a lawsuit against the tobacco companies, discouraging both potential plaintiffs and their attorneys from prosecuting such actions. For example, by eliminating the right to seek punitive damages for past behavior, the motivation to file a lawsuit is decreased. The discovery of egregious behavior on the part of the tobacco companies has made them vulnerable to punitive damages. This is important in an idealistic sense because it appeals to an individual's sense of justice. It is also valuable from a practical point of view because it increases the likelihood of a large jury verdict, which helps offset the risks attendant with bringing such a lawsuit.

Similarly, by eliminating class action lawsuits, the deal makes the filing of a lawsuit less likely. Ideally, class action lawsuits can present a comforting situation for plaintiffs who would otherwise be intimidated away from filing a lawsuit alone against the tobacco industry. It can also represent a cost savings for the individuals suing who are able to spread the costs over a group of similarly situated people. Similarly, class action lawsuits also provide protections for attorneys. Because they present the ability to spread the risk over a class of individuals, and because they make it more likely to recover a large verdict, some lawyers are more willing to accept class actions than individual cases. By eliminating class action lawsuits against the tobacco industry, fewer plaintiffs are likely to sue and recover damages and attorneys may be less likely to represent individuals.

One of the reasons the tobacco industry has been successful in defending personal injury lawsuits, is because of a concerted strategy to "blame the smoker." Through assumption of risks and comparative negligence defenses, the industry argues that smokers were aware of the risks and, therefore, bear responsibility for their own health consequences. They are aided in promoting these defenses by the warning labels the federal government requires be placed on each pack of cigarettes and court decisions which preclude many legal theories as a result of those warnings. For example, in *Cipollone*, the Supreme Court held that the Federal Cigarette Labeling and Advertising Act of 1965 prevents lawsuits against the tobacco industry based upon a failure to warn theory, one of the dominant theories in product liability actions, or on a theory of misrepresentation by overpromotion (*Cipollone v. Liggett Group, Inc.*, 111 S. Ct. 1386 (1991)). The Court did not preclude lawsuits alleging that the tobacco companies conspired to withhold health information.

More recently discovered evidence of industry wrongdoing and obfuscation has resulted in an evolution of the legal theories which may prove to be an adequate response to those defenses. This deal would eliminate the advances made by memorializing the preemptive authority of the Federal labeling act and the case law interpreting it. It is not clear how this preemption would actively limit the prosecution of future cases, but including this language in the deal will slow the evolution of the law.

Similarly, the restrictions placed on who can sue and who can be sued will stunt the evolution of the law and could preclude the development of new legal strategies against the tobacco related companies. Although it is not clear at this point what other theories could be brought it is not appropriate to restrict avenues for future lawsuits.

The amount of damages a plaintiff can receive in an action are capped on a per suit/per year basis, and the tobacco companies will be shielded by an aggregate cap for all lawsuits. These financial barriers will make it less appealing to bring lawsuits against the tobacco companies and more difficult to find legal representation in those suits which are brought. A plaintiff could not guarantee full recovery of damages in a single year, and even though the damages will roll over to the following year (without interest) there is no guarantee that the moneys will be fully paid. Should the aggregate cap be exhausted in a given year, there is the possibility some plaintiffs may be shut out from recovery altogether. Although this risk may be small given the additional barriers to suit already in place, this is one additional risk that is being borne by the

plaintiffs which reduces the attractiveness of filing suit.

The Deal Creates Additional Procedural Advantages for the Tobacco Industry

Once a case is brought there are further procedural advantages given to the tobacco industry. The first advantage is the time by which a plaintiff must bring suit. The deal embraces the Statutes of Limitations of the respective states, yet begins the clock ticking on when a plaintiff must file a suit from the time of “injury, discovery, notice or contamination/violation.” The use of the term “or” may result in the expansion of many Statutes of Limitation, modifying the law of a jurisdiction which uses the discovery rule. For example, if a person develops lung cancer from smoking, that person will have a set amount of time to file suit before their claim becomes stale. If they wait too long, they will not be able to file their claim. The tobacco companies are likely to argue that a person should be precluded from filing suit, because the person should have filed when they knew they were exposed to a carcinogen rather than when they were diagnosed with cancer. As a result, the tobacco companies may gain more protection from lawsuits.

The tobacco companies also gain an evidentiary advantage. Under the Agreement evidence of “reduced risk” products are excluded under the deal. While most evidence of subsequent remedial measures is excluded in trial, there are exceptions to this rule, such as to prove technological feasibility. This evidentiary change provides the tobacco companies with additional protections from liability.

There is also a significant change to the medical reimbursement suits filed by medical insurers, pension plans and other third party payers. While these suits currently operate on epidemiological evidence of large groups, which benefits the plaintiffs, there is a provision in the deal which would require that these suits be filed under a subrogation theory. By filing suit under this theory it essentially places the payor in the shoes of the individual smokers. Thus, instead of using epidemiological evidence of the represented group, the plaintiffs would need to present the cases of each of the individuals for which the group wants to obtain recovery one at a time. This change makes these lawsuits much more costly to prosecute and provides the tobacco companies a new array of defenses to defeat these suits. The tobacco companies can extend the already exhaustive discovery process, try to blame individual smokers, and attempt to discover confounding factors in the illness of each smoker. This change clearly benefits the industry and provides an insuperable barrier to payers seeking the recovery of health related expenditures.

The result of all of these restrictions is that fewer plaintiffs will seek to recover against the industry, potential plaintiffs will find it more difficult to find legal representation, fewer legal theories will be available to prosecute against the tobacco industry, and should a case get to trial certain procedural advantages will be given to the tobacco companies. Thus, while this deal technically maintains the rights of individuals to sue, it makes bringing such cases very difficult from an economic and legal perspective and grants the tobacco industry great protection from future litigation.

The Deal Removes Incentives for the Tobacco Companies to Act More Responsibly

The changes to the civil liability structure will also provide protections to the industry which will solidify its market and help guarantee future profitability. One of the primary reasons for having a civil liability system is to provide incentives for products manufacturers to behave honestly and produce safe products. The cost and risk attendant with litigation makes many corporations risk averse such that they strive to create safe products. A large jury verdict in a civil liability case can create shock waves throughout an industry. The changes to the civil liability system will eliminate these incentives.

First, it eliminates much of the liability exposure the tobacco industry currently faces: the governmental lawsuits, the nicotine dependency lawsuits, the class actions, punitive damages in all cases for

past acts and third-party payer suits not based on subrogation theories. These cases were expensive for the tobacco industry to defend and exposed the industry to the risk of large damage awards (including in some cases treble damages, attorneys fees, and punitive damages). Furthermore, it increases the barriers to litigation for individuals who still wish to sue the industry, giving additional levels of protection.

Second, under the deal the tobacco companies share the damage awards for all past costs. This arrangement will decrease the incentive for any one company to assist with the prosecution of lawsuits against other tobacco manufacturers, or otherwise act in a responsible manner.

Third, the damage awards are capped on an annual basis. There is a provision in the deal which holds that the judgement will run against the manufacturers, but that manufacturers will receive an 80 cent on the dollar credit against the annual payment. The way this is phrased creates ambiguities which make it unclear how large the actual pool will be and how the companies will be required to pay for the damages. The answer to these ambiguities will determine the extent the civil liability system can be used to create incentives for proper corporate behavior. But in many ways the answers are irrelevant because the industry will be able to calculate a sum certain exposure and budget it accordingly. The result being, the risk from litigation is small and easily accounted for.

The deal also fails to provide funds so that injured persons can be adequately compensated. Full compensation of costs is clearly not a goal of the settlement and could not be. With nearly 500,000 deaths per year related to tobacco the medical costs, costs of lost income and the non-economic costs related to these deaths and extending into the future is staggering. This outcome of the deal raises issues of justice, because it denies the ability to fully recover judicially appropriate damages, and may selectively deny recovery to people who are similarly situated as those who do recover damages.

The restrictions on future lawsuits will create the same barriers to suit that exist as the restrictions on suits for past damages. The only differences are that punitive damages will be allowed and that the defendants will not share liability. The allowance of punitive damages will not dramatically decrease the barriers to suit because of the caps on liability. The elimination of joint liability will provide some incentive for the individual companies to avoid tortious behavior, because they can no longer be free riders. This effect will be small, however, because damages caps will still be in place, as will the other structural impediments which protect the industry from the risks of civil litigation.

Access to Tobacco Industry Information

The tobacco companies have been lying for decades regarding both when and what they knew about the dangers of tobacco products and the addictiveness of nicotine [Glantz, 1996 #24]. As more and more documents are reviewed in the course of the current lawsuits, the disclosures become even more damning for the industry. As a result, many public health groups have demanded that the tobacco companies “come clean” by releasing all of the documents about what they knew and when.

Section E(7) of Title I is intended to provide access to tobacco industry information and confirms the subpoena power of the FDA to obtain information from the tobacco companies in their regulatory authority. As set out in Appendix VIII, the tobacco companies and their trade groups would establish a depository in Washington D.C. to house all non-privileged documents regarding health research, addiction, or dependency, less hazardous cigarettes, studies of the smoking habits of minors, and the relationship between advertising and promotion and youth smoking produced by the companies pursuant to the litigation or otherwise in their possession, which would be open to all interested parties. The industry will review those health-related documents that have not been produced because of claims of lawyer-client privilege and either provide the name of the document on a so-called privilege log or release it. A special three judge panel will be put in place to hear all complaints regarding the claims for privilege. This panel’s decisions will be binding nationwide, and only subject to review by grant of certiorari by the United States Supreme Court. The companies would be subject to a continuing obligation to disclose newly discovered or developed documents.

By limiting disclosure to the specific categories, the deal will sanction withholding of documents related to legal, public relations, anti-trust, and political strategies used by the tobacco industry to keep the public in the dark about the health dangers of tobacco use. Many believe that these documents are the core of the alleged conspiracy by the tobacco companies. The deal does not ensure full disclosure.

The tobacco industry has shown a great reluctance to release any documents. The discovery process in the ongoing lawsuits has been extremely contentious. Multiple appeals have been taken with many rulings against the tobacco companies. Nevertheless, there is still the perception that there are millions of documents to which the plaintiffs are entitled and which the tobacco companies are not releasing. Some courts, notably in the Florida and Minnesota State Attorneys General actions, have even ruled that the claims of privilege alleged by the tobacco companies are invalid due to the crime fraud exception to evidentiary rules (See for example, *Minnesota v. Philip Morris Inc. et al.*, State of Minnesota, Minnesota District Court County of Ramsey Second Judicial, Court File No. C1-94-8565, Memorandum and Order With Respect to non-Liggett Defendants’ Objections to the Special Master’s Report, September 10, 1997, December 16, 1997.) In addition, there is a belief that the tobacco companies may be hiding additional documents overseas.

Therefore, it is highly unlikely that the tobacco companies, still vulnerable to attacks on their corporate character in the media and still defending lawsuits in other countries, will be completely forthcoming in their delivery of documents to the depository. Similarly, the appointment of a three judge panel provides protection to the companies because it removes jurisdiction from judges who are familiar with the industry’s recalcitrance. The single panel for review will also subject the industry to a single challenge, as opposed to the multiple jurisdictional challenges in the ongoing lawsuits. Furthermore, the appeal procedures, combined with the legal immunity granted to the industry by other aspects of the deal which remove most economic incentives to sue, make it unlikely that anyone would seriously challenge industry claims of privilege. With the extremely small number of cases accepted by the U.S. Supreme Court on certiorari, the tobacco industry also has a protection against appeals.

In addition, the prosecution of multiple lawsuits across the country creates a steady army of individuals and an abundance of resources to scrutinize the documents produced by the industry. With the

voluminous amount of information held by the tobacco industry, a consequence of eliminating or restricting the lawsuits would be that many fewer resources would be devoted to scrutinizing the documents regarding industry behavior.

The documents the industry so badly wants to keep out of the public's eye are those that will likely be most valuable. For example, these documents may substantiate the allegations of conspiracy within the tobacco industry. Based on documents that have been made public to date, the most important documents probably do not report scientific research, and would not have to be disclosed under the deal. Moreover, the industry has routinely claimed that even scientific research reports are covered by the attorney client privilege.

Furthermore, there is a widespread feeling in the public health community that the tobacco companies must acknowledge the harms caused by their products. The normal legal paradigm that settlements eliminate the need for admissions of culpability, fails in this instance. The tobacco companies have denied the dangers and addictiveness of their products for decades. They have employed a strategy by which they intentionally create doubt about the scientific basis of the hazards of tobacco. Under oath, tobacco industry CEO's told a Congressional subcommittee that they believed nicotine was not addictive, when their own documents indicated differently. Therefore, some in the public health community feels it is imperative for the tobacco companies to admit publicly that tobacco causes cancer, heart disease, asthma and other diseases, that nicotine is addictive, that they marketed towards youth, and that they have had and withheld this knowledge for years. This is considered by many to be a necessary part of any "settlement" with the tobacco companies, as it was with an earlier settlement with Liggett [Burns, 1997 #61; Warner, 1997 #62]. The disclosure of documents alone, even if complete, is insufficient.

Reformation of the Tobacco Industry

The main resistance to public health reform has been the actions of the tobacco companies themselves. Through their actions, the legislative and regulatory processes have been undermined. It is widely believed that they have engaged in conspiratorial and deceptive behavior which has hindered public health measures. The deal attempts to modify this behavior in Section G of Title I. Included within the requirements are the establishment of a new corporate culture which would be consistent with the enforcement of youth access restrictions and procedures which would promote obedience with the law. Another provision would require the tobacco companies to extend these controls to lobbyists. Other provisions would: eliminate the Tobacco Institute and the Council for Tobacco Research; require that any reconstituted trade group be subject to governmental supervision; protect whistle blowers; and provide for enforcement of the required changes in corporate governance.

There is no denying that true reform cannot occur without a reformation of the tobacco culture. The deal is insufficient at accomplishing these goals because it adopts the wrong model for reform. The model adopted appears to be one similar to that used to inform and educate corporations about environmental compliance issues. This model is ineffective for two reasons.

First, it is predicated on the theory that misconduct occurs because violations occur in the lower employee ranks. For example, although a company may try to obey the environmental laws, if the factory workers are still throwing buckets of wastes out the back door, the program will fail. In many cases it is discovered that the employees were acting simply out of ignorance of the relevant law or corporate policy, and that once informed they will comply with the appropriate standards. Therefore, in the environmental context an internal education and compliance program will be able to retrain the workers, remedy violations when they happen, and eliminate recalcitrant workers. In the tobacco industry, however, the recalcitrant individuals are at the highest levels of management. Documents made public to date show that efforts to hide the evidence that nicotine is addictive and smoking is dangerous involved the highest levels of corporate management [Glantz, 1996 #24]. The CEOs appeared in a hearing held by Congressman Henry Waxman on April 14, 1994 and denied that nicotine was addictive; these are the people who determine corporate direction. If the corporate officers were intent on changing the corporate culture, they could have done so already.

Second, the incentives in the deal work against corporate reformation. In the traditional environmental context, the corporation can maintain profitability (or improve it) by changing manufacturing practices in a manner consistent with good environmental practice. This is not true for the tobacco industry. Good public health and a profitable tobacco industry are mutually exclusive. The tobacco industry is well practiced in getting around such restrictions, as it has with its voluntary code on advertising, which is supposed to protect children from tobacco advertising [Richards, 1996 #69].

In order to truly reform the corporate culture, changes will need to be made at the top of the corporate structure. The highest corporate officers will need to be held personally responsible for all corporate actions. The most effective way to change the corporate culture would be to subject the companies and their agents to full legal liability -- civil and criminal -- for their actions. The deal reduces the likelihood that this will happen.

Furthermore, there need to be stronger incentives for the tobacco industry to control its products all through the stream of commerce. While the deal seeks to hold the tobacco industry responsible for its "agents," it is not clear whether this refers to third party distributors or retailers. Because only retailers would be penalized for unlawful sales under the licensing scheme, it is reasonable to expect that the tobacco companies would be held responsible for the retailer actions. Even if they are envisioned to be related under

the current structure, there would be nothing to prevent the tobacco industry from modifying its distribution structure to eliminate the relationship between the retailers and the manufacturers to insulate the manufacturers from behavior by distributors, while quietly encouraging the distributors to engage in forbidden behavior.

Similarly, the provisions for the elimination of the Tobacco Institute and the Council for Tobacco Research are insufficient to create an incentive to reform industry behavior. While new trade associations are subject to antitrust oversight, and the appointment of external directors, the trade associations will be able to continue many of their same activities. Because many of the most egregious activities of the tobacco industry were conducted through the auspices of the trade groups, it would not be unreasonable to forbid the formation of new trade associations or to require that any new trade associations be held in receivership. In addition, while the Tobacco Institute and Council for Tobacco Research were the most active agencies for supporting the activities of the tobacco industry in the past [Glantz, 1996 #24], there are new organizations, such as the Center for Indoor Air Research, which now promote the tobacco industry's goals [Barnes, 1996 #70]. The deal is silent about how these new organizations would be modified.

Finally, despite the possible benefits to allowing the tobacco companies to coordinate youth reduction strategies, the anti-trust exemption granted the companies in Appendix IV of the deal for this purpose will invite future conspiratorial behavior on the part of the tobacco companies. The tobacco industry, through its past practices, has given no indication that it is entitled to any protection from the antitrust laws, no matter how small.

State Settlements

As of the writing of this report, three states, Mississippi, Florida, and Texas, have settled their Attorney General lawsuits against the tobacco industry. These settlements have a political impact on the possibility for a national deal because they show that Congressional action is not necessary for a positive resolution of the state claims. The expense and risk attendant with this litigation is extremely large. As a result, federal legislation has an appeal in that it removes this risk. On the other hand, favorable settlements (from a public health perspective) reduce the need for federal legislation.

These settlements have provided essentially full cost recovery of Medicaid costs for the states involved. The settlements have also included important public health provisions, such as ending tobacco advertising on billboards and substantial funding for state anti-tobacco programs. Each of the settlements has included a “most favored nation” clause, which requires that if any subsequent settling state achieves better terms, those terms apply retroactively to the earlier settling states. Thus, while Mississippi, the first state to settle, only obtained a money settlement, the fact that Florida added public health policy concessions to its settlement meant that similar terms also apply to Mississippi. Likewise, the Texas settlement included additional improvements in the public health provisions, that apply to the earlier states. The pattern of individual state settlements with progressively stronger terms and most favored nation clauses provides an alternative to a single national resolution.

The state settlements, especially when read in conjunction with settlements in other cases such as the Mangini and Broin cases, show that there is an ability to gain public health programs as a function of a legal settlement with the tobacco industry. This indicates that the Attorneys General can be successful in recovering money and public health benefits without the need for federal legislation. See the table below for a brief summary of the public health components of the settlements.

Although it is dangerous to extrapolate any pattern from these three settlements, because each case presented a unique legal and factual situation, the experience of the states in these three cases does provide additional data for states and federal policymakers to evaluate the possible risks and benefits of continued litigation against the tobacco companies.

Comparison of State Settlements of Medicaid Tobacco Litigation ¹			
	Mississippi	Florida	Texas
Settlement Date	July, 1997	August, 1997	January, 1998
Approximate annual tobacco-induced Medicaid costs ²	\$61 million	\$230 million	\$314 million
First year payment	\$170 million	\$550 million plus \$200 million for anti-tobacco pilot program	\$1015 million ³ plus \$264 million for anti-tobacco pilot program
Average annual payment ⁴	\$127 million	\$410 million	\$540 million
Billboards, Transit Advertisements, and Stadium Advertisements ⁵		Quickly remove all within 1000 feet of schools or playgrounds; remove all within approximately 6 months	Same
		State allowed to substitute anti-tobacco ads	Same
Vending Machines		Industry agrees to support legislation eliminating vending machines except in adult-only facilities	Same

Comparison of State Settlements of Medicaid Tobacco Litigation ¹			
	Mississippi	Florida	Texas
Retailer Licensing		Industry agrees to support strengthening civil penalties for sales of tobacco to children	Same
Youth Penalties		Industry agrees to support increased penalties for possession of tobacco by children (pro-industry concession)	Same
Anti-tobacco Pilot Program		\$200 million Directed at youth Duration of 24 months after approval of settlement	\$264 million Same Duration at least 24 months, after reasonable start up period (improvement over Florida)
Other anti-tobacco programs			\$200+ million for smoking cessation, enforcement of youth access, discouraging youth smoking, and general anti-tobacco educational programs
Other public health programs		Children's health	Children's health, cancer research, substance abuse, indigent health costs, etc.
Release	Complete	Complete release of economic claims. No release of non-economic claims.	Complete (expect for Hill and Knowlton)
Protection of witnesses		Industry agrees not to take legal action against witnesses or whistleblowers	Same
Document Disclosure		State and defendants agree to cooperate to secure expedited review of decisions regarding inapplicability of assertion of privilege with respect to documents already under consideration by Special Master	Existing confidentiality designations shall remain undisturbed until Dec. 31, 1999. After then, any party to the action may make motions with respect to these materials. Counsel can seek disclosure of this material in other actions.
Most favored nation	Yes	Yes	Yes
<p>Notes:</p> <ol style="list-style-type: none"> 1. This comparison only deals with financial and public health provisions; it does not deal with attorneys fees or how it relates to the June 20, 1997 Proposed Settlement negotiated with the Attorneys General and others. 2. Approximate Medicaid costs applying national average fraction of smoking-induced Medicaid costs (4.78%) to total state Medicaid expenses, using 1995 values. 3. The sum is the amount of payments specified; it differs by about \$100 million from the total of first year expenditure accounted for in the Settlement Agreement. 4. Total payments over 25 years divided by 25, excluding first year payments. 5. Excludes point of sale and NASCAR sporting events. 			

**A Public Health Analysis of the
Proposed Resolution of Tobacco Litigation**

Technical Appendices

Brion J. Fox, J.D.
James M. Lightwood, Ph.D.
Stanton A. Glantz, Ph.D.

Institute for Health Policy Studies
School of Medicine
University of California San Francisco
San Francisco, CA 94109



February 1998

Supported in part by National Cancer Institute Grant CA-61021 and the University of California Tobacco Related Diseases Research Program Grant 6FT-0105. Opinions expressed reflect the views of the authors and do not necessarily represent the sponsoring agency or the Institute for Health Policy Studies. This report is available on the World Wide Web at <http://galen.library.ucsf.edu/tobacco/ustl/>.

APPENDIX A: ECONOMIC IMPACTS OF THE TOBACCO PAYMENTS

This appendix is divided into three sections. Section I looks at the face value of the payments of the proposed deal. The focus is on the amount of the payments compared to medical costs of tobacco use, and estimating the likely cost per pack to the industry. Price effects of the passthrough, volume adjustments and the lookback provisions are not included. Section II is an analysis of the overall impact on industry profits, payments, and public sector funds, which includes the price effects of the lookback . Section III is a sensitivity analysis of the annual change in price, consumption and payments. Sections II and III are based on the model used in the FTC analysis [1] of the proposed deal.

Funds and Budgets

The funds and budgets defined by the deal are described in Titles VI, VII and VIII of the proposed deal. This section presents an analysis of the payments, assuming stationary tobacco sales and ignores the volume adjustment clause, the lookback, and price effects, which will be discussed further below. The assumption of stationary sales is reasonable, since the 20 year decline in annual tobacco sales stopped in 1993 and has been approximately 23.5 billion packs per year since then, with sales in 1996 of 23.7 billion packs [2].

Title VI describes the funding of the deal, Title VII describes the budgeting of the Public Health Funds, and Title VIII the Civil Liability Fund. The Title VI funding of the deal consists of three components: an initial Lump Sum Payment, an annual Base Payment which extends into perpetuity, and an eight year Public Health Trust Fund. An adjustment for inflation is applied to all annual payments. The annual payments will be increased proportional to the growth of the consumer price index (presumably the CPI-All Urban Consumers), or 3 per cent, which ever is greater. Our analysis assumes that the inflation adjustment is perfect for general economy-wide inflation as measured by the CPI; and all dollar amounts presented here are in current dollars as of the first year of the deal. Title VI also includes clauses for payment protection in case of bankruptcy, annual payment adjustments for changes in sales volumes, and a passthrough clause. The sales volume adjustment and bankruptcy are discussed in other sections.

Title VII describes two specified budgets for public health programs. One is the Public Health Trust Fund, which is to be administered by an appointed Presidential Commission and is devoted to tobacco related medical research. The second is the Public Health Funds, which consist of smoking education, smoking cessation programs, community anti-tobacco programs, and replacement funds for lost tobacco company arts and sports sponsorships.

Title VIII describes the Civil Liability Fund. This Fund is one third of the Annual Base Payments to be reserved for any individual civil judgments against the tobacco industry. If judgments against the industry exceed the annual fund allotment, then the remainder is paid out of the next annual fund allotment. If the fund is not exhausted each year, a Presidential Commission will determine the use of the funds, which can include public health expenditures, compensation to claimants not otherwise entitled to compensation, or other purposes.

The deal specifies no separate budget for the compensation related to the original purpose of the Attorneys General lawsuits, which was to recover Medicaid expenditures due to smoking. This analysis includes Medicaid reimbursement as a budgeted item. It assumes the relevant amount is the total national vendor payments, which were approximately \$120 billion in 1996 (data from Medicaid statistics page on HCFA Web site (HCFA Statistics: Expenditures, Table 32.--Medicaid/Type of Service on internet site <http://www.hcfa.gov/stats/hstats96/blustat.htm>). It assumes that 4.7% of Medicaid costs are due to smoking [3].

Table A1. Summary of Funds, Budgets and Medicaid Smoking Costs (in \$billion 1997)							
Year	Base Payment	Public Health Trust*	Public Health Funds**	Civil Liability	Remainder***	Medicaid Smoking Costs	
						Medical Inflation	
						Low	High
1	6.0	2.5	2.1	2.0	1.9	5.7	5.9
2	7.0	2.5	2.2	2.3	2.5	5.8	6.2
3	8.0	3.5	2.2	2.7	3.1	6.0	6.5
4	10.0	4.0	2.3	3.3	4.3	6.1	6.9
5	10.0	5.0	2.8	3.3	3.9	6.2	7.2
6	12.5	2.5	2.8	4.2	5.5	6.3	7.6
7	12.5	2.5	2.8	4.2	5.5	6.4	7.9
8	12.5	2.5	2.8	4.2	5.5	6.5	8.3
9	15.0	0.0	2.8	5.0	7.8	6.6	8.8
10	15.0	0.0	2.8	5.0	7.8	6.7	9.2
11+	15.0	0.0	2.8	5.0	7.8	6.9	9.7

* Seven year Presidential Public Health Trust Fund.
** Net of Public Health Trust Fund.
*** Remainder of Medicaid and other medical costs.
NOTE: Additional Lump Sum Cash Payment of \$10 billion is not included in this table.

Two cases are analyzed. The low cost case assumes that Medicaid enrollment increases at 1.18 per cent per year, and that medical care inflation is the same as economy wide inflation. This is the average increase for the last 10 representative years, with growth rate data taken from recent issues of Health Care Financing Review, Statistical Supplement [4, Table 105, p. 370] and the Health Care Financing Administration Internet site on the Medicaid statistics page (HCFA Statistics: Populations, Table 11.-- Medicaid Recipients/Trends on Internet site <http://www.hcfa.gov/stats/hstats96/blustats.htm>). The years 1990 to 1993 are excluded because of large, and probably one time, program changes that lead to large increases in the enrollment of women and children. The annual growth rate used here is based on the annual growth rates from 1982 to 1989, and 1994-1996. This annual adjustment to Medicaid assumes that future enrollees are similar to those in the past and the fraction of Medicaid costs due to smoking remains the same. This case also assumes that the medical inflation rate is the same as the general inflation rate.

The high cost case assumes that the growth rate in Medicaid enrollment is 1.18 per cent per year, and that the medical inflation rate continues to be about what it has been for the last ten years. The medical inflation as measured by the MCPI (The Medical Consumer Price Index) has exceeded the general CPI regularly for the last 50 years, despite massive changes in the health care system such as the dramatic growth of private comprehensive health insurance, social health insurance programs, and capitated managed care. A reasonable high cost case must assume that this trend will continue. The high cost case assumes that the last ten year average difference between the growth of the general CPI and the MCPI will continue into the indefinite future. The average difference is 3.15 percentage points per year, using 1986-1995 annual data from the U. S. 1996 Statistical Abstract [5, Table 745.--Consumer Price Indexes (CPI-U), by Major Groups: 1939 to 1995, p. 483].

Table A1 presents a summary of the funds and budgets for the first ten years. The last line labeled year 11+ represents the perpetual annual base payments that begin in year eleven. The Public Health Trust Fund is specified on a separate line in Title VII, and the language describing its administration in Title VII specifies that the total face value of the fund payments must be used for medical research. Therefore it is assumed that this item in the budget has its own reserved fund. The other budgeted items (Public Health Funds, Civil Liability, and Medicaid Smoking Costs) must be funded out of the annual Base Payment. The language of the deal is somewhat ambiguous as to whether the term "Public Health Funds" includes the

Public Health Trust Fund. In text below, the term "Public Health Funds" will refer to programs specified under Title VII, exclusive of the Public Health Trust Fund medical research program. The term "Public Health Trust" or "Public Health Trust Fund" will refer to the eight year payments for the Public Health Trust research funds administered by a Presidential Commission. The use of the initial lump sum payment is not specified in the deal, so it is not included in the analysis of the annual funding, unless it is explicitly mentioned in a discussion of alternative scenarios.

Table A2 shows the total funds and budgets under the low and high Medicaid cost cases. The table shows that the annual payments are less than the budgeted items in most years. The shortfall is particularly severe in the initial five years, when less than 90 percent of the total budget is funded under both low and high cost cases. Under the low cost case, the budgets are not fully funded until year 9, and under the high cost case, the budgets are never fully funded. The lump sum payment cannot eliminate this shortfall. Assuming that the initial lump sum is invested at 5 per cent real interest per year, the undiscounted difference between the shortfall and the value of the lump sum will be about \$3 billion for the low, and \$12 billion for the high cost case over the first ten years.

The deal cannot be fully funded after the first ten years if the medical inflation rate exceeds the CPI regardless of the priority of those claims. This is because the real value of the payments are fixed, but Medicaid costs will increase dramatically. Assuming that the level of smoking and the fraction of costs due to tobacco does not change, funds will be adequate if medical inflation matches the CPI. For the low cost case, the undiscounted sum of the budgets for years 11 to 25 is \$230 billion, for high cost it is \$317 billion. With annual real funding at \$15 billion, this totals \$225 billion over the same period. So 98 per cent of the budgets can be funded in the low cost case but only 71 per cent in the high cost case. Medicaid costs are by far the largest budgeted items after year ten, and these costs alone exhaust the Base Payments starting around year 22 of the agreement in the high cost case. The adequacy of the compensation for Medicaid smoking costs during this period is questionable. The answer will depend crucially on projected smoking levels, and the rate at which tobacco related Medicaid cost respond to changes in consumption, and the rate of medical inflation.

The ratio of the total funding to the total budgets can be used to determine the percentage funding received by each program if they all share risk of a shortfall equally. The deal does not discuss any risk sharing mechanism, and does not discuss the priority of claims in the event of a shortfall.

The deal language in Titles VI to VII seems to imply that the Public Health Trust Fund and the Civil Liability Fund do have priority to the funding. Both has its own governing commission, and the amounts of

year	Total Funds	Available for Medicaid	Total Budgeted		Total Budgeted	
			low cost case		high cost case	
			\$billion	% Funded	\$billion	% Funded
1.0	8.5	1.9	12.4	69	12.6	68
2.0	9.5	2.5	12.9	74	13.3	72
3.0	11.5	3.1	14.3	80	14.9	77
4.0	14.0	4.3	15.7	89	16.5	85
5.0	15.0	3.9	17.2	87	18.3	82
6.0	15.0	5.5	15.6	96	16.9	89
7.0	15.0	5.5	15.7	95	17.2	87
8.0	15.0	5.5	15.8	95	17.6	85
9.0	15.0	7.8	14.2	106	16.2	92
10.0	15.0	7.8	14.3	105	16.6	90
11+	15.0	7.8	14.3	105	17.0	88

funding devoted to these budgeted items are explicitly stipulated. Therefore it will be assumed that the these two budgets have priority to the funds. This analysis will focus on the implications of different priorities for Medicaid reimbursement and the Public Health Funds. The Civil Liability Fund may be used for other purposes if it is not exhausted by litigation awards. Therefore the significance of the shortfall may depend on the disposition of the Civil Liability Fund. If the Fund is not exhausted each year, the relevant Commission may decide to fund the Public Health Funds programs or Medicaid reimbursement. Language in Title VIII explicitly allows this fund to be used for other purposes. Even if all the Civil Liability Fund was used for the Public Health Funds, this will not permit full funding of the Public Health Funds programs, and Medicaid reimbursement until year four under both the high and low cost cases. Use of the Civil Liability Fund for Medicaid reimbursement will exhaust the Base Payments starting around year 16 of the agreement under the high cost case.

Table A3. Funding of Budgets Under Different Cases (per cent funded)				
year	Medicaid Reimbursement		Public Health Funds	
	medical cost inflation		medical cost inflation	
	low	high	low	high
a. Priority to Public Health Funds*				
1	33	32	100	100
2	72	40	100	100
3	53	48	100	100
4	72	64	100	100
5	63	54	100	100
6	90	74	100	100
7	89	71	100	100
8	88	68	100	100
9	113	85	100	100
10	111	82	100	100
11	110	78	100	100
b. Priority to Medicaid reimbursement**				
1	69	67	0	0
2	80	75	0	0
3	90	82	0	0
4	100	98	28	0
5	100	94	21	0
6	100	100	77	33
7	100	100	75	21
8	100	100	72	9
9	100	100	128	56
10	100	100	126	43
11	100	100	123	29
*Public Health Trust is fully funded and the Civil Liability Fund is exhausted each year, with the balance available for Medicaid.				
**Civil Liability Fund is exhausted each year, Medicaid paid to the maximum extent possible, and balance made available for Public Health Trust.				

The priority of the claims on the funds by the various budgets will have a dramatic effect on the level of funding. This is because the absolute size of the budgets differs substantially. Table A3 shows the effect on funding for two different priorities. Table A3 assumes that the Civil Liability budget is always fully funded. This fund is explicitly devoted to legal settlements, and because the governing Commission has such wide latitude in the disposition of the funds. The first part of Table A3 shows the funding of the Medicaid reimbursement, assuming that the Public Health Funds are fully funded. In this case the about one third of the

Medicaid costs are paid in the first year. This rises gradually to over 100 per cent of the claims in the low cost case, and around 80 per cent in the high cost case by year 10. The second part shows the effect of Medicaid reimbursement having priority. Here the Medicaid reimbursement is initially funded at about 70 per cent in the first year. This gradually rises to full funding in year four in the low cost case, and year six in the high cost. Then the Public Health Funds programs have no funding in the initial years of the agreement. In the low cost case, the about a third or fourth are funded starting in year 4, and this steadily increases to full funding in year 9. In the high cost case, there are no available funds until year 6. In the high cost case, the funding of the Public Health Fund programs is erratic and never rises much above 50 per cent. This is because the annual changes in the Base Payments and the Medicare costs are large compared to these programs. Allocation of a portion of the initial \$10 billion lump sum payment would alleviate most of this problem in the low cost case, but not in the high cost.

The sales volume adjustment would make this analysis unrealistic if cigarette sales had been increasing with the population, as has Medicaid enrollment. However, cigarette sales have been declining or stationary in the last twenty years, and this represents about 86 per cent of tobacco consumption. Therefore using the Base Payments with no sales volume adjustment is an optimistic analysis.

Funding is inadequate for the budgeted items in the initial years in both the low and high cost cases. The adequacy of funding in the later years depends crucially on projected Medical inflation and the growth rate of Medicare costs due to smoking. The enrollment growth projections seem reasonable as indices of the number of people who will use public funds for smoking related illnesses in the short to mid run future. Many illnesses due to smoking do not resolve quickly. Cancers caused by smoking often take ten years or more to cause symptoms leading to medical treatment. The length of time needed after smoking cessation for cancer, obstructive respiratory disease, can be usually long [6]. (Cardiovascular disease is one exception, where the benefits of cessation accrue relatively quickly, over a period of a few years [7].) Therefore the use of historical Medicaid enrollment growth rates is probably a reasonable way to forecast the level of tobacco related Medicaid expenditures, assuming no excess medical inflation exists, at least for the next five to ten years. In this case, the deal has approximately adequate funding except in the initial years. If medical inflation continues at or close to the level of the last ten years, then the funding is inadequate. The volume adjustment will probably not be a major factor in determining the level of funding, given the level of proposed funding for anti-tobacco programs in the deal. The volume adjustments are discussed briefly below.

An additional issue is the fraction of direct medical costs due to smoking that are reimbursable under the deal. The agreement explicitly disallows several types of civil suits, and puts a cap on total awards. Full compensation of all direct costs is clearly not a goal of the deal. However it is interesting to determine the

Table A4. Total Reimbursable Tobacco Related Direct Medical Costs (per cent)		
Year	Medical Inflation	
	low cost case	high cost case
1	5	4
2	5	5
3	6	5
4	7	7
5	7	7
6	9	8
7	9	8
8	9	8
9	11	9
10	11	9
11	10	8

NOTE: Tobacco related Medicaid costs are excluded from direct medical costs.

maximum amount of the direct medical costs that are reimbursable. Table A4 shows these amounts. This table assumes that the current direct medical costs due to smoking are \$50 billion dollars. This estimate is conservative, since it is the estimated cost for 1993 [3]. Tobacco related Medicaid costs are deducted total medical costs to avoid double counting. The low cost case assumes that these costs grow annually at the same rate as the population with medical cost inflation being equal to the growth of the general CPI. The US Census mid-level population projections are used to calculate growth rates (US Bureau of the Census, Resident Population Projections of the United States accessed through Internet site <http://www.census.gov/population/projections/nation/npaltsrs.txt>). The average annual growth rate is assumed to be 0.84 per cent for the first ten years of the agreement, and 1.3 per cent for years 11 to 25 starting from 1997. The high cost case increases the annual growth rate by an additional 3.15 per cent to account for excess medical care inflation over the general rate. Table A4 shows that less than 10 to 11 per cent of total direct medical costs are reimbursable under the deal in the first eleven years. This is also true for years 12 through 25.

Title VIII.B.9 contains language that suggests that the total amount of money available for civil settlements is more than that stipulated in the Title VI. This section describes a cost sharing system where money paid for a civil judgment comes both from the Civil Liability Fund and the individual company that must pay the judgment. Eighty per cent of the judgment comes from the Civil Liability Fund and 20 per cent from the company. The language is vague, but seems to say that the 20 per cent company risk share is in effect until the company's share of the annual contributions to the Civil Liability fund is exhausted in settlements. If this is the case, then the potential amount of money that could be paid in civil judgments is 25 per cent greater than the Civil Liability Fund itself. Then the fraction of annual direct medical costs that are reimbursable range from 12 to 14 per cent in the first eleven years of the agreement. Another effect of this cost sharing provision is that it gives individual companies some limited incentive to avoid civil litigation and settlements. There is no incentive to avoid settlements out of the Civil Liability Fund without this provision.

After Tax Cost of The Deal

year	Total Payments	After Tax Payments	Value of Tax Deduction
1	9.8	6.4	3.4
2	10.8	7.0	3.8
3	12.8	8.3	4.5
4	15.3	9.9	5.4
5	16.3	10.6	5.7
6	16.3	10.6	5.7
7	16.3	10.6	5.7
8	16.3	10.6	5.7
9	16.3	10.6	5.7
10	16.3	10.6	5.7
11+	15.0	9.8	5.3

NOTE: Assumes 35 per cent effective tax bracket, and advertising savings of \$1.4 billion.

Title VI.D specifies that all payments made under the deal are ordinary business expenses that are tax deductible. Table A5 shows how this effects the net cost of the agreement to the tobacco industry. This analysis assumes an effect tax rate of 35 per cent on corporate income, which is the same rate used in the FTC analysis [1], and derived from Tobacco Institute publications [2].

Table A6. Deal Cost per Pack Sold (in dollars per pack, and per cent of price per pack)				
Year	Before Tax Payments		After Tax Payments	
	\$	%	\$	%
a. Without Lookback Provision				
1	0.36	19	0.23	12
2	0.39	21	0.26	14
3	0.47	25	0.30	16
4	0.56	29	0.36	19
5	0.59	31	0.39	20
6	0.59	31	0.39	20
7	0.59	31	0.39	20
8	0.59	31	0.39	20
9	0.59	31	0.39	20
10	0.59	31	0.39	20
11+	0.55	29	0.35	19
b. Including Lookback Provision				
1	0.36	19	0.23	12
2	0.39	21	0.26	13
3	0.47	25	0.30	16
4	0.56	29	0.36	19
5	0.64	34	0.42	22
6	0.64	34	0.42	22
7	0.67	35	0.43	23
8	0.67	35	0.43	23
9	0.67	35	0.43	23
10	0.68	35	0.43	23
11+	0.64	33	0.40	21

NOTE: Assumes stationary sales of 23.7 billion packs per year (1996 sales) and costs allocated in proportion to cigarette to industry sales (86 per cent of tobacco sales in form of cigarettes). Assumes initial lump sum payment amortized over ten years at 5 per cent real rate per annum. Average price per pack assumed to be \$1.90.

Allocating the cost per pack of the initial lump sum payment to the initial year of the deal is probably unrealistic. Allocating all of the lump sum payment in the first year would result in a large increase due to the initial \$10 billion payment, followed a price drop and subsequent smaller increases. The industry would most likely prefer to avoid such large price variability. However, the up front payment is allocated according to market share, and therefore appears as additional cost per pack which will be approximately the same for all companies. The volume adjustment does not affect the up front payment, however over the first ten years of the deal, it only affects the cost per pack by one or two cents. The impact on the industry is the same as the annual payments, except that there is no requirement that they be passed through. However, there is no reason that it will not be passed through just like the other annual payments in the deal. It is assumed here that the initial lump sum payment in amortized over a ten year period at a 5 per cent real rate of interest per annum.

The annual value of the payments made by the industry are shown in Table A5. No adjustments are made for price effects of the passthrough payments or volume adjustments. Table A5 shows that the annual

after tax cost of the deal to the industry varies from between \$6 and \$7 billion dollars in the first year, to around \$10 to \$11 in the following years. The annual value of the tax deduction is between \$3 and \$4 billion in the initial years, increasing to between \$5 and \$6 billion per year later. The present discounted value of the tax deduction over the first 25 years of the deal is \$95 billion dollars at a 2.5 per cent real discount rate, and \$71 billion at 5 per cent and \$56 billion at 7 per cent. The annual value of the tax deduction is larger than the tobacco control and research expenditures described in the Public Health Funds programs.

Table A6a shows the cost of the deal per pack under the cases described above. The before tax cost per pack is between 36 and 59 cents, the tax deduction reduces this cost to between 23 and 39 cents. Table A6b shows the cost of the deal per pack, including the cost of the lookback provision, using the results from Appendix B. Table A6b shows that the costs increase starting in year 5, by 64 to 67 cents before tax, and by 21 to 23 cents after tax. Table A6b uses the assumptions of Appendix B, that the cigarette industry pays up to the entire \$2 billion fine under the cap, and that the lookback payments are passed through.

The average cost of a name brand pack of cigarettes has ranged between \$1.95 and \$2.00 in recent years; when generics are included, the average price is about \$1.87 to \$1.90 [2]. The average price is assumed to be \$1.90 here to simplify calculations and to agree with the FTC report. Cigarettes are about 86 per cent of the tobacco sold in the US, and it assumed that tobacco companies will allocate costs roughly according to sales. Title VI.B.7 requires manufacturers to passthrough all cost increases. Table A6 shows that this requirement implies that the before tax cost per pack will result in a 19 to 31 per cent increase in the price. The more relevant figure is the after tax increase, since this represents the net cost to the industry. The after tax price increase ranges from 12 to 20 per cent. These estimates are within a few cents of the estimate in the FTC report. Unlike the FTC, we assume that the \$10 billion up from payment is included, and we do not include the effect of the excise tax increase. However, we are also including only the portion of the payments that are due from the cigarette portion of the industry. So the net effect is an estimate virtually the same as the FTC analysis.

Financial Analysis Using the Federal Trade Commission Model

This section reports some estimates of the net impact of the deal using the methodology of the Federal Trade Commission report on the financial effects of the deal [1]. The FTC report contains a useful approach to modeling the deal that also provides important insights. We extend the model used by the FTC analysis to cover some cases which were omitted in their report.

The FTC report uses the following approach: It assumes that the cost structure of production remains constant over potential changes in production and sales levels. The FTC makes a convenient simplification by noting that the effect of the volume adjustment in the deal will keep the average amount of annual payments per pack approximately constant. This simplification ignores some of the details of the volume adjustment for the annual payments (such as the slight difference in adjustment for sales increases vs. sales decreases), however these are of secondary importance. The cost is distributed across companies by market share. The deal also contains broad anti-trust exemptions, which will help the industry maintain its current pricing structure. Assuming that the passthrough clause refers to the stated value of the annual payments, apart from any other costs of the deal, the report assumes that the annual payments can be approximately modeled as an excise tax on cigarettes. Based on past experience, the FTC report assumes that the industry can passthrough at least 100 per cent of the base payments. The FTC then calculates industry profits and public revenues under the assumption of a fixed cost structure for various passthrough rates.

The FTC report reviews the history of the relationship between tax increases (mainly federal and state excise tax increases) and concludes that cigarette companies can pass 100 per cent or more of cost increase on to the consumer. Most past economic research quoted in the report found passthrough rates from

102 to 107 per cent, though one estimate is as high as 200 per cent. Hence, the 100 per cent passthrough of annual payments is likely to happen even if it were not mandated by the deal. Furthermore, the FTC report concludes that the broad anti-trust exemptions in the deal will allow the individual firms in the industry to achieve greater passthrough rates than in the past, and therefore assumes that the deal passthrough rate will be greater than 100 per cent. It does not give an estimate of a what the passthrough rate might be, but analyzes the consequences of passthrough rates of 125 and 200 per cent.

The FTC report assumes in the base case that the industry will not passthrough the initial payment of \$10 billion. In contrast, we assume that the industry will amortize the up front payment over ten years and add the annual cost per pack to the price. The FTC report also notes that one of the financial benefits of the deal is protection from civil liability. The FTC does not estimate the value of this protection, but does report an independent analysis that implies that value of the protection for Phillip Morris is between \$75 and \$100 billion [8]. The FTC report extrapolates amount to the entire industry to estimate that the immunity from civil liability is worth \$150 to \$200 billion for the whole industry.

The economics of the deal as described in the FTC report [1] are as follows.

- The deal functions as a contract that gives the industry a cap on civil liability in perpetuity. The present discounted value of this protection may be worth \$150 to \$200 billion. In return for this protection the industry agrees to make annual payments with a face value equal to around \$350 billion over 25 years and pay \$10 billion up front.
- The annual base payments are essentially an additional excise tax (called, say, the "settlement tax") that the industry will help administer. The funds from the tax will be given to the states for medicaid reimbursement and to public health research and programs
- The annual payments cost the companies nothing directly, since they are required to raise prices to cover the additional cost per pack of the settlement tax.
- There is an indirect cost of the settlement tax which is incurred by the industry. That is lost revenue

Table A16. Components of Cost of a Pack of Cigarettes, 1995-1997 (\$/pack)			
year	1997 FTC [U. S. Federal Trade Commission, 1997 #9]	1995 Harris [Harris, 1996 #11]	1997 composite
total price per pack	1.90	1.88	1.9
profit	0.32	0.31	0.32
excise tax, federal	0.24	--	0.24
excise tax, state	0.32	--	0.32
excise tax, total	0.56	0.53	0.56
total profit and excise tax	0.88	0.84	0.88
price less profit and total excise tax	1.02	1.04	1.02
distribution costs	--	0.52	0.50
advertising & marketing	0.23	--	0.23
legal	0.025		0.02
sub total advertising, marketing and legal costs	0.255	0.52	0.75
residual (other production costs)	0.77*	0.52**	0.27
* includes distribution costs			
** includes advertising and promotional marketing costs			

due to lower sales volume. If the passthrough is exactly 100 per cent, then the increase in revenue from the price increase exactly equals the cost of the annual payments. However, the industry does not recover revenue from sales lost to increased prices.

- The cash price of the deal is the \$10 billion up front payment.
- The cost of the deal can be reduced by the industry if the passthrough rate can be increased above 100 per cent. Passthrough rates above 100 per cent will increase total revenue flowing to the industry over costs of production and excise taxes because of the inelastic demand.

Table A17. Financial Effects of Deal FTC model Baseline case with \$50 billion excise tax break rescinded (\$billion 1997).						
	no deal		deal		difference	
	undis-counted	dis-counted	undis-counted	dis-counted	undis-counted	dis-counted
Passthrough rate = 100 per cent						
after tax industry profits	118	59	102	48	-16	-11
payments	0	0	303	144	303	144
total public sector revenues	455	222	714	344	259	122
Passthrough rate = 125 per cent						
after tax industry profits	118	59	138	64	+20	+5
payments	0	0	303	145	303	145
total public sector revenues	455	222	728	351	273	129
Passthrough rate = 200 per cent						
after tax industry profits	118	59	223	103	+105	+44
payments	0	0	330	157	330	157
total public sector revenues	455	222	782	376	327	154
Note: all figures in current 1997 dollars.						

Note that there is an additional cost to the industry in the form of the profit penalty, which is like an increase in the income tax, but the effect of this is minor. The profit penalty is included in the FTC report. The FTC report does not include the effect of the Lookback provision.

Other assumptions for the FTC base case are given below:

price increase ratio (passthrough rate)	100%
1997 price per pack	\$1.90
1997 sales volume (packs)	24.2 billion
corporate income tax rate	35%
present value discount rate (annual)	7%
demand trend growth rate (annual)	-0.6 percent/year
demand elasticity	0.4
advertising and legal savings (per pack)	\$0.05

The FTC report uses the cost structure for the average pack of cigarettes in Table A16; these values are similar to those used in an analysis by Harris of the industry's capability to generate revenues to pay the costs of smoking-induced disease [9].

The results of the baseline scenario from the FTC report are given in Table A17 for the first 25 years of the deal. They include the new federal excise tax enacted by Congress in 1997, but not the \$50 billion offsetting tax break that was enacted and rescinded. The Lookback provision is not modeled. Without the deal, the industry undiscounted sum of after tax profits over the next twenty five years is \$118 billion and the discounted present value is \$59 billion. The deal will reduce the undiscounted sum to \$102 billion, and the discounted present value to \$48, for a net loss of discounted present value profit of \$11 billion over 25 years. Of this, \$10 billion is from the up front payment that is not passed through and around \$1 billion is in lost profits from reduced sales. The total payments are \$303 billion (after the volume adjustment) and the discounted present value of the payments is \$144 billion. The total payments to into public funds (industry payments under the deal, income taxes, and excise taxes paid by smokers) is \$455 billion (discounted present value \$222 billion) without the deal and \$714 billion (discounted present value \$344 billion) with the deal. The deal will increase industry payments into public funds by a discounted sum of \$122 billion over the next 25 years.

The FTC report does not give an interpretation of these results for the overall impact of the deal. Our interpretation is as follows: Suppose the industry raises the price of cigarettes just enough to implement a 100 per cent passthrough of the annual payments stipulated in Title VI, but does not passthrough any of the initial lump sum payment and there is no Lookback provision. Then the industry is essentially paying \$11 billion in current 1997 dollars over the next 25 years. The industry's civil liability is capped, and this may be worth \$150 to \$200 billion. In return it is agreeing to help various governments collect additional excise taxes with a discounted present value equal to \$144 billion over the next 25 years. This increases the discounted present value of the industry's total payments to the public sector over the next 25 years by \$122 billion. In summary, the cigarette industry is buying \$150 to \$200 billion in liability protection for \$11 billion of its own money (over the next 25 years) and agreeing to help increase excise tax collections from smokers over the next 25 years by \$144 billion.*

If the industry can increase cigarette prices by more than 100 per cent of the annual payments, then it can purchase its protection from civil liability for less than \$11 to \$13 billion. In that way it would recover the \$10 billion up front payment and also the lost revenue from the decrease in sales volume. Assuming that the industry does not passthrough the \$10 billion up front payment, the breakeven point for the industry passthrough is about 115 per cent of the annual payments, in which case the discounted present value of its profits will be the same over the next 25 years with or without the deal. It will have purchased the liability protection for nothing. If the industry can increase prices by more than 115 percent of its cost increase, it will increase the discounted present value of its profits. This result is shown in Table A17 using the FTC calculations for passthrough rates of 125 and 200 per cent. A passthrough rate of 125 per cent means that the industry increases cigarette prices by 125 per cent of the annual payments. The results show that a passthrough rate of 125 per cent would increase industry profits by \$5 billion, and total public sector receipts by about \$7 billion. A rate of 200 per cent would increase industry profits by \$44 billion, and total public receipts by \$32 billion. As shown in Table A17, the effect of the passthrough rate does not affect the public sector revenues nearly as much. The FTC report does not comment on what passthrough rate is most likely. It

*The tobacco industry published a critique of the FTC analysis which disputed the FTC conclusion that the deal could actually increase industry profits [Lorillard Tobacco Co., Phillip Morris Cos. Inc., R. J. Reynolds Tobacco Co., and UST, Inc., Impact of the Proposed Resolution on the United States Cigarette Industry, Report submitted to Senate Democratic Task Force on the Tobacco Settlement, October 8, 1997]. The FTC published a response [Evaluation of the Tobacco Industry Analysis Submitted to Congress on October 8, 1997, Staff of FTC, Federal Trade Commission, US Department of Commerce, November 10, 1997] to the industry critique showing that the industry had made several errors, all of which biased the results towards the conclusion that the deal would cost the industry money and carefully defending the FTC's analysis. We concur with the FTC's defense of its work.

does note that industry profits vary more than the total public payments over a range of parameter values. The reader is referred to the FTC report [1] for more details.

We reproduced the FTC model and could reproduce the FTC results within 10 per cent. We used our reproduction of the FTC model to look at the case in which the \$10 billion up front payment is amortized by the industry over the course of the agreement and passed through in the cigarette price. If the industry does passthrough the full amount of the \$10 billion up front payment and amortizes it over 10 years this results in an additional price increase between 6.5 and 7 cents per pack. The industry saves the full \$10 billion in the first year but loses some profits because of the additional price increase. The net result is that the total industry cost is \$6 to 7 billion, assuming a price increase of 7 cents per pack over the first 10 years. If the industry amortizes the up front payment over ten years, the breakeven rate is about 108 per cent. The results are similar if the up front payment is amortized over 25 years.

The reasoning behind our assumption that all of the up front payment will be passed through is as follows: First, the up front payment will be sunk cost. After the initial payment is made, it cannot be recovered or altered in anyway. Assuming each firm will contribute to the up front payment according to market share, this will produce a roughly equal charge on a pack of cigarettes across the industry. Each firm will have to either borrow the money for the up front commitment, or borrow money it wouldn't otherwise have to in order to execute its business plans. If the costs of borrowing are similar across firms in the industry, then the annual amortized cost per pack of the up front payment will be roughly the same across the firms. The only difference between the up front payment and the annual base payments is that there is no volume adjustment for the up front payment. However, the effects of the volume adjustment are on the price increase per pack from an amortized up front payment is only two or three cents per pack in the first ten years of the deal. Therefore financing of the up front payment will produce a cost for all firms in the industry that approximates an additional excise tax incurred in the first year of the deal. We assumed that this virtual tax would be passed through along with the annual payments, especially given the deal anti-trust exemptions. There is nothing to prevent this from happening unless the passthrough provision is interpreted to mean government administered command pricing for the cigarette industry.

Analysis of the Lookback Provision

In the next section we use a modified version of the FTC model with the effects of the lookback provisions included.* We include the \$10 billion up front payment in the cost of the deal. This does not change the conclusions significantly and makes the analysis more comparable with the FTC results. Recovery of the other costs of the deal will be expressed in terms of the percentage of annual payments passed through. If the passthrough rate is 100 per cent, then only the annual payments are passed through. If it is greater than 100 per cent then all of the annual payments, and some of the up front payment, profits from lost sales, and lookback provision costs are recovered also.

Table A18 shows the results for the Lookback Provision with a cap of \$2 billion on annual surcharges, and assuming that youth smoking patterns do not change, and there is no additional decline in youth smoking recruitment. Otherwise, we use the FTC assumptions. We assume in this scenario that the industry consciously decides to ignore the Lookback Provision, and will use marketing techniques to compensate for the price increase in the youth market, thereby keeping total sales volume approximately constant, except for price effects.

*All figures reported here are from our spreadsheet version of the FTC analysis. Some slight discrepancies exist because of rounding. We also do not include the \$50 billion tax break that Congress enacted, then rescinded.

Table A18 shows that with a passthrough rate of 100 per cent, the industry can cover the cost of the surcharges with an additional average price increase of 10 cents per pack after year 7 and the discounted present value of the cost of the deal for the industry increases slightly to \$13 billion, so total industry profits are reduced by about one third, from \$59 billion to \$46 billion. The discounted present value of payments increase to \$154 billion, and discounted present value of total public sector revenues increases to \$351 billion.

The industry can recover the cost if it can achieve a passthrough rate of 115 per cent. A 200 per cent passthrough can be covered by an average of 10 cent per pack price increase after year 7 (rounded to the nearest cent), and this doubles industry profits, from \$59 to \$119 billion. The \$2 billion cap on the surcharge is not binding in this case because of price effects on youth daily smoking prevalence. Discounted settlement payments increase from the 100 per cent passthrough case to \$154 billion. The discounted present value of public revenues increases by \$158 billion from the no deal case, to \$372 billion, a \$21 billion increase over the 100 per cent passthrough case.

	no deal		deal		difference	
	undis- counted	discounted	undis- counted	discounted	undis- counted	discounted
Passthrough rate = 100 per cent						
after tax industry profits	118	59	98	46	-22	-13
payments	0	0	329	154	329	154
total public sector revenues	458	224	730	351	272	127
Passthrough rate = 125 per cent						
after tax industry profits	118	59	144	67	26	8
payments	0	0	332	155	332	155
total public sector revenues	458	224	744	357	286	133
Passthrough rate = 200 per cent						
after tax industry profits	118	59	259	119	140	60
payments	0	0	336	158	329	154
total public sector revenues	458	224	773	372	336	158

The results for the case in which all firms in the industry receive the full 75 per cent abatement are almost identical to the no Lookback case, again assuming that sales volume remains about the same.

Table A19 shows the case in which there is no cap on the Lookback penalties. This case is approximated by setting the annual Lookback payments to what they would be if only the price effect decreased youth demand, the 30 per cent target reduction was in effect in years 5 and 6 and the maximum 60 per cent target were in effect after year 6. The average annual penalty from year 7 to 25 would then be approximately \$3.2 billion, which is $(1-(2/3)) \times 60 \times \80 million. The $(1/3)$ factor is used because the price effect alone may reduce youth smoking by approximately 20 per cent (assuming a .6 youth elasticity), which is one third of the maximum 60 per cent target reduction. This estimate overstates the effect slightly because the maximum penalties would be smaller in the two years when only a 50 per cent reduction is required.

Table A19 shows that the Lookback provision reduces the discounted present value industry profits

to \$97 billion. The discounted present value of settlement payments is \$161 billion, and the discounted present value public sector revenue is \$357 billion. The breakeven passthrough rate is rises slightly, but is still 115 percent when rounded to the nearest percentage point. A 125 per cent passthrough rate results in a discounted present value profit of \$67 billion, an increase of about 15 per cent from the no deal level. The payments decline slightly from the 100 per cent passthrough case because the lookback surcharges decline from price effects on youth prevalence. The discounted present value total public sector revenues are \$753 billion. The 200 per cent passthrough case is the same as the lookback with the cap because the \$2 billion cap because the cap is not binding this magnitude of price increase.

Table A19. Financial effects of the Deal, FTC model Baseline case with Lookback provision without cap (amounts in \$billion 1997).						
	no deal		deal		difference	
	undis- counted	discounted	undis- counted	discounted	undis- counted	discounted
Passthrough rate = 100 per cent						
after tax industry profits	118	59	97	46	-21	-13
payments	0	0	350	161	350	161
total public sector revenues	458	224	746	357	288	132
Passthrough rate = 125 per cent						
after tax industry profits	118	59	145	68	27	9
payments	0	0	342	159	342	159
total public sector revenues	458	224	753	360	295	136
Passthrough rate = 200 per cent						
after tax industry profits	118	59	259	119	140	60
payments	0	0	336	158	336	158
total public sector revenues	458	224	773	372	336	148

The results for compliance with the Lookback provisions depend on assumptions on the implications of delaying recruitment of youths into habitual smoking until after age 18. If delaying most recruitment until age 18 does not change adult smoking behavior and brand preference significantly, then total sales volume should stay about the same. Youth consumption accounts for only 3 to 4 per cent of total sales volume (counting both direct purchases and indirect purchases through other adults). If the industry simply shifts the age of initiation up, the results for this case should be the same as for the deal with no Lookback provision, which is the first analysis presented. In Tables A18 and A19, we assumed that there is no reduction in recruitment to smoking.

We next assume that delaying recruitment until age 18 does reduce adult smoking. The worst case scenario for the industry is that it loses all of the adult smokers who would have been recruited as youths. In this case, the industry would eventually lose 60 per cent of the current adult smokers. In Table A20 we assume that the industry institutes a program to reduce youth daily smoking to target levels. Youth sales volume is shifted downward to eliminate the gap between youth reductions from price effects and the relevant target level for that year. It is assumed that all youth smoking recruitment is reduced in proportion to daily smoking and these potential youth smokers are lost to the market forever. Annual sales volumes are reduced proportionally as the new smaller cohorts of adult smokers age. We assume that youth consumption is 3 per cent of the total market, and 60 per cent of this is lost each year as youth recruitment is reduced to target levels. This implies an additional non-price reduction of 1.8 per cent per year in addition to the base case 0.6 per cent reduction in overall demand due to secular trend. It is assumed that the average life cycle of a new youth smoker is 25 years [10].

The results for the first 25 years are shown below in table A20. A passthrough rate of 100 per cent reduces the discounted present value of industry profits to \$41 billion, for about a one third drop from no deal levels. The discounted present value payments are \$122 billion. Total discounted present value public sector

payments are \$296 billion. The breakeven passthrough rate is about 129 per cent. At higher passthrough rates the industry profits increase over no deal levels, but has little effect on total settlement payments or total public sector revenues. Even in this worst case for the industry of a 100 per cent passthrough rate, compliance with the Lookback provisions produce results that are comparable to non-compliance either with or without the annual \$2 billion cap.. This result is consistent with the calculations in Appendix B that suggested that the Lookback penalty is a reasonable approximation for the lifetime discounted profit of a new smoker.

Table A20. Financial effects of the Deal, FTC model Baseline case with Lookback reductions in smoking demand (amounts in \$billion 1997).						
	no deal		deal		difference	
	undis- counted	dis-counted	undis- counted	dis-counted	undis- counted	dis-counted
Passthrough rate = 100 per cent						
after tax industry profits	118	59	81	41	-38	-19
payments	0	0	240	122	240	122
total public sector revenues	458	224	572	296	114	71
Passthrough rate = 125 per cent						
after tax industry profits	118	59	114	57	-4	-2
payments	0	0	235	121	235	121
total public sector revenues	458	224	576	299	118	75
Passthrough rate = 200 per cent (0,0.10)						
after tax industry profits	118	59	200	99	82	40
payments	0	0	244	126	244	126
total public sector revenues	458	224	605	314	146	90

These results are, however, somewhat misleading. The Lookback does not begin until the fifth year of the deal, and the 25 year time horizon from the first year of the deal is not long enough to account for the average 25 year life cycle of a typical new youth smoker. Therefore present value analysis of Table A20 does not fully reflect the long term consequences of compliance. Table A21 shows the annual financial flows of the industry when the full reduction in adult smoking occurs, which will be 30 years after the beginning of the deal. The results show that the industry sales volume would shrunk by almost half, from 20.2 to 10.3 billion packs.

Table A21. Annual industry financial flows 25 years after start of lookback, meeting youth tobacco reduction goals		
	No Reduction	Reduction
Annual sales volume (billion packs per year)	20.2	10.3
Industry revenue (\$billion 1997 per year)	38.4	29.1

The industry may prefer noncompliance with the cap to compliance because of the potential for this kind of drastic reduction in market volume even if the passthrough rate needed to retain profits a current levels is not particularly high. The present value calculations over the next twenty five years hides the fact the final state of the industry looks very different in the end. The dominant firms may fear unexpected changes in market share as the industry changes its market strategy to avoid recruitment of youths. These individual firms may be facing potentially very large loses of market share and profits which would be larger than industry averages. Young adult smokers may not buy the current leading brands in the youth market. If large changes in market share accompany the sales volume reduction, then the payments may no longer appear to be excise taxes to the individual firms in the industry, price competition may increase and the oligopolistic market solution that preserves excess economic profits may breakdown. Then the profitability of the industry as a whole may be severely damaged.

Sensitivity Analysis

This section presents a sensitivity analysis of the average changes in price, annual cigarette consumption and annual payments over the first 25 years of the program as a function of what costs are passed through, price elasticity of demand, and the existence of non-price trend in consumption. The basic assumptions of the analysis are the same as in the FTC analysis [1].

Several different scenarios consist of different combinations of the assumptions on demand conditions and what settlement costs are passed through (in addition to the base payments). A guide to the keywords used to describe the scenarios follows. “No Up front” refers to the case in which the up front payment is taken from company profits. “Up front” refers to the case in which the up front payment is amortized over ten years and passed through to the consumers. “No lookback” refers to the case in which no lookback payments are made, but youth recruitment is replaced by young adult recruitment. “Lookback” refers to the case in which the lookback capped annual payments are made each year, assuming an annual \$2 billion cap. “Decline” means there is a annual decline in consumption of 0.6% per cent caused by non-price factors. “No decline” means that consumption is stationary at the current level.

The baseline case, Scenario 1, is no lookback, no up front payment, declining consumption trend, a price elasticity of 0.4 (the base case analysis of the FTC with the \$50 billion excise tax break removed). We used the same low end price elasticity of demand as the FTC analysis. We used 0.6 for the high price elasticity because we felt this was more realistic than the 0.8 elasticity used by the FTC. A demand elasticity of 0.8 lies far outside the 95 per cent confidence interval of estimates of adult price demand elasticity [11,12].

Table A22 shows the results. The most important factor in determining the average change in consumption and payments is the elasticity of demand. The next most important factors, each of about equal importance, is the passthrough of the lookback payments and the existence of a nonprice decline in consumption. The least important factor is the passthrough of the \$10 billion up front payment.

Conclusions

The main conclusions of the analysis are:

The deal is not fully funded in the short run. The payments stipulated in the deal do not cover the Medicaid costs and proposed spending on programs. The deal is approximately fully funded in the long run if medical inflation is the same as general inflation. If medical inflation continues to exceed general inflation at recent levels, then only 88 per cent of the Medicaid expenditures can be reimbursed over the first 25 years. Any reduction in annual base payments from the volume adjustment will reduce the rate of reimbursement even further.

The deal recovers only a small fraction of the total medical costs of smoking. It is important to emphasize that by “full funding” of payments for tobacco-induced medical costs, we are only considering Medicaid costs plus the \$2 to \$5 billion set aside for the Civil Liability Fund, which only amount to about 5% to 10% of tobacco-induced medical costs (half that percentage if one includes lost wages [3]).

The value of the tax break is significant, and is larger than the spending in the proposed Public Health Funds programs.

Table A22. Sensitivity analysis of change in consumption and payments			
Scenario	elasticity = 0.2	elasticity = 0.4	elasticity = 0.6

	change price (\$)	change quant. (billion packs)	total payments (average annual pre-tax payment, \$billion)	change price	change quant.	change in payments	change price	change quant.	change in payments
1 No lookback, no upfront, decline	0.54	1.17	12.28	0.54	2.31	11.44	0.54	3.41	10.62
2 No lookback, upfront, decline	0.57	1.23	12.24	0.57	2.44	11.37	0.57	3.62	10.52
3 Lookback, upfront, decline	0.63	1.40	13.67	0.65	2.77	12.58	0.66	4.16	11.59
4 No lookback, no upfront, no decline	0.54	1.27	13.27	0.54	2.50	12.36	0.54	3.70	11.48
5 No lookback, upfront, no decline	0.57	1.33	13.24	0.57	2.63	12.29	0.57	3.90	11.37
6 lookback, upfront, no decline	0.64	1.49	14.66	0.65	2.99	13.63	0.66	4.50	12.55

Note. Figures are average annual changes over first ten years
Key to scenarios:
No lookback = lookback payments not passed through,
Lookback=lookback payments passed through,
No upfront = \$10 billion up front payment not passed through,
Upfront = \$10 billion up front payment passed through,
Decline = 0.6 per cent annual decline in consumption due to nonprice effects,
No decline = no secular trend in consumption.

Excluding the lookback provisions, the deal will cost the tobacco industry a discounted present value of \$11 billion in profits over the first 25 years of the program, assuming it does not passthrough the up-front payment. Industry profits remain unchanged if the price of cigarettes is increased by 115 per cent of the required passthrough payments. If does passthrough the up front payment, the deal will cost a discounted value of \$6 to \$7 billion. Industry profits remain unchanged if the price is increased by 108 per cent of the required passthrough. This is in return for benefits of between \$150 and \$200 billion.

Industry profits will be reduced by a discounted present value of \$13 billion dollars with the lookback provision with the \$2 billion cap and 100 percent passthrough of the settlement costs. This assumes that the industry does not comply with the lookback and pays the maximum \$2 billion dollar penalty every year beginning in year 7 of the agreement when the required reduction in youth smoking reaches 50 per cent. Industry profits will remain unchanged if the price of cigarettes increases by 115 per cent of the required passthrough.

The industry can recover the cost of the deal by increasing the price of cigarettes by 108 to 129 per cent of the annual base payments, depending on the scenario.

References

1. U. S. Federal Trade Commission. Competition and the Financial Impact of the Proposed Tobacco Industry Settlement. Washington, DC: October, 1997, 1997.
2. Tobacco Institute. *The Tax Burden on Tobacco*. Washington, DC: The Tobacco Institute. 1997.
3. Bartlett JC, Miller LS, Rice DP, Max WB. Medical care expenditures attributable to smoking--United States, 1993. *MMWR*. 1994;43:469-472.
4. HCFA Office of Research and Demonstrations. Health Care Financing Review, 1995 Statistical Supplement. US Department of Health and Human Services. 1995.
5. Bureau of the Census. Statistical Abstract of the United States 1996, US Department of Commerce, Bureau of the Census, Table 745.--Consumer Price Indexes (CPI-U), by Major Groups: 1939 to 1995. US Department of Commerce, Bureau of the Census. 1997.
6. USDHHS. The Health Benefits of Smoking Cessation: A Report of the Surgeon General, 1990. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic disease Prevention and Health Promotion, Office on Smoking and Health. 1990.
7. Lightwood JM, Glantz SA. Short-term economic and health benefits of smoking cessation: myocardial infarction and stroke [see comments]. *Circulation*. 1997;96:1089-96.
8. Black G, Rooney J. Tobacco: As Third Wave Draws to a Close, Revaluations Likely to Mirror 1987. Bernstein Research. August 6, 1997, 1997.
9. Harris JE. American cigarette manufacturers' ability to pay damages: overview and rough calculation. *Tobacco Control*. 1996;5:292-294.
10. Pierce JP, Gilpin E. How long will today's new smoker be addicted to cigarettes? *American Journal of Public Health*. 1996;86:253-256.
11. Wasserman J, Manning WG, Newhouse JP, Winkler JD. The effects of excise taxes and regulations on cigarette smoking. *Journal of Health Economics*. 1991;10:43-64.
12. Grossman M, Chaloupka FJ. Cigarette taxes, the straw to break the camel's back. *Public Health Reports*. 1997; 112:290-297.

APPENDIX B: ECONOMIC ANALYSIS OF THE LOOKBACK PROVISION

Introduction

This appendix provides some sample calculations illustrating how the Lookback provision would work, using the cigarette market as an illustration. Data are not available to model the provision with other forms of tobacco products. A few simple variations are presented to show the sensitivity of the calculations to differing assumptions. We also compare our analysis with that published by the Federal Trade Commission [1]. (The FTC analysis does not include the lookback provision.) The problems associated with using daily smoking as a measure of youth smoking prevalence are discussed.

Idea of Lookback Provision and Assumptions of Analysis

The idea of the Lookback provision is to deny tobacco companies any profit incentive to sell to youth under 18 (simply called youth hereafter) by capturing all the present discounted profits of any sales to youth over the target level. (The Lookback provision is a more modest version of a proposal by Glantz to capture the present value of all current and future revenues due to tobacco consumption by people who begin smoking as youth [2].) The provision is designed so that the manufacturer is denied not only the profits from the current sale, but any that will occur on average over that smoker's lifetime.

The Lookback provision sets the goal of reducing the prevalence of daily smoking among 13-17 year olds by 30% in 5 years, 50% in 7 years, and 60% in 10 years. If the industry fails to meet these targets, it pays a penalty of \$80 million for each percentage point by which the industry fails to meet these targets. The total penalty is capped at \$2 billion a year, and can be reduced if the industry makes "good faith" efforts to reduce teen smoking. Similar provisions apply to smokeless tobacco.

Current sales to youth are indexed by the prevalence of daily youth smoking. The idea is to use a weighted average of age specific daily smoking prevalence for ages 13 to 17 as an index of the aggregate proportion of youth who will smoke as adults. The provision assumes that there will be direct one-for-one relationship between changes in this index of daily smoking prevalence and the prevalence of all youth who will smoke as adults. If the penalty (called the surcharge) is levied difference between the actual percentage of daily youth smokers and the target percentage, and the amount of the penalty for each percentage point by which the target is missed is set at the correct level, then the industry will lose all the future profits from sales to more youths than the target allows. The surcharge is \$80 million for every percentage point missed in meeting the target 60% reduction in youth smoking. The Lookback provision targets and penalty become effective five years after the agreement is enacted.

This plan to capture future profits explains the "one time only" provision of the Lookback in section B.1.b(1) of Appendix V of the deal. This provision means the tobacco industry is penalized only once for missing the target for reducing daily smoking for a cohort of youth to prevent double counting.

An industry-wide cap on the damages is set at \$2 billion. We will assume that this cap applies to the cigarette portion of the industry. In practice, cigarettes account for 86 per cent of total tobacco sales, including smokeless tobacco, so there are circumstances in which the cap on the cigarette industry may be less than \$2 billion. We will use the \$2 billion cap in order to calculate an upper bound to the cost of the lookback provisions to the industry.

The lookback penalty is \$80 million per percentage point by which the target reduction in daily youth smoking prevalence is missed. Current youth daily smoking prevalence among 13-17 year olds is about 15 per cent)Trends in 30-Day Prevalence of Daily Use of Various Drugs for 8th, 10th, 12th Graders;

<http://www.isr.umich.edu/src/mtf/pr9701g.html> accessed through University of Michigan Monitoring the Future page at <http://www.isr.umich.edu/src/mtf>). The source for the population statistics by age is the US Bureau of the Census, July 1995 Post-censual estimate of resident US population (http://www.census.gov/population/www/estimates/nat_90s_detail.html). If, for example, the youth daily consumption was reduced to 9.75 per cent, then the percentage reduction would be 35%. The percentage point difference between the actual and required 60% reduction would be (60% - 35%) = 25 percentage points. The surcharge would be 25 × \$80 million = \$2 billion. Therefore, the cap will be in effect until youth daily smoking is reduced by 35 per cent, or slightly more than half of the required 60% reduction.

There is also a rebate provision. The industry can recover 75 per cent of the surcharge if they can show that they acted in compliance with the deal, had taken "all reasonable" measures to reach the target, or deserved a rebate because of "other relevant evidence." The terms of this provision very vague cannot be modeled. The surcharge is paid according to market share of the firms in the industry, but the rebates are applied for individually, so it is reasonable to suppose that the individual companies will have more incentive to attempt to get a rebate than reduce youth smoking.

Some assumptions must be made about average lifetime smoking behavior and the market environment first. The following assumptions are made for the base case analysis.

Current price of a pack of cigarettes:	\$1.9
Current profit margin on pack of cigarettes:	17% [1]
Demand price elasticity of youth smoking:	0.6 [3]
Demand price elasticity of adult smoking:	0.4 [1]
Average age of onset of daily smoking:	16 [4]
Average length of adult smoking after beginning daily smoking as youth:	25 years [5]
Average pack per day smoked by adults:	1.4 (calculation shown below)
Total new smokers per year:	1.7 million
New youth smokers per year (age 13-17):	1.15 million (derivation given below)
Annual discount rate:	5%
Average price increase:	30 per cent (FTC model in Appendix A, Scenario 2)

The average pack per day smoked by each smoker is derived from annual US cigarette consumption divided and the proportion of current smokers using the following formula:

$$cig/day = \frac{US\ consumption\ cig/year}{365 \cdot (prevalence\ of\ current\ smokers)} = \frac{2403}{365 \cdot 0.245} = 27.9\ cig/day = 1.4\ packs/day$$

This is essentially the Department of Agriculture method, and it is probably a better estimate of average consumption over the lifetime of a smoker than self reported averages. (Data and methodology are from the CDC Office on Smoking and Health Internet site <http://www.cdc.gov/tobacco>.) The average number of 1.7 million new daily smokers per year is from Preliminary Results from 1996 National Household Survey on Drug Use, Highlights: Cigarette Use (<http://www.health.org/pubs/nhsda/96hhs/rtst1006.htm>), and the on rates of smoking initiation reported by Gilpin, et al. [6].

The calculation for rates of initiation are as follows: Rate of new daily youth smokers is 61.9 per 1000 person years of exposure for ages 12-17. Source: Table 46.--Estimated Number (in Thousands) of Persons who Began Daily Cigarette Use During Each Year 1962-1995, Their Mean Age at First Daily Use, and Annual Age Specific Rates of First Daily Use (per 1000 Person-Years of Exposure), Based on 1994-

1996 NHSDS (<http://www.health.org/pubs/nhsda/96hhs/artab060.htm#E8E89>), accessed through Preliminary Results from 1996 National Household Survey on Drug Use, Appendix 5: Detailed Tables (<http://www.health.org/pubs/nhsda/96hhs/httoc.htm>).

Applying this rate to total annual exposure of 13 to 17 year olds (i.e., the population in those age groups from US Census in Table A2), this results in the following calculation: $(61.9/1000) \times 18583831 = 1.15$ million new youth smokers per year.

Alternatively, Gilpin, et, al [6] give rates of initiation to smoking for groups of adolescents. For 10 to 12 year olds, the rate is 2 per cent per year. For 14 to 20 year olds the rate is 6.5 per cent per year. Applying the 2 per cent rate to the number of 13 year olds in 1995, and the 6.5 per cent rate to the number of 14 to 17 year olds gives 1.03 million new youth smokers per year. We will use the higher figure of 1.15 million new youth smokers per year derived above.

The price elasticity of demand of youth for cigarettes is controversial. Some studies have found it to be 1.0 or even higher, others think it is close to zero [3]. The measurement is difficult because youth smoking is illegal, youth themselves purchase only about half of the tobacco they consume, and new smokers often consume sporadically. We will evaluate the effects of the Lookback provision for the cases of elasticities of 1 and 0 for youth smoking. The analysis assumes that tobacco is addictive, and that the addiction process occurs over a period of one to three years from the time experimentation with tobacco begins. Therefore it is assumed that reduced consumption among youth not only reduces current consumption, but also reduces the percentage of youth who experiment with tobacco and then go on to become addicted adults. Therefore a demand elasticity of one will mainly effect sales by reducing the number of eventual addicted adult consumers. The principle effect of youth demand elasticity is to reduce the number of new smokers per year, not aggregate cigarette consumption.

This analysis ignores tax effects and secondary effects on profits. Both the penalty and the profits are liable to taxation, but there could be differential effects. This analysis is in terms of before tax profits and penalties.

Base Case

This paragraph steps through the calculations for the present value of a new smoker assuming a pack costs \$1.90; it is the value of a new smoker without the deal. It is presented only so that readers can follow the logic of the computations. An average smoker consumes 1.4 packs per day at \$1.90 pack, \$972 per year in sales and \$165 ($\$972 \times 17\%$) in profits. (The industry average profit is 17% of retail revenues [1].) This income stream produces an undiscounted sum over 25 years of \$24,289 in revenue and \$4,129 in profit. Discounted at 5 per cent per year the present value of the revenue is \$14,378 and profit is \$2,444. Assuming that there are 1.15 million new youth smokers per year, this results in an undiscounted revenue stream of \$27.93 billion, and profits of \$4.75 billion. These amounts are equivalent to \$279 million undiscounted revenue and \$47 million profit for each percentage point change in the number of new teen smokers. The discounted revenue is \$16.5 billion, and the discounted profit is \$2.81 billion, or \$165 million revenue and \$28 million profit for each percentage point of the annual cohort of new youth smokers. It is the last figure, the \$28 million profit for each percentage point of annual new smokers, which corresponds to the value of the penalty per percentage point by which the target level is missed.

By expressing the target at a percentage of the total base year smoking prevalence, and imposing the \$80 million penalty per percentage point missed, the Lookback confiscates all the expected future profit associated with that years sales in excess of the target. The undiscounted profit evaluated at the pre-settlement price seems to be only around \$30 million per percentage point, so the \$80 million figure is more

than is required.

A more relevant figure is the profit after all the settlement price increases are implemented. We assume a 30 per cent price average annual price increase for the base case. This price increase means that the cost of a pack of cigarettes goes from \$1.90 to \$2.47, and corresponds to the average price increase with a secular decline of 0.6 per cent/year, and passthrough of the \$10 billion up front payment amortized over ten years (see Table A22). Assuming that the average cost per pack (83% of the \$1.90 current retail price, assuming a 17% profit rate) stay the same, then the cost per pack including taxes, distribution and advertising costs is $\$1.90 \times 83\% = \1.58 . A price increase of 30 per cent increases the profit rate from 17% to 36%. Since this is a simulation of the expected profit from a new youth smoker, no payments or surcharges associated with the tobacco deal are included.

The average annual cohort of new youth smokers would fall by 207,000 each year, assuming a 0.6 price elasticity for youth initiation. The discounted present value of the lifetime revenue for each new annual cohort of teen smokers would now average \$18 billion, and the corresponding present value of profits is \$6 billion. This situation results in a discounted lifetime profit of \$64 million per percentage point of the target missed.

Given reasonable assumptions, the \$80 million penalty is a close approximation to one percentage point of the aggregate lifetime profit from a cohort of new youth smokers at the post average post-deal price, including the passthrough but ignoring the costs of the annual payments. When the cost of the settlement is included, the discounted lifetime profit is around \$60 billion. It will be shown below that reasonable variations in the assumptions can alter the discounted profit by 30 to 80 per cent.

Sensitivity Analysis of the Penalty

This section presents some simple sensitivity analyses for some realistic scenarios. Lifetime discounted present value of profits from a new youth smoker will be called “profit” in the rest of this section.

High Profit Case. The following changes are made to the base case assumptions for the high profit case:

Demand price elasticity of youth smoking:	0.0 [3]
Demand price elasticity of adult smoking:	0.2 [1]
Annual discount rate:	2.5%
Average price increase during first 10 years:	37.5%

This scenario assumes that price is relatively unimportant; the price elasticity of youth smoking initiation is zero, as is the price elasticity of youth consumption, and adult price elasticity of consumption is 0.2. A lower bound of 2.5% is used as the annual discount rate, which is close the long run yield on US Treasury Bonds. The price increase of 37.5 per cent is based on one of the scenarios in the FTC report [1], and it corresponds to a price increase passthrough rate of 125 per cent. The discounted revenue stream from an annual cohort of youth smokers is now \$29 billion, and the discounted profit is \$12 billion. This corresponds to a profit of \$115 million for percentage point of the target missed.

Low Profit Case. The following changes are made to the base case assumptions for the high profit case:

Demand price elasticity of youth smoking:	1.0 [3]
Demand price elasticity of adult smoking:	0.6

Annual discount rate:	7%
Average price increase:	25 %

This scenario assumes high price sensitivity; the price elasticity of youth smoking initiation is 1.0, as is the price elasticity of youth consumption, and adult price elasticity of consumption is 0.6. The upper bound of 0.6 for adult price elasticity is based on discussion in the Appendix A section Financial Analysis using Federal Trade Commission Model, subsection Sensitivity Analysis. An upper bound of 7% is used as the annual discount rate, which is recommended rate that the FTC uses for such estimates. The price increase of 25 per cent. This is the case in which the industry does not passthrough the \$10 billion up front payment, and there is no secular decline in demand. The discounted revenue stream from an annual cohort of youth smokers is now \$13 billion, and the discounted profit is \$4 billion. This situation corresponds to a profit of \$44 million for each percentage point of the target missed.

The conclusion is that \$80 million dollars is a reasonable approximation of the discounted present value lifetime profit of one percentage point of the annual cohort of new youth smokers when evaluated at price increases stipulated in the tobacco deal. The base case produced an estimate of \$60 million. However, reasonable variations in some of the parameters can change the profit substantially. Our high case produced a profit of \$115 million, and our low case produced a profit of \$44 million per percentage point of the annual cohort of new youth smokers.

Price per Pack of Noncompliance

This section calculates the cost per pack sold of noncompliance with the lookback provision. This scenario concerns only the 50 and 60 per cent reductions in youth daily smoking prevalence that are mentioned in the deal. The price effects alone will keep the total cost of noncompliance to about \$1 billion per year in years 5 and 6 when the target reduction is 30 per cent. The \$2 billion cap will be met in year 7 and following years when the larger target reductions are in force.

If youth sales do not decline at all and current sales volume is maintained, the \$2 billion cap will limit the impact of the Lookback provision. There is a Lookback proposal for both cigarettes and smokeless tobacco. Cigarettes account for about 86% of the sum of these to market segments, so presumably there would be \$2 billion 86% = \$1.72 billion cap on the cigarette industry. We will use \$2 billion to simplify calculations and get an upper bound to the price per pack.

Since the industry cannot track the sales of individual cigarettes, they will amortize the cost over all current sales, so noncompliance can be measured as cost per pack. Current sales are 23.66 billion packs per year. The cost of no change in youth daily smoking would only be 8.5 cents per pack before tax and 5.5 cents after tax, assuming a 35 per cent tax rate. If firms receive the full 75% good faith rebate the costs will be reduced to 2.1 cents before tax, and 1.4 cents after tax. These costs could easily be absorbed by the tobacco companies as a cost of doing business.

If youth demand elasticity is 0.6, then the total sales volume will eventually decline, so the industry will amortize the fixed, capped penalty of \$2 billion over a smaller sales base, and the cost per pack will eventually increase until the before tax cost is just under 10 cents per pack 30 years after the implementation of the deal. The fixed cap also produces a perverse incentive. Because total payments for exceeding the target are fixed, and this will be amortized over declining revenue as sales fall, the cost per pack is minimized by either doing nothing, or coming within 20 percentage points of the target. Under reasonable assumptions about the cost per pack of production, the industry can minimize the cost per pack by either doing nothing or meeting the target. The cap gives the industry added incentives to do nothing.

This analysis will look at the case of a 0.6 price elasticity [3], which is applied to both youth consumption and youth uptake. So a one per cent increase in price will decrease consumption by 0.6 per cent, and also decrease the rate of new youth daily smokers by 0.6 per cent. Then the passthrough price increases can have a significant impact on youth consumption, and significantly reduce the surcharges paid under the Lookback Provision. The lower pass-through price increase would be sufficient to meet 40% of the initial 30% youth daily smoking reduction and about 20% of the final 60% reduction. The higher increase would meet about two-thirds of the initial 30% reduction, and about a third of the final 60% target. Finally, it should be remembered that the elasticity estimates are controversial. It is unclear what effect, if any, price increases have on the uptake of youth smoking. In short, the price elasticity may only reflect total numbers of cigarettes smoked by youth and not the number of youth smokers.

Discussion

The main conclusion of the analysis is that the Lookback provision will not be very effective because the cap reduces the potential losses to less than 10 cents per pack. If companies can qualify for a substantial portion of the maximum 75 per cent rebate for good behavior, the cost of noncompliance will be trivial.

An additional problem is the fact that the penalties are based on estimates of current profit rates, which could change dramatically as industry economics change. There are also uncertainties associated with the selection of the discount rate used to derive the \$80 million per percentage point penalty.

Three other aspects of the provision present problems in the short run. The first is that the total incentives of the penalty have not been analyzed. The second is that the Lookback provisions do not take effect until five years into the settlement. The third is the measure used to index the prevalence of youth smoking, which is the average of daily smoking from 13 to 17 years of age.

The incentives of the Lookback provision penalty have not been thoroughly analyzed. There are two issues. One is the appropriate level of penalty from a public policy perspective (e.g., should there be a punitive component to the penalty). That issue will not be considered here. The second is whether confiscation of lifetime profit from a portion of the youth market provides enough incentive to change industry behavior. The industry will retain the profits from the portion of sales allowed under the targets. Changing marketing and retail merchandising strategies to prevent youth sales presents risks for the industry as a whole and for individual firms that may lose market share. The issue of whether the penalties provide enough incentive for the industry to meet the youth consumption targets has not been analyzed. The issue is especially important because of the likelihood that individual firms will be able to get some rebates for good faith effort, even if it may not be the full 75 per cent each year.

The delay of the Lookback presents a problem because this allows five years of youth smoking without any penalty. A delay would be reasonable if youth smoking can only be reduced incrementally each year, and the effects of an anti-youth program are cumulative. Then it would be reasonable to delay implementation so that the settlement provisions and tobacco industry programs would have the time needed to meet the goals. There is evidence that the prevalence of youth smoking can be changed quickly, perhaps within one year and certainly within two years. In this case the delay seems too long.

The use of the average level of daily use among 13 to 17 year olds is much more troublesome. The rationale for this measure is not explained, and may be liable to substantial manipulation. The rationale will be discussed first. If the point of the Lookback is to capture all the lifetime profits of each cohort of youth smokers, there are more direct indices than average daily smoking of all 13 to 17 year olds. A simple alternative would be to simply measure all individuals who are daily smokers, or regular users, or addicted by the time they reach their eighteenth birthday. It would be easier to define a measure that was a better measure

Table B1. Per cent of teen ever smokers experiencing withdrawal symptoms by frequency of smoking		
Days smoked in last month	Any withdrawal symptoms	Urge to smoke
0 days	44	22
1-14 days	66	37
15-29 days	88	71
30 days	93	82

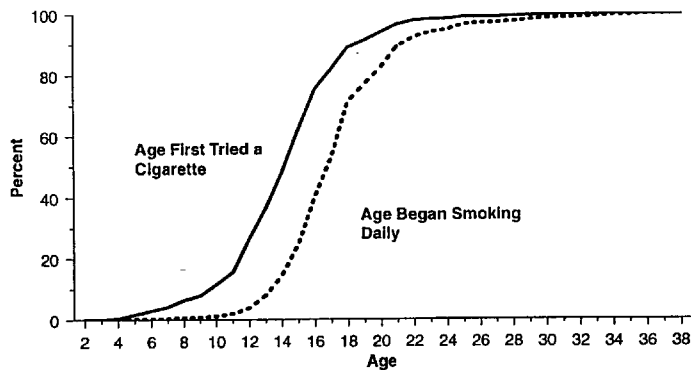
Source: Barker, D. [Barker, 1994 #45, Table 2, p. 748]

of probable lifetime smoking behavior. The measure chosen would be easier to measure precisely because it would be focused on a population with a larger percentage of daily users. It would eliminate the need for a double counting adjustment.

In fact, the use of an average of daily smokers over 13 to 17 year olds, when used with the double counting adjustment, may seriously underestimate the number of youth smokers who will eventually become addicted as adults. To show why, we will first argue that taking an average prevalence of daily smoking over age groups is conceptually mistaken. Taking an average assumes that the behavior of each age group is independent of the other groups. But it is known that addiction is a cumulative process that usually takes one to three years. Therefore the number of eighteen year old daily smokers is not independent of the number younger smokers. The number of seventeen year old smokers already contains most of the information needed to measure daily smokers in that cohort who started daily smoking at younger ages and at an earlier date. Taking an average merely takes the number that is really needed to measure the tobacco consumption of a well defined age group, and divides it by five. Then smaller numbers, also divided by five, are added it, but they do not make up for the underestimate.

It may be argued that the purpose of the Lookback is to discourage youth consumption generally, and too much focus should not be placed on the tobacco companies' recruitment of youths into the ranks of adult addicts. But if that is the case, then penalties should be levied on the total amount of youth tobacco consumption, rather than daily smokers. To focus on daily smokers implies you are attempting to measure advanced addiction which causes the youth smoker to continue smoking for the next 25 years even though he or she does not intend to do so. The development of an advanced addiction is not independent over time. If advanced addiction is to be measured, looking at daily addicts at seventeen will provide most of the information about advanced addiction at earlier ages. If the purpose of the measure is to identify a proportion of a unique and well defined cohort of the population that passes from youth to adulthood, then measuring addiction among seventeen year olds is the natural approach. During each calendar period, a unique and well defined group of people pass from being less than 17 to being 18 or over, and everyone who was addicted at a younger age will be almost certainly addicted at seventeen. Another flaw with the construction of the Lookback provision is that changes in the percentage of youth who smoke daily is not a good index of the percentage of all youth who smoke and will go on to become adult addicts because symptoms of addiction begin at less than daily consumption (Table B1). 71 per cent of those not counted in the Lookback measure (daily smoking) have an urge to smoke, and 88 per cent have experience some type of withdrawal symptom. Table B2 shows that high percentages of teen smokers are already trying to quit.

Figure 1. Cumulative Age of Initiation of Cigarette Smoking*-- United States, 1991



Source: National Household Survey on Drug Abuse
*Among persons 30-39 years old who have ever smoked daily



Figure 1 shows the relationship between age of first use and age when daily smoking began. Note that, while three quarters of new smokers smoke their first cigarette by age 15 (solid line), they do not become daily smokers until age 18 (dotted line). Thus, because the Lookback is structured to base the penalties on the rate of daily smokers under age 18, the deal “gives away” the 25% of addicted smokers who do not become daily smokers until after age 18. Moreover, the tobacco industry could meet the goals in reducing “teen” daily smoking by modifying its marketing strategies to shifting the two curves in Figure 1 to the right (i.e., older ages) by about 2 years. By delaying initiation and transition to daily smoking slightly, the

industry could meet the goals of the Lookback provision while having no long-term effects on the total number of smokers in the long run. Thus, a critical assumption behind the penalty is invalid, and the number of youth smokers who go on to develop an adult addiction may be seriously underestimated [7].

Nicotine is as addictive as cocaine, heroin and opiates [8]. This conclusion is supported by evidence which shows that the physiological mechanisms of these drugs are related. Almost as many frequent but non-daily smokers suffer withdrawal symptoms associated with addiction as daily smokers. Symptoms of addiction begin before the onset of daily smoking. Limiting the measure of youth smoking to daily smokers will allow the tobacco industry to comply with the lookback provision as currently written, but it will continue to recruit new adult smokers by addicting them as youths. All the industry has to do is increase the age of initiation until most daily smoking in newly addicted smokers occurs after their eighteenth birthday.

Conclusion

Table B2. Attempts to quit smoking by adolescents.			
	Percentage of respondents answering "yes"		
	1976-1979	1980-1984	1985-1989
"Do you want to stop smoking now?"			
Among those who smoked at all during the last 30 days	46.1	47.1	42.5
Among those who had smoked >= 1 cigarette/day during the last 30 days	46.1	47.2	43.9
"Have you ever tried to stop smoking and found that you could not?"			
Among those who smoked at all during the last 30 days	31.5	31.4	27.8
Among those who had smoked >= 1 cigarette/day during the last 30 days	38.5	41.6	39.4

Source: Monitoring the Future Study quoted in [Lynch, 1994 #18, Table 2-1, p.52]

The fatal economic problem with the Lookback provision is that the cap on maximum penalties is too low and the provision for abatements for “good behavior” are too generous. As currently designed it removes the lifetime profit associated with any youth sales in a given year above a certain target. The provision as written requires the transfer of lump sums which are essentially estimates of the net present value of future revenue streams

Unfortunately the measure of youth smoking prevalence (average daily smoking across age groups) is seriously flawed. It may be a serious underestimate of the appropriate measure, namely people who will go on to become addicted smokers. The measure, daily smoking prevalence, is also probably subject to manipulation in a way that could maintain the number of long-run addicted smokers by simply shifting the age of initiation up approximately two years.

References

1. U. S. Federal Trade Commission. Competition and the Financial Impact of the Proposed Tobacco Industry Settlement. Washington, DC: October, 1997, 1997.
2. Glantz SA. Removing the incentive to sell kids tobacco. A proposal. *Jama*. 1993;269:793-4.
3. Grossman M, Chaloupka FJ. Cigarette taxes, the straw to break the camel's back. *Public Health Reports*. 1997; 112:290-297.
4. Centers for Disease Control. The average age of initiation to daily smoking is from data on initiation to daily smoking.
5. Pierce JP, Gilpin E. How long will today's new adolescent smoker be addicted to cigarettes? *Am. J. Pub. Health*. 1996;86:253-256.
6. Gilpin EA, Lee L, Evans N, Pierce J. Smoking initiation rates in adults and minors: United States, 1944-1988. *Am. J. Epid*. 1994;140:535-543.
7. Stolerman IP, Jarvis MJ. The scientific case that nicotine is addictive. *Psychopharmacology*. 1995;117:2-10.
8. USDHHS. The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Health Promotion and Education, Office on Smoking and Health. 1988.

APPENDIX C: THE POLITICAL ENVIRONMENT

The Agreement has been referred to as a negotiated “Settlement” of the attorneys’ general and other lawsuits. The deal, however, went far beyond the scope of what could be negotiated as a part of any settlement. But the deal never purported to be a settlement in the legal sense of the word. State attorneys general do not have the authority to give the tobacco industry protection from any or all lawsuits — the industry’s primary objective in the negotiations. No litigant may negotiate on behalf of others without their explicit permission. Therefore it would require national legislation to implement the terms of the deal as negotiated. As a result, it is necessary to view the provisions of the Agreement as subject to the normal forces of the political process.

A central principle upon which the deal is based is that the ongoing litigation — particularly the cases brought by the Attorneys General — has put so much pressure on the tobacco industry that the industry is now willing to agree to compromise legislation that will serve the public health in order to achieve relief from the legal uncertainties it faces. In effect, the tobacco industry and public health community would go to Congress as partners in which the industry’s considerable political resources would be used to support a mutually agreed upon deal. Indeed, in the early weeks following the announcement of the deal on June 20, 1997, proponents of the deal were arguing that it should be implemented as negotiated.

Since then, there has been widespread criticism of the deal as originally negotiated. The Koop-Kessler Commission [1], which consisted of representatives from a wide range of public health groups, has outlined a much stronger set of policy goals for any federal tobacco control policy and President Bill Clinton has outlined a set of principles for any legislation that goes beyond the deal [2]. The American Cancer Society, perhaps the most influential organization supporting national legislation, has identified seven areas in which the deal is inadequate [3]. At the same time, the tobacco industry has repeatedly stated that it wants the deal enacted into law as written.

Historical Tobacco Industry Influence over the Political Process

Historically, the tobacco industry has dominated Congressional decision making on tobacco policy [4]. Moreover, the tobacco industry has a history of going to Congress with seeming public health compromises when it is under pressure from the public health community, yet emerging in a stronger position [5]. For example, in the mid-1960s the tobacco industry was under pressure from many states and localities and some federal agencies to restrict certain forms of advertising. It went to Congress and agreed to warning labels on cigarette packages (and, later, advertising). At the time, the public health community thought this was a victory. It soon became clear that the Federal Cigarette Labeling and Advertising Act of 1965 (Public Law 89-92) [5] provided the tobacco industry an additional defense in the product liability lawsuits. Because of the warnings on the sides of cigarette packs, the tobacco companies can say that consumers were adequately warned about the risks of smoking and willingly accepted those risks. This is a tradeoff that in hindsight proves to have been a poor one for the public health. Likewise, in 1971, when anti-tobacco counter advertising required by the FCC Fairness Doctrine was cutting into cigarette sales, the industry agreed to end broadcast advertising in Congress in order to get rid of the anti-tobacco advertisements [5]. Again, the public health community viewed this as a victory and now realizes that it was a defeat.

One of the main factors motivating opponents of the deal is that history is repeating itself. Indeed, the industry has long considered the option of trading some payment for damage done to public health via a “superfund” in exchange for Congressional limitations on liability [6].

Finally, the public health groups historically have not been not as well organized as the tobacco industry nor have they been as well funded. This lack of organization and low commitment of institutional

resources has placed the public health groups in a disadvantageous lobbying position.

Current tobacco industry influence in Congress

The tobacco industry maintains a substantial and growing presence in the Congress. In 1995-1996, Philip Morris was the single largest source of “soft money” contributions to political parties, giving \$2,520,518 to the Republicans and \$496,518 to the Democrats. In total, tobacco interests gave more than \$5 million to the Republicans and nearly \$1 million to the Democrats [7]. In 1997, the tobacco companies have increased their lobbying presence as a result of the prospects for a deal in Congress [7].

In addition, the tobacco industry has shown its influence by including provisions which would restrict FDA money for enforcement of the recent tobacco control provisions. It also was able to include in the 1997 session a budgetary provision which would allow it to deduct from any future tobacco legislation the impact of a tobacco tax increase included as a part of the budget. Each of these provisions was later rescinded.

The fact that the provisions were easily rescinded indicates to supporters of a legislative solution a significant change in the federal politics of tobacco. Nevertheless, the fact that the provisions were included in the first place indicates the tobacco industry still holds a great amount of lobbying influence. The balance between the power of the tobacco industry and the public health groups has clearly shifted, but the power of the tobacco industry should not be underestimated. Furthermore, as any complicated legislation evolves and accommodations are made for special interests, the public health interest may be undervalued as just one more special interest. Similarly, the more complex the legislation the more room that there is for special provisions which could favor the tobacco industry. As experience in the states has shown, the tobacco industry will often influence legislation in subtle ways which effectively undermine the usefulness of the legislation [8]. These dynamics must be considered when evaluating any tobacco control proposal to shield it from such influences.

State vs. Local Authority

There are risks inherent in any national approach to tobacco control. For example, a federal deal would likely result in the preemption of state and local tobacco control activities. Experience in regulating public health issues related to tobacco has shown that tobacco control activities are most effective on the state and local levels and that federal approaches are more subject to capture. The theoretical basis for this is fourfold. First, many believe that tobacco control is the result of social change and that social change is better effectuated on a grassroots level [9]. Second, in developing a national solution, policy-makers will moderate towards the least acceptable alternative for an entire nation, a middling solution. This will preclude more progressive cities and states from adopting more stringent tobacco control measures. Third, the presence of a federal regulation or law can often create a complacency in a given area of the law. Where the federal government has regulated, cities and states can be lulled into a false sense that no additional regulatory efforts need to be taken. Fourth, the tobacco industry has shown remarkable resiliency in adapting its strategies to fit within the established regulatory structure. For example, it has adapted new marketing techniques to replace those which are prohibited. It has developed direct marketing tools and sophisticated advertising methods to appeal to their target populations. States and localities are better able to react quickly and counter the tobacco industry’s efforts. Replacing state and local activity in the context of tobacco control will weaken tobacco control efforts.

References

1. Koop CE, Kessler DA. Final Report of The Advisory Committee on Tobacco Policy and Public Health. The Advisory Committee on Tobacco Policy and Public Health. July, 1997, 1997.

2. Clinton WJ (The White House, Office of the Press Secretary). Remarks by the President on Tobacco Settlement Review. September 17, 1997, 1997.
3. ACS. Constitutional Issues in Proposed Tobacco Settlement. Washington D.C.: American Cancer Society. 1997.
4. Fritschler AL. *Smoking and Politics: Policymaking and the Federal Bureaucracy*. Englewood Cliffs, New Jersey: Prentice-Hall. 1975.
5. USDHHS. Reducing The Health Consequences of Smoking. 25 Years of Progress. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic disease Prevention and Health Promotion, Office on Smoking and Health. 1989.
6. Glantz SA, Barnes DE, Bero L, Hanauer P, Slade J. *The Cigarette Papers*. Berkeley, CA: University of California Press. 1996:219-224.
7. Abramson J, Meier B. Tobacco Braced for Costly Fight. *The New York Times*. New York City. December 15, 1997: .
8. Siegel M, Carol J, Jordan J, Hobart R, Schoenmarklin S, DuMelle F, Fisher P. Preemption in Tobacco Control: Review of an Emerging Public Health Problem. *JAMA*. 1997;278:858-863.
9. Glantz S. Achieving a smokefree society. *Circulation*. 1987;76:746-752.

APPENDIX D: PUBLIC HEALTH BENEFITS OF THE DEAL

The primary public health benefits of the deal are a series of tobacco control measures that, before the explosion of litigation against the tobacco industry, would have been considered major steps forward by US standards. These benefits include:

- Codification of FDA authority over tobacco
- Increased advertising and marketing restrictions
- Improved cigarette warning labels
- Increased measures to limit youth access to tobacco
- Licensing of retail tobacco product sellers
- Mechanisms to encourage innovation into safer products
- Funding for national anti-tobacco counter advertising
- National standards regarding environmental tobacco smoke

Codification of FDA Regulatory Authority

The Agreement provides for increased regulatory supervision over the tobacco industry. This supervision is to be largely supervised by the Food and Drug Administration pursuant to its powers under the Food Drug and Cosmetic Act (21 U.S.C. § 301 et seq.). Within Title I of the deal, are the majority of the provisions related to FDA authority. The deal both specifies some actions which the FDA must make pursuant to its authority and places restrictions on how it can utilize its authority. For example, the provisions of the deal would operate only as specified for the first five years and the FDA cannot change them except for extraordinary circumstances.

Section E of Title I describes the regulatory regime under which cigarettes and smokeless tobacco products would be governed. The advantages of codifying the authority to regulate the cigarettes in the FDA arise from the belief that the FDA can combine both the health and technical expertise to supervise a product such as tobacco. In addition, with the scientific evidence confirming the pharmacological properties of nicotine, it is reasonable to treat nicotine as a drug and cigarettes as a drug delivery device. Furthermore, the FDA has already asserted this authority and begun the process of regulating tobacco products [1]. By codifying the FDA jurisdiction, the deal would remove the threat that an appeals court, or Congress itself, could remove the jurisdiction to regulate nicotine from the FDA.

A difficulty with having the FDA regulate tobacco is that tobacco is not a traditional medical device or drug. Drugs and medical devices are intended to improve the health of the consumers when used as intended. Tobacco products do not provide health benefits. As a result it is unclear what difficulties regulating a known hazardous product will have on the regulatory functioning of the FDA.

Jurisdiction

Sections E(2) and E(3) of Title I identify that tobacco will be regulated as both a drug and as a medical device, classified in a new subcategory of Class II medical devices and that the FDA will be able to regulate tobacco products. Class II medical devices are devices regulated by the FDA which are deemed necessary to need “special controls” in order to be regulated effectively.

The current FDA regulations were issued pursuant to the general authority of the FDA to regulate restricted medical devices. The FDA had already assumed jurisdiction over tobacco as both a drug and a medical device. It chose, pursuant to its own authority over combination products which are both drugs and devices, to regulate the product as a device. This authority was upheld by the United States District Court for

the Middle Court for the Middle District of North Carolina Greensboro Division (*Coyne Beahm, Inc. et al v. United States Food and Drug Administration*, case number 2:95CV00591, April 25, 1997). The FDA intentionally did not classify tobacco products as a particular form of medical device.

Although a Class II classification may prove reasonable treating tobacco products with special controls, there is no obvious benefit of legislating this classification rather than leaving this decision in the hands of the FDA. In addition, it is not clear what effect classifying tobacco products in a new “subcategory” of Class II medical devices is intended to mean and what effect that will have on the regulatory process.

FDA Authority

Subparagraph a of Title V set out the regulatory authority of the FDA. It gives the FDA authority over all products covered by the deal sold in U.S. commerce, but sustains the current regulatory authority of the Bureau of Alcohol Tobacco and Firearms, the Federal Trade Commission (except as to testing of tobacco products) and the United States Department of Agriculture.

The definition of tobacco products which will govern the FDA regulatory actions is that which is currently used by the FDA in its regulatory regime. This is:

(a) Cigarette means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) Cigarette tobacco means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

....

(i) Smokeless tobacco means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

(21 C.F.R. Section 897.3)

Note that this definition does not include all forms of tobacco products, such as cigars. Thus, legislation modeled on the deal could exempt cigars, a small but rapidly growing segment of the tobacco market.

The FDA authority is limited to domestic products. This is an abdication of America’s responsibility to global health issues. As tobacco companies increase their international market sales, the health problems related to tobacco will increase outside the US [2].

In addition, simply granting the authority in the FDA to regulate the industry will not, by itself, ensure effective regulation. The FDA may be vulnerable to influence by either political forces or by the industry. Even assuming that the money provided in Title VII(a)(2) for the enforcement of FDA programs is protected from the uncertainties of the legislative process, there are substantial ways in which the FDA can be undermined. First, restrictions could be placed on the FDA's actions, such as limiting what programs the FDA could use its money for, or by not providing adequate funding for the existing FDA programs. Second, the FDA's actions will be subject to intense political scrutiny. The office of the Commissioner is a highly politically charged office which is only as strong as the political process allows. Third, the industry could work through official and unofficial channels to influence agency behavior.

What follows is a brief summary of the most important of the public health programs contained within the deal. From these summaries it is clear that the deal attempts to implement a broad range of programs, but each of the programs is far less than ideal. For a more detailed analysis of each of the individual programs refer to the briefing papers.

Performance Standards

As part of its general regulatory authority the FDA will be able to regulate the content of tobacco products. Section E(3) of Title I identifies that the FDA will be able to require product modification including the regulation of nicotine, and shall be able to establish "Performance Standards" for tobacco products.

The authority under this section is intended for medical devices for which the FDA can pursuant to 21 U.S.C. Section 360d(a)(2)(a) "provide reasonable assurance of its safe and effective performance." Tobacco products cannot be made safe, so this authority is at best ambiguous. Trying to regulate a hazardous product in a scheme that is designed to regulate safe products will create conflicts and ambiguities. The drafters of the deal recognized some of these ambiguities by identifying that the FDA would have this authority despite other provisions in the FDCA which tobacco products would violate by their nature. For example, the deal is to take effect despite: 21 U.S.C. Section 360f which allows the FDA to ban a device which "presents substantial deception or an unreasonable and substantial risk of illness or injury"; Section 352(j) which deems a product misbranded, and subjects the manufacturer to penalties if the product is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"; and Section 360h(e) which allows the FDA to recall a product if "the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences." Under these standards, tobacco products should be banned, recalled, and the manufacturers cited for misbranding them, which is clearly not envisioned by the deal. The result of these conflicting standards, i.e. regulating a hazardous product in a regime intended to regulate helpful products, may force the FDA to restrict its regulatory powers.

FDA ability to require tobacco products to meet performance standards

Section E(5) of Title I outlines the authority of the FDA to regulate the performance standards of tobacco products pursuant to its authority under 21 U.S.C. 360d. Subparagraph a holds that for the first twelve years after the deal is in place the Agency showing "substantial evidence" and after satisfying other procedural safeguards, can adopt performance standards which would modify existing tobacco products (including the reduction of but not the elimination of nicotine) and a) will result in the significant reduction of health risks to consumers, b) is technologically feasible and c) will not result in the creation of a significant market for contraband. Sub-Subparagraph a also requires the appointment of a Scientific Advisory Committee to look at the effects of nicotine levels, and within three years the "tar" levels of cigarettes must be below 12mg.

Sub-Subparagraph B, establishes the regulatory standards for the time after the initial 12 year period. It keeps the same required findings of fact and establishes that the review standard for the findings would be governed by a “preponderance of the evidence” standard. It adds further procedural rights to the tobacco companies to challenge FDA actions and provides a 2 year phase in period for the elimination of nicotine.

The recognition that nicotine is addictive by the regulatory community has transformed the public’s and regulator’s understanding of tobacco use from a risky product to a drug problem. Some authorities have argued that by removing the addictive substance from the product, the product becomes less desirable and people will be able to quit and enjoy a healthier lifestyle. This provision of the deal guarantees that the FDA will have the authority to remove nicotine, but puts off the FDA’s ability to act on this idea for at least 12 years. In addition, this limitation moderates the FDA authority so that the action will be phased in so the tens of millions of addicted smokers and the industry can adapt with the least amount of disruption. Finally, the standard of proof needed to be met by the FDA to regulate tobacco products is higher than that for regulating other products.

Restrictions placed on FDA authority to regulate performance standards

This section is one of the most controversial elements of the deal; it has received widespread criticism. It is drafted in such a manner that the tobacco companies are gaining special regulatory treatment by the placement of restrictions on FDA’s authority. The fact that these provisions are restrictions can be seen by the fact that these provisions are inconsistent with the general grant of FDA authority provided in Section E(3) to Title I of the deal.

Some of the restrictions placed on FDA authority include: 1) the FDA cannot prohibit the sale of the cigarette in its “basic form”; 2) the deal places extraordinary procedural barriers on the Agency before it can adopt performance standards for tobacco products; 3) the regulatory standards for review are heightened from the normal process, which gives special treatment to the tobacco industry; 4) the specific restriction on nicotine reduction ties the FDA’s hands dramatically; and 5) the deal provides that the FDA will need to make burdensome findings of fact before it can eliminate harmful constituents from tobacco products.

Good Manufacturing Practices

Another regulatory power that the deal purports to give the FDA is the ability to regulate the manufacturing practices of the tobacco companies. Section E(6) of Title I would have the FDA regulate the manufacturing practices of the tobacco industry, in a manner similar to other FDA-regulated manufacturers. This provision like many of the others, simply confirms FDA-authority which already exists, as assumed by the FDA. Although the FDA has not currently utilized this authority, because tobacco products are considered drugs and medical devices, it is reasonable to expect that the tobacco companies as manufacturers of the devices would be subject to the registration and supervision requirements contained within 21 U.S.C. Section 360d. Furthermore, even if such codification of the FDA authority is necessary, it is redundant to include a special provision granting FDA authority over the manufacturing practices of the industry in an additional section of the Agreement.

Disclosure of Hazardous Constituents of Cigarettes

The deal, within Section F of Title I, also includes a description of the FDA’s ability to require the tobacco companies to provide evidence of the safety of and disclose the non-tobacco constituents of tobacco products. This provision places great restrictions on FDA authority. First, the procedure by which additives are deemed to be safe is written to benefit the tobacco industry by providing them more than ample time to develop a record and the FDA inadequate review time to review the science. Second, the definition of what

tobacco companies need to test for favors the tobacco industry by limiting the hazards from tobacco itself. Third, the testing and disclosure requirements only extend to constituents added in the manufacturing process, not to all processes associated with the production such as growing and curing. Fourth, the public disclosure requirements may preempt the ability of states to pass stronger laws.

Increased Advertising and Marketing Restrictions

The Agreement also makes specific proposals for regulating the tobacco industry's marketing and advertising practices. For example, Section A of Title I of the Agreement embraces much of the restrictions on marketing and advertisement contained in the FDA rule as promulgated, 61 Fed. Reg. 44396 (August 28, 1996). The deal would also expand on the FDA provisions by banning outdoor advertisement, limiting the content of advertisements, banning Internet advertisement, and restricting tobacco sponsorships, product placement, and requiring disclaimers on products identified as "light" or "low tar".

As is identified in the deal, many of the proposed benefits are already embodied in the current FDA regulations or could be. It is also likely that tobacco imagery and marketing would remain ubiquitous throughout the country even if the deal is implemented. In addition, many of these marketing restrictions are being obtained in the individual state settlements.

Improved Cigarette Warning Labels

Another regulatory control specified in the deal is improved tobacco warning labels. Section B of Title I of the deal would amend the warning labels on cigarette packages and advertisements as well as those for smokeless tobacco products. The warnings would be more explicit and occupy a larger percentage of the pack of cigarettes and advertisements than is now the case. In addition this section would place the testing of cigarettes for tar and nicotine content into the hands of the FDA. The FDA could also require that the labels disclose the nicotine and tar contents of cigarettes. There is also a clause which would allow for the disclosure "by other means" of other constituents. Presumably this last requirement is included as a mode for distributing the information obtained in subsection F of Title I.

The advantages to the new warning and disclosure system is that it will more clearly define the risks inherent in the use of tobacco products. Current warnings are incomplete and worn out [3]. There is a concern, however, that the warnings may prove to have a limited effect on smoking rates. Multiple surveys have shown a general awareness of the hazards of tobacco use [3]. There is also current research which indicates that this information has not been translated into personal knowledge of the effect of smoking on ones life expectancy [4].

Increased Measures to Limit Youth Access to Tobacco

Another specific regulatory control specified in the Agreement is improved measures to restrict youth access to tobacco products. Section C of Title I codifies much of the FDA rules. In addition, the deal would go beyond the current FDA rule by banning all vending machine sales and restricting self-service displays of cigarettes to adults only locations. (The state settlements have implemented similar restrictions.)

The restrictions put forward are already a part of the FDA program or readily could be. In short, there is no need for the deal to accomplish these objectives. There is also a question as to whether this proposal reflects a good investment of resources. There is not good evidence that youth access programs reduce teen smoking prevalence or consumption [5].

Licensing of Retail Tobacco Product Sellers

The deal also provides for a national licensing program for tobacco retailers. Section D of Title I would mandate minimum standards by which states would institute licensing schemes for tobacco retailers with specific penalties for violations. There would be comparable licensing schemes for entities under federal jurisdiction and Indian lands.

By requiring a licensing scheme it will be easier to control and supervise those with the direct control over the distribution of cigarettes. By having certain and guaranteed penalties, retailers will know the risks to violating the laws and will be given the necessary inducements to enforce the laws. Moreover, by including Indian tribes in this and other regulations under the deal, the authors have taken into consideration a specially vulnerable population and insured against a possible loophole in the tobacco distribution scheme.

The licensing scheme as designed in the deal presents certain problems. First, although the deal identifies that it would promote a national “minimum standard” it is not clear whether this would in effect preempt state licensing schemes which currently exist. It appears that the civil sanction scheme in particular will be mandatory and not allow for stronger local sanctions. Second, the licensing scheme is unlikely to induce distributors to comply with the terms of the deal.

Mechanisms to Encourage Innovation Into Safer Products

The Agreement also provides mechanisms for the FDA to move the market towards safer products. Section E(4) of Title I creates incentives for the introduction of less hazardous tobacco products to the market by requiring the disclosure and cross-licensing of such technology. The FDA is also given the authority to require that such products be brought to market.

Despite past failures [6] at a harm reduction strategy (so-called “safer cigarettes”), the idea of alternative nicotine delivery devices or less hazardous cigarettes has reemerged as a serious issue for debate within the public health community. If one assumes static consumption rates and technology that reduces the danger of cigarettes by 50%, close to a quarter million lives could be saved each year. Even with declining consumption, offering people who continue to smoke less dangerous products, illness could be avoided and lives saved. At the same time, the experience of the “tar wars” of the 1950's and 1960's and the experience with filter cigarettes showed that many people continued smoking cigarettes because they believed they were safer, when, in fact, the dangers persisted. Past experience indicated that the net effect of these earlier “improvements” was negative for the public health because any slight benefit by reducing the toxicity of an individual cigarette was overwhelmed by the impact on overall smoking rates and cigarette consumption [3]. Nevertheless, there is still the possibility of delivering nicotine in a less dangerous manner. By providing the FDA with the authority to act as repository of the developed technology and as a conduit for that technology to find its way to the market, may improve the likelihood that safer technologies will penetrate the market and improve competition into safer products.

Funding for National Anti-tobacco Counter Advertising

Counter advertising is a proven element of an effective tobacco control program [7]. The deal provides funding for such a program and attempts to insulate it from political interference.

National Standards Regarding Environmental Tobacco Smoke

The deal also provides specific provision to limit people’s exposure to secondhand smoke. Title IV of the Agreement presents a national program to significantly reduce exposure to secondhand tobacco smoke by restricting smoking in workplaces. Smoking would be restricted to areas which were ventilated outside

and maintained at a negative pressure to adjoining areas, with exceptions made for the hospitality industries.

The adverse health effects due to exposure to secondhand tobacco smoke are well documented, resulting in approximately 53,000 deaths a year and extensive morbidity, particularly among children [8-11]. By restricting smoking in public places, this deal will help reduce this morbidity and mortality. Furthermore, this deal probably protects the rights of states and localities to pass more extensive regulations.

The greatest strides towards clean indoor air has been occurring at the local, and, to some extent, the state level [12,13]. There is the concern that many localities and states, which might have otherwise passed stronger legislation will fail to act on the impression that the federal standard is sufficient. The experience in California after it passed a reasonably strong, but preemptive, state smoke free workplace law supports this view [14]. There is an advantage obtained by the process of educating a community and community leaders about the benefits of restricting secondhand tobacco smoke and involving them in the tobacco issue generally, which would be lost with the passage of federal legislation. When California passed its preemptive smoke free workplace law, community organizing around issues on youth access also fell off because the motivation of local community coalitions to form over secondhand smoke was dissipated [14].

One of the failures of the secondhand smoke regulations in the deal are that they fail to effectively address all workplaces. Workers in hospitality industries suffer the greatest exposures to secondhand smoke [15,16] and the greatest lung cancer rates in nonsmokers [15]. This will also restrict the ability of individuals who wish to both maintain a healthful lifestyle and visit any of the hospitality industries. Furthermore, there is no reason to exclude these industries. The arguments for allowing this exception is that otherwise the hospitality industries will suffer economically [17-21]. This argument has repeatedly been shown to be wrong [19,20].

In addition, it is not clear that the deal represents an improvement over the status quo. For example, OSHA is currently reviewing and preparing to issue final regulations governing secondhand tobacco smoke which are more restrictive than the terms of the deal [22]. In addition, community action has historically made rapid progress in this area and it could again [13]. Moreover, with the mushrooming scientific evidence on the dangers of secondhand smoke so clearly established the regulatory environment is ripe for passing restrictions on environmental exposures.

References

1. Food and Drug Administration. Regulations restricting the sale and distribution of cigarettes and smokeless tobacco products to protect children and adolescents. . *Federal Register*; August 11, 1995:41314-41451.
2. Peto R. Smoking and death: the past 40 years and the next 40. *BMJ*. 1994;309:937-939.
3. USDHHS. Reducing The Health Consequences of Smoking. 25 Years of Progress. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic disease Prevention and Health Promotion, Office on Smoking and Health. 1989.
4. Schoenbaum M. Do smokers understand the mortality effects of smoking? Evidence from the Health and Retirement Survey. *American Journal of Public Health*. 1997;87:755-759.
5. Rigotti NA, DiFranza JR, Chang Y, Tisdale T, Kemp B, Singer DE. The Effect of Enforcing Tobacco-Sales Laws on Adolescent Access to Tobacco and Smoking Behavior. *New England Journal of Medicine*. 1997;337:1044-1051.
6. Glantz SA, Barnes DE, Bero L, Hanauer P, Slade J. *The Cigarette Papers*. Berkeley, CA: University of California Press. 1996:219-224.
7. Siegel M, Biener L. Evaluating the Impact of Statewide Anti-Tobacco Campaigns: the Massachusetts and California tobacco Control Programs. *Journal of Social Issues*. 1997;53:147-168.

8. USDHHS. The Health Consequences of Involuntary Smoking. A Report of the Surgeon General. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control. 1986.
9. National Research Council Committee on Passive Smoking. *Environmental Tobacco Smoke: Measuring Exposures and Assessing Health Effects*. Washington, DC: National Academy Press. 1986.
10. Office of Environmental Health Hazard Assessment. Health Effects of Exposure to Environmental Tobacco Smoke. Sacramento, CA: California Environmental Protection Agency. September, 1997, 1997.
11. US Environmental Protection Agency. Respiratory health effects of passive smoking: Lung cancer and other disorders. US Environmental Protection Agency. 1992.
12. Glantz S. Achieving a smokefree society. *Circulation*. 1987;76:746-752.
13. Glantz S. Back to Basics: Getting smoke free workplaces back on track. *Tobacco Control*. 1997;6:164-167.
14. Macdonald H, Glantz S. The political realities of statewide smoking legislation: The passage of California's Assembly Bill 13. *Tobacco Control*. 1997;6:41-54.
15. Siegel M. Involuntary smoking in the restaurant workplace: A review of employee exposure and health effects. *JAMA*. 1993;270:490-493.
16. Gerlach KK, Shopland DR, Hartman AM, Gibson JT, Pechacek TF. Workplace smoking policies in the United States: Results from a national survey of over 100,000 workers. *Tobacco Control*. 1997; 6:199-206.
17. Samuels B, Glantz S. The politics of local tobacco control. *JAMA*. 1991;266:2110-2117.
18. Traynor M, Begay M, Glantz S. New tobacco industry strategy to prevent local tobacco control. *JAMA*. 1993;270:479-486.
19. Glantz S, Smith LR. The effect of ordinances requiring smoke-free restaurants on restaurant sales. *Am. J. Pub. Health*. 1994;84:1081-1085.
20. Glantz SA, Smith LR. The effect of ordinances requiring smokefree restaurants and bars on revenues: A follow up. *American Journal of Public Health*. 1997;87:1687-1693.
21. Susser M. Goliath and some Davids in the tobacco wars. *American Journal of Public Health*. 1997;87:1593-1595.
22. US Occupational Safety and Health Administration. Indoor Air Quality (Proposed Rule). *Federal Register*. 1994;59:15968-16039.

APPENDIX E: SUPPORTING LEGAL RESEARCH AND ANALYSIS

History of tobacco civil liability

The deal did not arise in a vacuum. Rather, it arose after the tobacco industry found itself subjected to an unprecedented number of lawsuits and public disclosures that exposed the industry to great risks. The litigation poses an enormous financial risk to the industry with the possible realization of large scale damage awards. The litigation also poses a public relations risk to the industry with the possible disclosure of industry wrongful behavior. These risks created an atmosphere in which the tobacco industry was willing to consider negotiating a solution. This recent wave of cases, can be organized into three main groups: product liability actions, nicotine dependency actions, and health care reimbursement actions.

Product Liability

The individual product liability cases are predicated on the theory that smokers were injured by tobacco products. This injury would be compensable if the tobacco companies failed to disclose the risks to smoking or because they created an inherently dangerous product. The traditional product liability actions, which were for many years viewed as unwinnable because of the tobacco industry's "efforts to blame the smoker", received a new life with the release of the private tobacco industry documents regarding the dangers of smoking and the addictiveness of nicotine. Plaintiff's attorneys are now able to point to the words of the tobacco industry and show how it was in possession of information which may have helped consumers make informed choices. By concealing this information, the tobacco industry allegedly prevented the smokers from making truly informed decisions regarding the dangers of smoking. By reducing the effectiveness of the assumption of risks defense, plaintiffs' attorneys have increased the tobacco industry vulnerability to personal injury claims. For example, in 1996 a jury awarded \$750,000 in a personal injury case against the tobacco companies [1].

There are also class action lawsuits which are extensions of the product liability lawsuits. They provide the additional benefits (for the plaintiffs) of pooling the risks for plaintiff attorneys and provide economies of scale for the prosecution of these lawsuits.

There are also private party and class action personal injury lawsuits which have been filed by non-smokers alleging harms related to second-hand smoke. The best known of these lawsuits, Broin, a class action filed by non-smoking flight attendants, recently settled.

Nicotine Dependence Lawsuits

The nicotine dependency lawsuits arose from a belief on the part of a consortium of plaintiff's attorneys that the tobacco companies should be held liable for addicting smokers. These actions were led by the national class action *Castano v. American Tobacco Company*, which was filed in federal Court in Louisiana. The plaintiffs demanded that the tobacco companies fund smoking cessation programs to counter their nicotine dependency. The Court of Appeals for the Fifth Circuit, decertified the plaintiff class because of the variation in state laws, which would have required the federal court to apply different legal standards to different class member depending on their state of residence (*Castano v. American Tobacco Co.*, 84 F.3d 734 (1996)).

Since the *Castano* class was decertified, however, there have been a number of nicotine dependency lawsuits filed within the state courts. Thus, by having the national class action decertified, the tobacco companies face nicotine dependency class actions for each state and territory of the United States. In the product liability actions, plaintiffs have had a difficult time succeeding because the tobacco industry has

maintained that smokers have been adequately warned about the risks of smoking and that the smokers willingly accepted those risks. Nicotine addiction presents a different case because it was not widely known, was specifically denied publicly by the industry, and intimates a lack of freedom of choice on the part of the smokers. These lawsuits in some measure deprive the industry of its strategy of blaming the smokers.

Health Care Reimbursement Suits

The increased health care costs due to smoking are in excess of \$50 billion a year [2]. The health care reimbursement actions seek to force the tobacco industry to internalize these health related costs of smoking which are currently being borne by others. Besides the 40 state attorneys general, medical reimbursement suits have also been filed by the Commonwealth of Puerto Rico, one private insurer, union groups, pension funds, foreign countries, and more than a dozen cities and counties.

Unlike the product liability actions which are based mostly on common law principles, the majority of these actions are based upon statutory claims, such as consumer protections acts, antitrust laws and racketeering laws. The industry, therefore, is more limited in the defenses that it can use. For example, in the traditional product liability case, the tobacco industry will claim that the smoker assumed the risk and shift the focus off the case onto the plaintiff. In an antitrust lawsuit the focus of the case will remain the tobacco industry and its allegedly wrongful behavior. In addition the plaintiffs in these cases have a greater ability to seek fines and penalties for the violations of the laws. Furthermore, the cases also seek a number of equitable remedies which may prove to be the most effective in terms of accomplishing public health goals by eliminating fraudulent or conspiratorial behaviors. Some of the specific relief sought includes the elimination of the Tobacco Institute and the Council for Tobacco Research, the disclosure of tobacco industry documents, the elimination of advertisement that is targeted towards youth, and the disclosure of tobacco ingredients.

Historically, the tobacco companies have overwhelmed small plaintiffs by burdensome and expensive trial tactics. These lawsuits present large plaintiffs who have sufficient resources to match the tobacco companies war of attrition tactics. The combined resources behind these cases combined with the new legal theories under which they are being brought seriously undermine the tobacco industry's traditional (and successful) defenses against litigation.

Pressures for Settlement

With the pressures of the litigation, the tobacco industry became interested in exploring ways to offset the risks of continuing the normal course of business. At the same time, many attorneys general and plaintiffs attorneys recognized the newfound weakness and sought the capitulation of the tobacco industry rather than the extended battle. This trend began with a negotiated settlement between Liggett Tobacco company and five of the suing states on March 15, 1996. (*Attorneys General Settlement Agreement With Brooke Group Ltd. And Liggett Group, Inc.*, March 15, by and among the State of West Virginia, State of Florida, State of Mississippi, Commonwealth of Massachusetts, and State of Louisiana (collectively, "Plaintiffs"), and Brooke Group Ltd. ("Brooke Group"), a Delaware corporation, and Liggett Group, Inc. ("Liggett"), a Delaware corporation.). The trend was accelerated with a deal entered into on March 20, 1997 between Liggett and 22 of the attorneys general who had sued the tobacco industry (*Attorneys General Settlement Agreement*, March 20, 1997). As a result of this settlement, Liggett executives made public statements in which they admitted that nicotine is addictive, smoking causes various diseases and that tobacco companies market their products to children. Liggett also agreed to assist the states in prosecuting their actions against the remaining tobacco companies and provide the states with confidential tobacco industry documents. Liggett also paid a modest sum of money to the states.

There are also other pressures which led the tobacco companies to explore the possibility of settling

the lawsuits. For example, many of the lawsuits also seek to recover “punitive” or “exemplary” damages from the tobacco industry. These damages are intended to punish the tobacco industry for its wrongful conduct and to deter such conduct in the future. Finally, many of the actions are based upon laws which have provisions for treble damages, such as many of the antitrust and racketeering laws.

There are also pressures on the plaintiffs which make the prospect of settlement appealing. For example, it has proven difficult and nearly impossible to bring a product liability case to trial. As for the other theories of relief, such as the health care reimbursement suits, the nicotine dependency suits, and the class action lawsuits, these are undeveloped areas of the law. There are no guarantees that the law will develop in the favor of the plaintiffs. In addition, even if the theories are ultimately refined and legal strategies are discovered after a period of time, some states (or other plaintiffs) will have already tried and lost their cases and with it the chance to encourage reform. A settlement removes that risk.

The process of litigation is also time consuming. From the time a complaint is brought until when a trial is conducted years will have passed. The appeals process adds even more time. A settlement can be enforced immediately, removing the delays. This would benefit both sides to the litigation. A settlement would also avoid the risks which are attendant with both sides if the Tobacco Companies are driven into bankruptcy.

These pressures to settle gave rise to the deal. They also gave rise to various settlements. For example, Mississippi, the first of the states to bring a Medicaid suit settled its case on July 3, 1997 for a large sum of money. (*In re Mike Moore, Attorney General ex rel, State of Mississippi*, State of Mississippi Tobacco Litigation in the Chancery Court of Jackson County, Mississippi, Cause No. 94-1429, Memorandum of Understanding July 2, 1997). Florida, the second of the state lawsuits scheduled to go to trial, also settled on August 25, 1997. (*Florida v. American Tobacco Co.*, Case No. 95-1466 AH, Court of the Fifteenth Judicial Circuit, Palm Beach Florida, Settlement Agreement 8/25/97). The terms of that settlement included both cash and the agreement of the tobacco industry to support various public health measures such as a ban on billboards and funding an anti-smoking education campaign. Texas, the third case scheduled to go to trial settled on (*Texas v. American Tobacco Co.*, Case No. 5-96CV-91, USDC E.D.Texas (Texarkana Division) Comprehensive Settlement Agreement and Release 1/16/98), for similar terms as Florida, but corrected some limitations on the anti-tobacco pilot program created by the settlement. Broin, the flight attendants class action lawsuit, also settled. In the Broin settlement (*Norma R. Broin v. Philip Morris*, Case No. 91-49738, Circuit Court of the Eleventh Judicial Circuit, Dade County Florida, Settlement Agreement, 10/9/97) the tobacco industry agreed to fund a large public health fund in return for the plaintiffs agreeing to decertify their class. In a California based lawsuit, Mangini, (*Janet C. Mangini v. R.J. Reynolds Tobacco Co. et al.*, Case No. 939359, Superior Court of the State of California County of San Francisco, Settlement and Consolidation Agreement, 9/8/97) RJReynolds settled by agreeing to eliminate “Joe Camel” from its advertisements and paying a small sum of money to various plaintiffs such as the City/County of San Francisco.

These settlements represent a major shift in tobacco industry litigation tactics. Until now, the industry made a point of never settling a case. There is an important distinction between these settlements, which are binding agreements between the parties, and the June 20 Agreement, which involved proposing a law that would be binding on people not involved in the litigation.

Litigation as a Public Health Tool

The estimates of damages caused by the tobacco companies are enormous, over \$100 billion a year in medical costs and lost wages alone [2]. In addition, there are claims in many of the lawsuits for punitive and other consequential damages. As a result, not every lawsuit will need to be successful in order to exert

the economic pressures on the tobacco industry which in turn create the incentives for it to improve its behavior. Indeed, despite the fact that punitive damages are rarely actually awarded, the possibility of punitive damages can be a powerful economic incentive to encourage responsible corporate behavior with regard to public health and safety.

It is likely, that some of the lawsuits will be successful and result in the fair reimbursement of real damages and provide injunctive relief. Success will beget success and will lead to additional lawsuits by individuals, and domestic and foreign governments. With the extraordinary amount of damages at stake in these lawsuits, only a few victories will be necessary to force the tobacco industry to internalize many of the costs currently borne by society (in particular medical costs, and costs of premature death). This will incent the tobacco industry to improve its behavior, and increase the costs of tobacco. Similarly, the cases seek injunctive relief to force the companies to change the manner in which they do business. As a result, a few victories is likely to reap large public health benefits.

In addition, there is a value to the litigation even if it proves to be unsuccessful. The tobacco industry is subject to a litany of lawsuits, exhausting discovery procedures, and continual public disclosure regarding its misdeeds. As a result, with the litigation the public health community is in a good position to demand substantial change in other venues, such as legislative bodies.

When measuring a settlement or other resolution which would sacrifice litigation as a public health tool, that solution should provide substantially similar public health benefits as to those provided by the litigation. It should also take into account the indirect consequences of resolving the litigation. For example, if the tobacco industry is given immunity from lawsuits, then what precedential value will this have for other industries.

Industry Admission of Wrongdoing

One last benefit of the civil liability system is that it provides a sense of justice. The wrongdoers are held accountable for their misdeeds. This is one of the benefits to the lawsuits against the tobacco industry, because many in the public health community argue that the tobacco companies must acknowledge or be held accountable for the harms caused by their products [3,4]. For example, an integral part of the Liggett settlement was that the CEO of Liggett had to admit publicly that tobacco causes cancer, heart disease, asthma and other diseases. That nicotine is addictive. That the tobacco companies marketed towards youth. And that they have had and withheld this knowledge for years.

In the deal, as in most settlements, the defendant does not admit to wrongdoing. This coupled with the fact that future lawsuits will be harder to bring against the tobacco industry means that it will be much harder to hold the tobacco industry accountable for its misdeeds. This can be seen as a failure of justice.

References

1. Annas GJ. Tobacco Litigation as Cancer prevention: Dealing with the Devil. *The New England Journal of Medicine*. 1997;336:304-308.
2. Bartlett JC, Miller LS, Rice DP, Max WB. Medical care expenditures attributable to smoking--United States, 1993. *MMWR*. 1994;43:469-472.
3. Burns D, Benowitz N, Connolly GN, Cummings KM, Davis RM, Henningfield JE, Shopland DR, Warner KE. What should be the elements of any settlement with the tobacco industry? *Tobacco Control*. 1997;6:1-4.
4. Warner KE. Editorial: Dealing with Tobacco -- The Implications of a Legislative Settlement with the Tobacco Industry. *American Journal of Public Health*. 1997;87:906-909.

APPENDIX F: TEXT OF JUNE 20, 1997 PROPOSED RESOLUTION OF TOBACCO ISSUES ("THE DEAL")

PROPOSED RESOLUTION

PREAMBLE

This legislation would mandate a total reformation and restructuring of how tobacco products are manufactured, marketed and distributed in this country. The nation can thereby see real and swift progress in preventing underage use of tobacco, addressing the adverse health effects of tobacco use and changing the corporate culture of the tobacco industry.

The Food and Drug Administration ("FDA") and other public health authorities view the use of tobacco products by our nation's children as a "pediatric disease" of epic and worsening proportions that results in new generations of tobacco dependent children and adults. There is also a consensus within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease and other serious adverse health effects.

The FDA and other health authorities have concluded that virtually all new users of tobacco products are under legal age. President Clinton, the FDA, the Federal Trade Commission ("FTC"), state Attorneys General and public health authorities all believe that tobacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents. These officials have concluded that because past efforts to restrict advertising and marketing have failed to curb adolescent tobacco use, sweeping new restrictions on the sale, promotion and distribution of such products are needed.

Until now, federal and state governments have lacked many of the legal means and resources they need to address the societal problems caused by the use of tobacco products. These officials have been armed only with crude regulatory tools which they view as inadequate to achieve the public health objectives with which they are charged.

This legislation greatly strengthens both the federal and state governments' regulatory arsenal and furnishes them with additional resources needed to address a public health problem that affects millions of Americans, including most importantly underage tobacco use. Further, it is contemplated that certain of the obligations of the tobacco companies will be implemented by a binding, enforceable contractual protocol.

The legislation reaffirms individuals' right of access to the courts, to civil trial by jury and to full compensatory damages. Resolution through the Act of potential punitive damages liability of the tobacco industry for past conduct is only made in the context of the comprehensive settlement proposed by the legislation. It is not intended to have precedential effect, nor does it express any position adverse to the imposition of punitive damages in general or as applied to any other specific industry, case, controversy or product and does not provide any authority whatsoever regarding the propriety of punitive damages.

Among other things, the new regime would:

- Confirm FDA's authority to regulate tobacco products under the Food, Drug and Cosmetic Act, making FDA not only the preeminent regulatory agency with respect to the manufacture, marketing and distribution of tobacco products but also requiring the tobacco industry to fund FDA's oversight out of ongoing payments by the manufacturers pursuant to the new regime ("Industry Payments").
- Go beyond FDA's current regulations to ban all outdoor tobacco advertising and to eliminate cartoon characters and human figures, such as Joe Camel and the Marlboro Man, two tobacco icons which the public health community has long assailed as advertising appealing to our nation's youth.
- Impose and provide funding out of the Industry Payments for an aggressive federal enforcement program, including a State-administered retail licensing system, to stop minors from obtaining tobacco products, while in no way preventing the States from enacting additional measures.
- Ensure that the FDA and the States have the regulatory flexibility to address issues of particular concern to public health officials, such as youth tobacco usage and tobacco dependence.
- Subject the tobacco industry to severe financial surcharges in the event underage tobacco use does not decline radically over the next decade.
- Empower the federal government to set national standards controlling the manufacturing of tobacco products and the ingredients used in such products.
- Provide new and flexible regulatory enforcement powers to ensure that the tobacco industry works to develop and introduce less-hazardous tobacco products," including, among other things, vesting FDA with the power to regulate the levels of nicotine in tobacco products.
- Require the manufacturers of tobacco products to disclose all previously non-public internal laboratory research and all new internal laboratory research generated in the future relating to the health effects or safety of their products.
- Establish a minimum federal standard with tough restrictions on smoking in public places with enforcement funding from the Industry Payments, while preserving the authority of state and local governments to enact even more severe standards.

Authorize and fund from Industry Payments a \$500 million annual, national education-oriented counter-advertising and tobacco control campaign seeking to discourage the initiation of tobacco use by children and adolescents and to encourage current tobacco product users to quit use of the products.

- Authorize and fund from Industry Payments the annual payment to all States of significant, ongoing financial compensation to fund health benefits program expenditures and to establish and fund a tobacco products liability judgments and settlement fund.

-- Authorize and fund from Industry Payments a nationwide program, administered through State governments and the private sector, of smoking cessation.

The sale of tobacco products to adults would remain legal but subject to restrictive measures to ensure that they are not sold to underage purchasers. These measures respond directly to concerns voiced by federal and state public health officials, the public health community and the public at large that the tobacco industry should be subject to the strictest scrutiny and regulatory oversight. This statute imposes regulatory controls, including civil and criminal penalties, equal to, and in many respects exceeding, those imposed on other regulated industries. Further, it imposes on tobacco manufacturers the obligation to provide funding from Industry Payments for an array of public health initiatives.

The sale, distribution, marketing, advertising and use of tobacco products are activities substantially affecting interstate commerce. Such products are sold, marketed, advertised and distributed in interstate commerce on a nationwide basis, and have a substantial effect on the nation's economy. The sale, distribution, marketing, advertising and use of such products are also activities substantially affecting interstate commerce by virtue of the health care and other costs that federal and State governmental authorities have attributed to usage of tobacco products.

Various civil actions are pending in state and federal courts arising from the use, marketing or sale of tobacco products. Among these actions are cases brought by some 40 state Attorneys General, cases brought by certain cities and counties, the Commonwealth of Puerto Rico, and other third-party payor cases seeking to recover monies spent treating tobacco-related diseases and for the protection of minors and consumers. Also pending in courts throughout the United States are various private putative class action lawsuits brought on behalf of individuals claiming to be dependent upon and injured by tobacco products. Additionally, a multitude of individual suits have been filed against the tobacco products manufacturers and/or their distributors, trade associations, law firms and consultants.

All of these civil actions are complex, slow-moving, expensive and burdensome, not only for the litigants but also for the nation's state and federal judiciaries. Moreover, none of those litigation's has to date resulted in the collection of any monies to compensate smokers or third-party payors. Only national legislation offers the prospect of a swift, fair, equitable and consistent result that would serve the public interest by (1) ensuring that a portion of the costs of treatment for diseases and adverse health effects linked to the use of tobacco products is borne by the manufacturers of these products, and (2) restricting nationwide the sale, distribution, marketing and advertising of tobacco products to persons of legal age. The unique position occupied by tobacco in the nation's history and economy, the magnitude of actual and potential tobacco-related litigation, the need to avoid the cost, expense, uncertainty and inconsistency associated with such protracted litigation, the need to limit the sale, distribution, marketing and advertising of tobacco products to persons of legal age, and the need to educate the public, especially young people, of the health effects of using tobacco products all dictate that it would be in the public interest to enact this legislation to facilitate a resolution of the matters described.

Public health authorities believe that the societal benefits of this legislation, in human and economic terms, would be vast. In particular, FDA has found that reducing underage tobacco use by 50% "would prevent well over 60,000 early deaths." FDA has estimated that the monetary value of its present regulations will be worth up to \$43 billion per year in reduced medical costs, improved productivity and the benefit of avoiding the premature death of loved ones. This statute, which extends far beyond anything FDA has previously proposed or attempted, can be expected to produce human and economic benefits many times greater than such existing regulations.

As part of this settlement, the tobacco companies recognize the historic changes that will be occurring to their business. They will fully comply with increased federal regulation, focus intense efforts on dramatic reductions in youth access and youth tobacco usage, recognize that the regulatory scheme encourages the development of products with reduced risk and acknowledge the predominant public health positions associated with the use of tobacco products.

[Source/precedent: FDA Rule]

Contents

Preamble page 1-5

Title I: Reformation of the Tobacco Industry page 8

A. Restrictions on Marketing and Advertising page 8

B. Warnings, Labeling and Packaging page 9

C. Restrictions on Access to Tobacco Products page 11

D. Licensing of Retail Tobacco Product Sellers page 12

E. Regulation of Tobacco Product Development and Manufacturing page 13

F. Non-tobacco Ingredients page 19

G. Compliance and Corporate Culture page 21

H. Effective Dates page 23

Title II: "Lookback" Provisions/State Enforcement Incentives page 24

Title III: Penalties and Enforcement; Consent Decrees; Non-Participating Companies page 26

A. Penalties and Enforcement page 26

B. Consent Decrees page 27

C. Non-participating Companies page 28

Title IV. Nationwide Standards to Minimize Involuntary Exposure to Environmental Tobacco Smoke page 30

Title V: Scope and Effect page 32

A. Scope of FDA Authority page 32

B. State Authority page 32

Title VI: Programs/Funding page 34

A. Up Front Commitment page 34

B. Base Annual Payments page 34

C. Applicability page 35

D. Tax Treatment page 35

Title VII: Public Health Funds From Tobacco Settlement As Recommended by The Attorneys General For Consideration by the President and the Congress page 36

Title VIII: Civil Liability page 39

A. General page 39

B. Provisions as to Civil Liability for Past Conduct page 39

C. Provisions as to Civil Liability for Future Conduct page 41

Title IX: Board Approval page 42

Appendices:

Appendix I: Warnings in Advertisements

Appendix II: Retail Tobacco Product Seller Penalties

Appendix III: Application to Indian Tribes

Appendix IV: Industry Associations

Appendix V: "Lookback"

Appendix VI: State Enforcement Incentives

Appendix VII: Restrictions on Point of Sale Advertising

Appendix VIII: Public Disclosure of Past and Future Tobacco Industry Documents and Health Research Page 8

TITLE I: Reformation Of The Tobacco Industry

Title I of the legislation would incorporate and expand upon FDA's recent regulation of nicotine-containing tobacco products.

The following rules would apply to all tobacco products sold in the U.S. (including all its territories and possessions, as well as duty-free shops within U.S. borders). The new regime would be allowed to operate as described below for five years. FDA would have authority to make revisions even within this period under extraordinary circumstances. Thereafter, the FDA would be authorized to review and revise the rules under applicable Agency procedures.

A. Restrictions on Marketing and Advertising

The advertising and marketing of tobacco products would be drastically curtailed, including in ways that exceed the FDA rule as originally promulgated and in ways that have previously been challenged on First Amendment grounds. As in the FDA rule the new regime would:

-- Prohibit the use of non-tobacco brand names as brand names of tobacco products except for tobacco products in existence as of January 1, 1995 (897.16(a)) (The citations in this and in the next section are to Part 897 of the FDA's tobacco regulations, 61 Fed. Reg. 44396 (August 28, 1996).

-- Restrict tobacco product advertising to FDA specified media (897.30(a)(1)-(2))

- Restrict permissible tobacco product advertising to black text on a white background except for advertising in adult-only facilities and in adult publications (897.32(a)-(b))
 - Require cigarette and smokeless tobacco product advertisements to carry the FDA-mandated statement of intended use ("Nicotine Delivery Device") (897.32(c))
 - Ban all non-tobacco merchandise, including caps, jackets or bags bearing the name, logo or selling message of a tobacco brand (897.34(a)).
 - Ban offers of non-tobacco items or gifts based on proof of purchase of tobacco products (897.34(b))
 - Ban sponsorships, including concerts and sporting events, in the name, logo or selling message of a tobacco brand (897.34(c))
- Further, building on and going beyond the FDA rule, the new regime would:
- Ban the use of human images and cartoon characters - thereby eliminating Joe Camel and the Marlboro Man - in all tobacco advertising and on tobacco product packages
 - Ban all outdoor tobacco product advertising, including in enclosed stadia as well as brand advertising directed outside from a retail establishment (modifies 897.30(a)(1) and extends 897.30(b))
 - Prohibit tobacco product advertising on the Internet unless designed to be inaccessible in or from the United States
 - Establish nationwide restrictions in non adult-only facilities on point of sale advertising with a view toward minimizing the impact of such advertising on minors. These provisions, which are detailed in Appendix VII, restrict point of sale advertising that was otherwise permitted in retail establishments by the FDA rule.
 - Ban direct and indirect payments for tobacco product placement in movies, television programs and video games
 - Prohibit direct and indirect payments to "glamorize" tobacco use in media appealing to minors, including recorded and live performances of music -- Without limiting the FDA's normal rulemaking authority in this area, require that the use, in both existing and future brand styles, of words currently employed as product descriptors (e.g., "light" or "low tar") be accompanied by a mandatory disclaimer in advertisements (e.g., "Brand X not shown to be less hazardous than other cigarettes"); exemplars of all new advertising and tobacco products labeling shall be submitted to FDA concurrently with their introduction into the marketplace for FDA's ongoing review.

[Source/precedent: FDA Rule; 21 C.F.R. 101.70]

B. Warnings, Labeling and Packaging

The federally-mandated warning labels on cigarettes were last changed in 1984. Since then a number of countries, including Canada and members of the European Union, have imposed new warning labels. Further, the Federal Trade Commission's methodology to measure the "tar" and nicotine yields of cigarettes has been criticized as producing misleading information.

1. The legislation, through amendments to the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, would mandate new rotating warnings, to be introduced concurrently into the distribution chain on all tobacco product packages and cartons, and to be rotated quarterly in all advertisements. For cigarettes, the warnings would be:

- "WARNING: Cigarettes are addictive"
- "WARNING: Tobacco smoke can harm your children"
- "WARNING: Cigarettes cause fatal lung disease"
- "WARNING: Cigarettes cause cancer"
- "WARNING: Cigarettes cause strokes and heart disease"
- "WARNING: Smoking during pregnancy can harm your baby"
- "WARNING: Smoking can kill you"
- "WARNING: Tobacco smoke causes fatal lung disease in non-smokers"
- "WARNING: Quitting smoking now greatly reduces serious risks to your health"

For smokeless tobacco products, the warnings would be:

- "WARNING: This product can cause mouth cancer"
- "WARNING: This product can cause gum disease and tooth loss"
- "WARNING: This product is not a safe alternative to cigarettes"

--"WARNING: Smokeless tobacco is addictive"

For cigarettes, the warnings would occupy 25% of the front panel of the package (including packs and cartons) and would appear on the upper portion thereof. The legislation would contain a grandfather provision for existing brands with flip-top boxes comprising less than 25% of the front panel. For smokeless tobacco products, the warnings would appear on the principal display panel (e.g., a band around the can for moist smokeless tobacco products) and would occupy 25% of the display panel. The warnings would be printed in line with current Canadian standards (e.g., 17 point type with appropriate adjustments depending on length of required text) and in an alternating black on white and white on black format. The size and placement of warnings in advertisements would follow the requirements set forth in the existing United Kingdom standards. As described in Appendix I, the warning text and, where relevant, "tar" and nicotine (or other constituent) yield information would occupy 20% of press advertisements.

Cigarette and smokeless tobacco product packages would also carry the FDA mandated statement of intended use ("Nicotine Delivery Device") on the side of pack.

2. The FDA would be required to promulgate a rule governing the testing, reporting and disclosure of tobacco smoke constituents that the Agency determines the public should be informed of to protect public health, including, but not limited to "tar," nicotine and carbon monoxide. This authority would be transferred from the FTC and would include the authority to require label and advertising disclosures relating to "tar" and nicotine, as well as disclosures by other means relating to other constituents.

[Source/precedent: Canadian warning regulations; FDA Rule; FDCA, 21 U.S.C. Sec. 360h, with conforming amendment in light of FCLAA]

C. Restrictions on Access to Tobacco Products Preventing youth access to tobacco products is a major objective of this legislation and the FDA Rule. Without preventing state and local governments from imposing stricter measures, the legislation would incorporate every access restriction of the FDA Rule, and more. As in the FDA Rule, the legislation would:

- Set a minimum age of 18 to purchase tobacco products (897.14(a))
- Require retailers to check photo identification of anyone under 27 (897.14(b)(1)-(2))
- Establish the basic requirement of face-to-face transactions for all sales of tobacco products (897.14(c))
- Ban the sale of tobacco products from opened packages (897.14(d))
- Establish a minimum package size of 20 cigarettes (897.16(b))
- Impose retailer compliance obligations to ensure that all self-service displays, advertising, labeling and other items conform with all applicable requirements (897.14(e))
- Ban the sampling of tobacco products (897.16(d))
- Ban the distribution of tobacco products through the mail, including redemption of coupons, except for sales subject to proof of age, with a review after 2 years by FDA to determine if minors are obtaining tobacco products through the mail (goes beyond 897.16(c)(2)(i))

Building on and going beyond the FDA Rule, the legislation would:

- Ban all sales of tobacco products through vending machines (goes beyond 897.16(c)(2)(ii))
- Ban self-service displays of tobacco products except in adult-only facilities. In all other retail outlets, tobacco products must be placed out of reach of consumers (i.e., behind the counter or under lock-and-key) or, if on the counter, not visible or accessible to consumers (goes beyond 897.16(c)(2)(ii))

[Source/precedent: FDA Rule]

D. Licensing of Retail Tobacco Product Sellers

The legislation would mandate minimum federal standards for a retail licensing program that the federal government and state and local authorities would enforce through funding provided by the Industry Payments. Any entity that sells directly to consumers - whether a manufacturer, wholesaler, importer, distributor or retailer - would require a license.

Elements of the licensing program would include:

- Mandating compliance with the Act as a condition to obtain and hold a license
- Penalties for violations (See Appendix II)
- Suspension or revocation of licenses (on a site-by-site basis) for certain violations (see Appendix II)
- A requirement that distribution of tobacco products for resale to consumers be made only to licensed entities
- Licensing fees to cover the administrative costs of issuing state licenses (all other costs covered as noted above)
- Comparable federal licensing programs (with federal enforcement) for military facilities, U.S. government installations abroad, and other U.S. territories and possessions not otherwise under the jurisdiction of the States (including duty-free shops within U.S. borders)

-- Comparable licensing programs to govern tobacco product sales on Indian lands (see Appendix III)

(Source/precedent: Various state laws governing sales of tobacco products and alcoholic beverages)

E. Regulation of Tobacco Product Development and Manufacturing

This legislation, for the first time, would impose a regulatory regime to govern the development and manufacturing of cigarettes and smokeless tobacco products, including FDA approval of the ingredients used in such products and imposition of standards for reducing the level of certain constituents, including nicotine.

Elements of the regulatory regime would include:

1. Tobacco products shall have the same definition as contained in the FDA Rule. Jurisdiction shall also cover Roll Your Own, Little Cigars, Fine Cut, etc.

2. Tobacco will continue to be categorized as a "drug" and a "device" under the Food, Drug and Cosmetic Act ("FDCA"). The Agency's authority to regulate the products as restricted medical devices" will be explicitly recognized and tobacco products will be classified as a new subcategory of a Class II device pursuant to 21 U.S.C. section 360c. FDCA shall apply to these products as provided by the Act and the amendments to FDCA contained herein.

3. The Class II classification shall permit FDA to require product modification of tobacco products, including the regulation of nicotine content, and shall provide that the sale of tobacco products to adults in the form that conforms to Performance Standards established for tobacco products pursuant to Section 514 ("Section 514") of the FDCA (21 U.S.C. Section 360d) shall be permitted notwithstanding 21 U.S.C. Sections 360f, 352(j) and 360h(e)

4. Reduced Risks Products

Products sold that an objective, reasonable consumer would believe pose less of a health risk:

-- Tobacco product manufacturers will be barred from making claims that could reasonably be interpreted to state or imply a reduced health risk unless the manufacturer demonstrates to FDA that the product scientifically does in fact "significantly reduce the risk to health" from ordinary tobacco products. Currently employed product descriptors such as "light" and "low tar" will be regulated as described in 1(A) above.

-- FDA would have to approve all health claims (direct or implied), as well as the content and placement of any such claims in advertisements, to prevent the public from being misled and to prevent the advertisement from being used to expand, or prevent the contraction of, the marketplace.

-- For "less hazardous tobacco products," FDA will be authorized to permit scientifically-based specific health claims and to permit exceptions to the advertising restrictions that apply to other products if FDA determines that such advertising would reduce harm and promote the public health. The FDA will promulgate a rule to govern how these determinations will be made.

-- The manufacturers will be required to notify FDA of any technology that they develop or acquire and that reduces the risk from tobacco products and, for a commercially reasonable fee, to cross license all such technology, but only to those companies also covered by the same obligations. Procedural protections will be built in to resolve license fee disputes, if the private parties cannot agree among themselves first. If the technology reported to the FDA is in the early development stages, the manufacturer will be provided confidentiality protection during the development process.

-- The Agency shall also have the authority to mandate the introduction of "less hazardous tobacco products" that are technologically feasible, after a formal rule making subject to the Administrative Procedures Act ("APA"), with the right of judicial review. In doing so, the Agency shall have the authority to mandate that a manufacturer subject to this Act who owns such technology (at such manufacturer's election) either introduce such products, or, at a commercially reasonable market rate, license such technology to a manufacturer who agrees to bring the technology to market in a reasonable time frame. In the event that no manufacturer or licensee introduces such "less hazardous tobacco products," within a reasonable time frame set by FDA, then the U.S. Public Health Service may produce either itself, or through a licensing arrangement, any such product.

-- The goal of any rule mandating the introduction into the marketplace of "less hazardous tobacco products" for which the technology exists is to guarantee that a mechanism exists to ensure that products which appear to hold out the hope of reducing risk are actually tested and made available in the marketplace and not held back.

5. Performance Standards

To further the public health, to promote the production of "reduced risk" tobacco products, and to minimize the harm to consumers of tobacco products by insuring that the best available, feasible safety technology becomes the industry standard, FDA will have the authority to promulgate Performance Standards pursuant to Section 514 that require the modification of tobacco products to reduce the harm caused by those products (including the components that produce drug dependence), provided that the standard shall not require the prohibition on the sale to adults of traditional tobacco products in the basic form as described in the August 28, 1996 FDA Rule at 61 Fed. Reg. at 44616 (to be codified at 21 C.F.R. Section 897.3).

Specifically:

A. For a period of no fewer than twelve years following the effective date of the Act, the product Performance Standards will be governed by the following: The Agency 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, based upon a finding that the modification: (a) will result in a significant reduction of the health risks associated with such products to consumers thereof, (b) is technologically feasible, and (c) will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the product safety standard. In determining the risk of the demand for a market in contraband products, the FDA shall take

into account the number of dependent tobacco product users and the availability, or lack thereof, of alternative products then on the market and such other factors as the Agency may deem relevant.

The authority to require such product modification can be exercised upon a showing of "substantial evidence," based upon an administrative record developed through a formal rule making subject to the Administrative Procedures Act, with the right of judicial review, and any such modification 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. In the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition.

Additionally:

-- Within one year of the effective date of this Act, the FDA shall establish a Scientific Advisory Committee to examine and determine the effects of the alteration of nicotine yield levels and to examine and determine whether there is a threshold level below which nicotine yields do not produce drug dependence and, if so, to determine that level, and also review any other safety, dependence or health issue so designated by FDA.

-- Separate from and without detracting from the Agency's authority under the requirements of the Section 514 Performance Standard noted above, effective three years from the date of enactment of this Act, no cigarette shall be sold in the United States which exceeds a 12 mg "tar" yield, using the testing methodology now being used by the Federal Trade Commission.

B. After the initial twelve year period, the Agency will be permitted to set product safety standards that go beyond the standards it is authorized to set pursuant to the above noted provisions and, if it does so, any such product Performance Standards shall be governed by the following: The Agency will be permitted to 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, (the elimination of nicotine or other harmful constituent shall not be deemed to violate the prohibition on the sale of traditional tobacco products to adults, even if it results in a reduction of the number of the consumers who use the tobacco products then remaining on the market), based upon a finding that: (a) the safety standard will result in a significant overall reduction of the health risks to tobacco consumers as a group, (this includes the reduction in harm which will result from decreased drug dependence from the reduction and/or elimination of nicotine from (a) those who continue to use tobacco products, but less often, and (b) those who stop using tobacco products), (b) the modification is technologically feasible, and (c) the modification will not result in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard. In determining the overall health benefit of a change, the Agency shall consider the number of dependent tobacco users then in existence, the availability and demonstrated market acceptance of alternate products then on the market, and the effectiveness of smoking cessation techniques and devices then on the market and such other factors as the Agency may deem relevant.

Given the significance of such an action, the Agency will be permitted to require the elimination of nicotine or take such other action that would have an effect comparable to the elimination of nicotine based upon a "preponderance of the evidence" pursuant to, at a manufacturer's election, a Part 12 hearing, or notice and comment rule making, with a right of judicial review. Any such action shall be phased in, and no such phase-in shall begin in less than two years, to permit time for a meaningful Congressional review pursuant to the current procedures of the Regulatory Reform Act of 1996. In the event a party subsequently files a petition seeking an administrative review of whether a modification has, in fact, resulted in the creation of a significant demand for contraband or other tobacco products that do not meet the safety standard and the FDA denies the petition, the petitioner shall have the right to seek judicial review of the denial of the petition. In any judicial review, the deference accorded to the Agency's findings shall depend upon the extent to which the matter at issue is then within the Agency's field of expertise.

6. Manufacturing Oversight

The legislation would subject tobacco product manufacturers to good manufacturing practice standards ("GMPs") comparable to those applicable to medical device manufacturers, food companies and other FDA regulated industries, but tailored specifically to tobacco products. In this regard there would be:

- Implementation of a quality control system (e.g., to prevent contamination)
- Inspection of tobacco product materials (e.g., to ensure compliance with quality standards)
- Requirements for proper handling of finished product
- Tolerances for pesticide chemical residues in or on commodities in the possession of the manufacturer; existing EPA authority and oversight is retained
- Inspection authority comparable to FDA's authority over other FDA regulated products, including the ability to enter manufacturing plants and demand certain records
- Record keeping and reporting requirements

Tobacco farmers will face no greater regulatory burden than the producers of other raw products regulated by the federal government.

[Source/precedent: FDA Rule; FDCA, 21 U.S.C. Sections 346a; 360]

7. Access to Company Information

-- The Act would ensure that previously non-public or confidential the files of the tobacco industry - including internal documents - are disclosed to FDA, private litigants The details of the arrangement are set forth in documents from health research and the public. Appendix VI II.

-- Any subpoena authority FDA has with respect to manufacturers of medical devices generally would also apply to tobacco product manufacturers.

F. Non-tobacco Ingredients

Currently, at the federal level, tobacco manufacturers are required only to submit aggregated ingredient information (not by brand or company) to

HHS for monitoring and review. Nor do tobacco products manufacturers currently disclose to consumers ingredients information for each of the tobacco products they sell.

The legislation would supersede the current often-criticized federal ingredient law and confirm FDA's authority to evaluate all additives in tobacco products. No non-tobacco ingredient could be used in manufacturing tobacco products unless the manufacturer can demonstrate that such ingredient is not harmful under the intended conditions of use. Further, the legislation would require the manufacturers to disclose to FDA the ingredients and the amounts thereof in each brand. In addition, it would require manufacturers to disclose ingredient information to the public under regulations comparable to what current federal law requires for food products, reflecting the intended conditions of use.

Under this proposed legislation:

-- Manufacturers would be required to provide FDA on a confidential basis a list of all ingredients, substances and compounds (other than tobacco, water or reconstituted tobacco sheet made wholly from tobacco) which are added by the manufacturer to the tobacco, paper or filter of the tobacco product by brand and by quantity in each brand. For each such item, the manufacturer would identify whether or not it believes that the item would be exempt from public disclosure under the legislation.

-- Manufacturers would be required to submit, within 5 years of the enactment of the Act, for each ingredient currently added to the tobacco product, a safety assessment, based on the best available evidence, that there is a reasonable certainty in the minds of competent scientists that the ingredient (up to a specified amount) is not harmful under the intended conditions of use. FDA shall promulgate applicable regulations within 12 months.

-- Within a statutory time assessment(s) in accordance within 90 days, FDA shall period FDA must review with the applicable standard; approve or disapprove an ingredient's safety, and if FDA takes no action, the ingredient is deemed approved. FDA may also challenge any manufacturer's assertion that an ingredient would be exempt from disclosure to consumers under applicable regulations comparable to what current federal law requires for food products.

-- New ingredients or use of current ingredients beyond the specified maximum amount are subject to a comparable process prior to use.

-- FDA would be required to protect as strictly confidential ingredient information not otherwise subject to public disclosure. If not subject to such disclosure, this information will be treated as trade secrets under federal law, exempt from FOIA requests and protected by procedures which shall include the designation of an agent who will store it in a locked cabinet, maintain a record of any person who has access to the information and require a written confidentiality commitment from any such person.

-- Manufacturers would be required to disclose to the public ingredients information pursuant to regulations comparable to what current federal law requires for food products. During an initial 5 year period, each ingredient that would be exempt from disclosure under the food regime would be presumed not to be subject to disclosure unless FDA disproves its safety. However, manufacturers would be required to disclose all ingredients which they have been compelled to publicly disclose with respect to a particular brand in order to comply with a statute or regulation (e.g., MA Ch 94 §307B).

-- Manufacturers would be required to have procedures for the selection, testing, purchase, storage and use of ingredients.

The Act would:

-Provide for record keeping regarding ingredients

-Allow FDA access to such records, with protection of proprietary information

[Source/precedent: MA Chapter 94, §307B; 21 C.F.R. §§101.4, 101.105, and 101.170; 18 U.S.C. §1905; 5 U.S.C. §552(b)(4); MA proposed reg. 105 C.M.R. §660.200(G)]

G. Compliance and Corporate Culture.

A key element in achieving the Act's goals will be forcing a fundamental change in the way the tobacco industry does business. Accordingly, the Act will provide for means to ensure that the industry will not only comply with the letter of the law but will also have powerful incentives to prevent underage usage of tobacco products and to strive to develop and market less hazardous tobacco products.

First manufacturers would be required to create plans, with an annual review and update, to:

-- Ensure compliance with all applicable laws and regulations

-- Identify ways to achieve the goals of reduced youth access to and incidence of underage consumption of tobacco products and provide internal incentives for doing so

-- Provide internal incentives to develop products with reduced risk

Second, with a special emphasis on laws and regulations that make it unlawful to sell tobacco products to underage persons and other laws directed at the issue of underage tobacco use, the manufacturers must implement compliance programs that include, at a minimum, the following elements:

-- Compliance standards and procedures to be followed by employees and agents that are reasonably capable of reducing the prospect of violations

-- Assignment to specific individual(s) within high-level personnel of the organization of overall responsibility to oversee compliance with the relevant standards and procedures, especially in regard to preventing underage tobacco use

-- Use of due care not to delegate substantial discretionary authority to individuals who the organization knows, or should have known through the exercise of due diligence, had a propensity to disregard corporate policy

-- Steps to communicate relevant standards and procedures to all employees and other agents (including lobbyists), e.g., by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required

-- Internal audits, hotlines and other measures to promote compliance

-- Appropriate disciplinary mechanisms and measures (e.g., discipline of employees who violate marketing restrictions)

-- Reasonable steps to respond appropriately to a violation and to prevent further similar violations

Furthermore, the Act would provide "whistleblowers" in the tobacco industry with the maximum protection available under current federal statutes.

Beyond compliance with the letter of the law, manufacturers would be required to take affirmative steps in furtherance of the spirit of the new regime, including:

-- Promulgating corporate principles that express and explain the company's commitment to compliance, reductions of underage tobacco use, and development of reduced risk tobacco products

-- Designating a specific individual within high-level personnel of the organization with appropriate responsibility and authority to promote efforts to attain these new standards

-- Providing reports to shareholders on compliance as well as progress toward meeting these new standards

Manufacturers would also be required to work with retail organizations on compliance, including retailer compliance checks and financial incentives for compliance.

Third, each tobacco manufacturer would require all contract lobbyists (and any other third-parties who may engage in lobbying activities on behalf of a manufacturer) to agree that they will not support or oppose any state or federal legislation, or seek or oppose any governmental action on any matter, without the manufacturer's express authorization. Manufacturers would also require anyone lobbying on their behalf to agree in writing that a) they are aware of and will fully comply with all applicable laws and regulations; b) they have reviewed and will fully comply with the Act as it applies to them; c) they have reviewed and will fully comply with the Consent Decree as it applies to them; and d) they have reviewed and will fully abide by the manufacturer's business conduct policies and any other policies and commitments as they apply, especially those related to prevention of youth tobacco usage.

Fourth, within ninety days after the Act's effective date, the Tobacco Institute and the Council for Tobacco Research, U.S.A. would be dissolved and disbanded. Tobacco product manufacturers would be permitted to form new trade associations only in accordance with strict procedures and federal oversight designed to ensure compliance with antitrust and other applicable laws. (See Appendix IV)

Finally, companies would be subject to fines and penalties (including "Scarlet Letter" advertising) for breaching their obligations vis-a-vis the development, implementation and enforcement of compliance plans and corporate principles. These penalties shall follow the scheme set forth in the Clean Air Act, up to \$25,000 per day per violation with a total not to exceed \$200,000. In addition, each manufacturer's employees shall be directed to report to that manufacturer's compliance officer any known or alleged violations of this Act by retailers or distributors. In accordance with procedures established by FDA, the compliance officer shall be required to furnish all such reports to FDA for reference to appropriate federal or state enforcement authorities. The manufacturer shall be subject to fines or penalties in the event its compliance officer fails to furnish any such reports to FDA.

[Source/precedent: Federal Organizational Sentencing Guidelines; various federal consent decrees; various corporate environmental programs]

H. Effective Dates

Many of the foregoing requirements relating to the reformation of the tobacco industry will become effective shortly after the Act is signed by the President; including the following categories of new rules, which will be implemented on the dates indicated:

Category / Effective Dates on Final Passage

Retail Product Displays / 9 months

Retail signage / 5 months

Advertising / 9 months

Package Labeling / 1/3 in 90 days

1/3 in 120 days

1/3 in 180 days

Sponsorships / 12/31/98

Vending machines / 12 months

Sampling / 3 months

GMPs / 24 months in accordance with rulemaking, whichever is later

Corporate compliance / 12 month

Face-to-face transactions / 3 months

Ban on sales of open packs / 3 months

20 cigarettes per pack minimum / 3 months

Puerto Rico pack size / 12 months

TITLE II: "Lookback" Provisions/State Enforcement incentives

A central aim of this legislation is to achieve dramatic and immediate reductions in the number of underage consumers of tobacco products. The legislation accordingly contains a "look-back" provision giving tobacco product manufacturers significant economic incentives to take every possible step to ensure that the advertising, marketing and distribution requirements of this Act are met, and imposing substantial surcharges on the manufacturers in the event that underage tobacco-use reduction targets are not achieved.

The "look-back" provision sets targets for the dramatic reduction of current levels of underage tobacco use (as measured by the University of Michigan's National High School Drug Use Survey "Monitoring the Future"). Underage use of cigarette products must decline by at least 30% from estimated levels over the last decade by the fifth year after the legislation takes effect, by at least 50% from estimated levels over the last decade by the seventh year after the legislation takes effect, by at least 60% from estimated levels over the last decade by the tenth year after the legislation takes effect, and remain at such reduced levels or below thereafter. (These required reductions amount to even steeper declines from current levels of underage smoking.) Underage use of smokeless tobacco products must decline by at least 25% from current levels by the fifth year after the legislation takes effect, by at least 35% from current levels by the seventh year after the legislation takes effect, by at least 45% from current levels by the tenth year after the legislation takes effect, and remain at such reduced levels or below thereafter. FDA will annually assess the prevalence of underage tobacco use (based on the methodology employed by the University of Michigan survey) to determine whether these targets have been met.

If a target has not been met, FDA will impose a mandatory surcharge on the relevant industry (cigarette or smokeless tobacco) based upon an approximation of the present value of the profit the industry would earn over the lives of all underage users in excess of the target (subject to an annual cap of \$2 billion for the cigarette industry (adjusted each year for inflation) and a comparably derived cap for the smokeless tobacco industry). Tobacco product manufacturers could receive a partial abatement of this surcharge (up to 75%) only if they could thereafter prove to FDA that they had fully complied with the Act, had taken all reasonably available measures to reduce youth tobacco use and had not taken any action to undermine the achievement of the required reductions. A fuller description is provided in Appendix V.

In addition, the proposed Act goes well beyond the provisions of the Synar Amendment's "no tobacco sales to minors" law and related regulations, 42 U.S.C. § 300X-26, and the Final Rule promulgated thereunder, which became effective February 20, 1996 (61 Fed. Reg., June 19, 1996). The proposed Act requires the several States to undertake significant enforcement steps designed to dramatically reduce the incidence of youth smoking, and youth access to tobacco products. These enforcement obligations are funded by Industry Payments. Each state must maintain specific levels of enforcement effort, or the state risks the loss of a significant portion of the health care program funds otherwise payable to the state under the Act. Amounts withheld from states not doing an adequate enforcement job will be reallocated to states with a superior "no sales to minors" enforcement record. No state will be held responsible for sales to underage consumers outside that state's jurisdiction.

The details of these state enforcement incentives are set forth in Appendix VI.

TITLE III: Penalties and Enforcement; Consent Decrees; Non-Participating Companies

A. Penalties and Enforcement

-- This legislation will be enforceable both by the federal government, including FDA and civil and criminal divisions of the Department of Justice, and by the several States. FDA will also have the authority to contract directly with state agencies to assist with enforcement. If conduct is subject to a particular State's consumer protection law or similar statute, such state may proceed under that law.

-- State enforcement actions - whether brought under the Act or a State's consumer protection law - could not impose obligations or requirements beyond those imposed by the legislation (except where the legislation does not specifically preempt additional state-law obligations), and would be limited to the civil and criminal penalties established by the legislation and by the prohibition on duplicative penalties. State enforcement proceedings under the Act (or predicated on conduct violating the Act), except those exclusively local in nature, would be removable to federal court. Nothing in the Act precludes a State from enforcing its laws in the ordinary fashion as to matters not covered by the Act or Protocol.

-- Civil and criminal penalties for violations of the legislation based on those governing other drugs or devices regulated under the Food, Drug and Cosmetic Act and, where applicable, under Title 18 of the U.S. Code.

-- In addition, the industry faces civil penalties of up to \$10 million per violation for any violations of the obligations to disclose to the FDA research about tobacco-product health effects and information regarding the toxicity of non-tobacco ingredients and constituents used in their products. This penalty is ten times the largest penalty faced by other drug or device manufacturers for similar violations.

-- To reflect the fact that not all States have filed lawsuits against the tobacco industry, but that the intent of the negotiators is to provide the benefits of the settlement to all States, the industry also will enter into a binding and enforceable national tobacco control

Protocol embodying certain terms of the proposed resolution. As an enforceable contract, which would not be subject to facial constitutional challenge, this Protocol will provide benefits and enforcement rights to the federal government and all states.

B. Consent Decrees

-- Certain terms of the agreement will also be reiterated in consent decrees between the tobacco industry and the states that will not take effect until after enactment of the Act. These consent decrees will be identical to, and will reiterate, the terms of the agreement with respect to: (1) restrictions on advertising, marketing and youth access to tobacco products; (2) trade associations; (3) restrictions on lobbying; (4) disclosure of tobacco smoke constituents; (5) disclosure of non-tobacco ingredients; (6) disclosure of existing and future industry documents relating to health, toxicity and addiction; (7) compliance and corporate culture; (8) obligations to make monetary payments to the States reflecting their reasonable share of the total provided by the Act; (9) obligations of the industry to deal only with distributors and retailers that operate in compliance with applicable provisions of law respecting the distribution, sale and marketing of tobacco products; (10) warnings, labeling and packaging (to the extent noted below); and (11) dismissal of other pending litigation specified by the parties.

-- The consent decrees will not contain provisions as to: (1) product design, performance or modification; (2) manufacturing standards and good manufacturing practices; (3) testing and regulation with respect to toxicity and ingredients approval; and (4) the national FDA "Lookback" provisions.

-- The consent decrees will provide that their terms are to be construed in conformity with the Act and the Protocol and with each other. State proceedings to enforce the provisions of the consent decrees may be brought in state court, subject to an acceptable procedure to ensure consistent rulings with respect to conduct that is not exclusively local in character. State proceedings to enforce the consent decrees may seek injunctive relief only, and may not seek criminal or monetary sanctions. A State shall not be limited from seeking criminal or other sanctions for a company's subsequent violation of an injunction entered by the court in an action brought to enforce the consent decree -- The provisions of the consent decrees will remain enforceable regardless of whether subsequent changes in the Act or in any other provision of law diminish the obligations of the companies in the areas covered by the consent decrees, except: (1) where such changes create federal requirements that produce obligations in conflict with those contained in the consent decrees; (2) with respect to the allocation of funds; and (3) with respect to warnings, labeling and packaging. With respect to warnings, labeling and packaging, if the requirements of the Act are later modified, or if Congress subsequently prohibits warnings on tobacco products, the consent decrees will be modified to conform to such requirements. However, if Congress later eliminates altogether the warning requirement in the Act, the warnings originally set forth in the Act (the so-called Canadian warnings) shall be mandated and enforceable under the consent decrees.

-- In addition, the parties recognize that certain provisions of the consent decrees and the agreement may require them to act (or refrain from acting) in a manner that they might otherwise claim would violate the federal or state constitutions. They will therefore in the consent decrees expressly waive any claim that the provisions of the consent decrees or the agreement violate the federal or state constitutions. The 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.

C. Non-participating companies

-- The regime envisioned by the resolution would be substantially undercut if certain companies were free to ignore the limitations it imposes, and were instead able to sell tobacco products at lower prices (because they were not making the payments described above) and through less restricted advertising and marketing activities. The resolution accordingly anticipates the possibility that some manufacturers of tobacco products may not consent to the institution of this regime. Rather than seeking to impose on such manufacturers the advertising restrictions, full required payments and corporate culture changes set forth above, the resolution avoids constitutional questions that might otherwise be raised by establishing a separate regime for non-participating manufacturers.

-- Non-participating manufacturers would be subject to the access restrictions and regulatory oversight set forth above. They would receive none of the civil liability protections described in Title VIII. Their product would be subject to a user fee equal to the portion of the payments by participating manufacturers allocated to fund public health programs and federal and state enforcement of the access restrictions. -- The resolution further recognizes that - unlike the participating manufacturers - non-participating manufacturers will not have made consensual payments to settle governmental actions for health care costs, to settle class actions and in to provide consideration for the partial settlement of individual tort actions (including punitive damages claims). Because such actions would remain wholly unsatisfied, it is vital that the claimants be ensured that funds will be available to satisfy any judgments that may be obtained. Accordingly, the resolution requires that each nonparticipating manufacturer place into an escrowed reserve fund each year an amount equal to 150% of its share of the annual payment required of participating manufacturers (other than the portion allocated to public health programs and federal and state enforcement). These escrowed funds would be earmarked for potential liability payments, and the manufacturer would reclaim them with interest 35 years later to the extent they had not been paid out in liability.

-- Moreover, the resolution also recognizes that - because nonparticipating manufacturers are not subject to the corporate culture commitments requiring manufacturers to monitor distributor and retailer compliance with the underage access restrictions -distribution and retail sales of those manufacturers' products present a particularly great obstacle to the achievement and enforcement of the access restrictions. Accordingly, the resolution provides that the exemption from civil liability applicable to distributors and retailers of the products of participating manufacturers will not apply to distributors and retailers who handle tobacco products of non-participating manufacturers.

Title IV: Nationwide Standards To Minimize Involuntary Exposure To Environmental Tobacco Smoke

Until now, there has been no minimum or other federal standard governing smoking in public places or at work. The legislation would:

-- Restrict indoor smoking in "public facilities" (i.e., any building regularly entered by 10 or more individuals at least one day per week) to ventilated areas with systems that:

- Exhaust the air directly to the outside;
- Maintain the smoking area at "negative pressure" compared with adjoining areas; and
- Do not recirculate the air inside the public facility.

- Ensure that no employee shall be required to enter a designated smoking area while smoking is occurring. Cleaning and maintenance work in a designated smoking area shall be conducted while no smoking is occurring.
- Exempt restaurants (but not "fast food" restaurants) ("Fast food" restaurant means any restaurant or chain of restaurants which primarily distributes food via customer pick-up (either at a counter or drive-through window). In addition, OSHA would be authorized to issue regulations clarifying this definition to the extent necessary to ensure that the intended inclusion of establishments catering largely to minors is achieved. Any such regulation may consider such factors as whether a restaurant either has attached playgrounds or play areas for children, uses ad campaigns that feature or prominently include cartoon characters and/or toy giveaways or advertises "happy meal" or other comparable kids-combination platters, and other factors OSHA deems relevant.) and bars (including those in hotels), private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.
- Direct OSHA to issue, not later than one year after the effective date of the legislation, regulations implementing and enforcing the preceding standards, with enforcement costs paid out of the Industry Payments. The smoking restrictions outlined in this Title would take effect on the first anniversary of the enactment of the legislation irrespective of whether the implementing regulations have been promulgated.

The legislation would not preempt or otherwise affect any other state or local law or regulation that restricts smoking in public facilities in an equal or stricter manner. Nor would the legislation preempt or otherwise affect any federal rules that restrict smoking in federal facilities.

[Source/precedent: H.R. 3434, as reported out of committee; WISHA workplace smoking rule; state law exemptions for the "hospitality sector"]

TITLE V: Scope and Effect

A. Scope of FDA Authority

- All product sold in U.S. commerce
- Covers new entrants; imports; U.S. duty free, etc.
- BATF to retain fiscal authority over tobacco products
- FTC to retain existing authority, except for "tar", nicotine, and carbon monoxide testing
- Grower Limitation: FDA jurisdiction does not extend to the growing, cultivation or curing of raw tobacco (USDA has exclusive authority).

B. State Authority

1. Preservation of State and Local Government Laws and Legal Authority

- While setting a federal "floor" for tobacco control measures in many substantive areas, this legislation preserves, to the maximum extent, state and local government authority to take additional tobacco control measures that further restrict or eliminate the product's use by and accessibility to minors.
- This legislation also permits state and local governments to enact measures that further restrict or eliminate employee and general public exposure to smoking in workplaces and in other public and private places and facilities.
- The legal authority of a state or local government to further regulate, restrict or eliminate the sale or distribution of tobacco products, and to impose state or local taxes on such products, also remains unchanged.
- The legislation retains similar flexibility for Indian tribes, military facilities and other federal agencies.

2. Uniformity of Warning Labels, Packaging, Labeling and Other Advertising Requirements; Manufacturing Requirements

- Current federal law providing for national uniformity of warning labels, packaging and labeling requirements, and advertising and promotion requirements related to tobacco and health, is preserved, except that this legislation gives FDA express authority to require changes in the language of the warnings, subject to the standard requirement that it provide public notice and a hearing opportunity prior to making such changes.
- Similarly, the provisions of FDCA designed to provide uniformity in product manufacturing and design requirements relating to medical devices will apply to tobacco products, except that any application by a State or locality for an exemption permitting it to adopt additional or different requirements relating to performance standards or good manufacturing practices may only be granted if the requirement would not unduly burden interstate commerce. Further, to ensure that FDA has an adequate opportunity to evaluate non-tobacco ingredients as described in Title 1(F), no exemption relating to ingredients may be applied for until the fifth anniversary of the effective date of the Act.

TITLE VI: Programs/Funding

TOTAL 25 YEAR PACKAGE FACE VALUE - \$368.5 Billion

A. Up Front Commitment - Lump Sum Cash Payment - \$10 Billion

1. Payable on Statute Signing Date.

B. Base Annual Payments - 25 Year Total Face Value is \$358.5 Billion (Figures Subject to Inflation Protection and Volume Adjustments)

1. Duration - annual payments in perpetuity
2. Commencement - 12/31 of first full year after statute signing
3. Face Amounts (includes payments from all industry sources):

Year 1 2 3 4 5 6-8 9 after

Total Payments \$8.5B \$9.5B \$11.5B \$14B \$15B \$15B \$15B \$15B
 Base Amount: \$6B \$7B \$8B \$10B \$10B \$12.5B \$15B \$15B
 Public Health Trust \$2.5B \$2.5B \$3.5B \$4B \$5B \$2.5B

4. Inflation Protection for Annual Payments

-- Greater of 3% or CPI applied each year on previous year, beginning with first annual payment.

5. Adjustment for Volume Decrease (Adult Volume Only) or Total Volume Increase

-- Beginning in year 1; payment made equal to scheduled annual payment times the ratio of actual relevant domestic tobacco product unit sales volume to relevant base volume. In the event of a decline in volume, relevant actual volume and relevant base volume are adult volume figures; in the event of an increase in volume, relevant actual volume and relevant base volume are total volume figures. Base volume is 1996 volume.

-- Any reduction in an annual payment will be reduced by 25% of any increase above the industry's base year net operating profits (after application of inflator discussed above) from domestic sales of tobacco products.

6. Payment Protection

-- Provide for payment priority/continuation during bankruptcy/ reorganization proceedings. Protocol cannot be rejected in bankruptcy. Obligation for annual payments responsibility only of entities selling into domestic market

7. Pass-Through

-- 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.

C. Applicability

1. Applicable to All Sellers of Tobacco Products

-- Through protocol and statute to protocol signatories.
-- Through alternative statutory provisions to non-signatories.

D. Tax Treatment

All payments pursuant to this Agreement (including those pursuant to Title II) shall be deemed ordinary and necessary business expenses for the year of payment, and no part thereof is either in settlement of an actual or potential liability for a fine or penalty (civil or criminal) or the cost of a tangible or intangible asset.

TITLE VII: Public Health Funds From Tobacco Settlement As Recommended By The Attorneys General For Consideration By The President And The Congress

BASED ON THE PREMISE OF \$1 BILLION FOR THE FIRST YEAR AND GRADUALLY INCREASING TO \$1.5 BILLION THEREAFTER, ADJUSTED FOR INFLATION AFTER THE FIRST YEAR.

BASED ON THE PREMISE OF \$1 BILLION FOR SMOKING CESSATION FOR THE FIRST 4 YEARS AND \$1.5 BILLION THEREAFTER, ADJUSTED FOR INFLATION.

(A) ALLOCATION OF GRANT MONIES AMONG PROGRAMS - The use of moneys under this Section shall be limited to programs established under this Section, shall be adjusted for inflation annually from the effective date, and shall be allocated among such programs as follows:

- (1) \$125,000,000 for the first three years and \$225,000,000 annually thereafter to the Secretary of HHS to accomplish the purposes described in Paragraph (B) of this Section (Reduction in Tobacco Usage);
- (2) \$300,000,000 annually for the FDA to carry out its obligations under and to enforce the terms of this Act, including for grants to the states to assist in the enforcement of the provisions of the Act;
- (3) \$75,000,000 for the first two years, \$100,000,000 in the third year, and \$125,000,000 annually thereafter to fund state and local tobacco control community based efforts modeled on the ASSIST program, designed to encourage community involvement in reducing tobacco use and the enactment and implementation of policies designed to reduce the use of tobacco products;
- (4) \$100,000,000 annually to fund research and the development of methods for how to discourage individuals from starting to use tobacco and how to help individuals to quit using tobacco;
- (5) Beginning in the second year, \$75,000,000 annually for a period of ten (10) years to compensate events, teams or entries in such events, who lose sponsorship by the tobacco industry as a result of this Act, or who currently receive tobacco industry funding to sponsor events and elect to replace that funding, provided that the event, team, or entry is otherwise unable to replace its tobacco industry sponsorship during those given years. Funds used for this purpose shall promote a Quit Tobacco Use theme. After a ten year period, no additional funds shall be used for this purpose and the funds previously allocated to this purpose shall be used as follows: 50% to supplement funding of the multimedia campaigns in paragraph (1) of this subsection; 25% to supplement the funding of the enforcement provisions of paragraph (2) of this subsection; and 25% to supplement the funding of community action programs in paragraph (3) of this subsection.

(B) ESTABLISHMENT OF PROGRAMS BY THE SECRETARY - The Secretary shall establish programs to accomplish the following purposes---

- (1) the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit through media-based and non-media based education, prevention and cessation campaigns. The Secretary may make grants to state health departments to assist in carrying out the purposes of this provision.
- (2) the research into and development and public dissemination of technologies and methods to reduce the risk of dependence and injury from tobacco product usage and exposure;
- (3) the identification, testing and evaluation of the health effects of both tobacco and non-tobacco constituents of tobacco products;

(4) the promulgation of such other rules and regulations as are necessary and proper to carry out the provisions of this Act, as well as the development of such other programs as the Secretary determines are consistent with the goals of the Act.

(C) Public Education Campaign - \$500,000,000 shall be spent annually in such multi-media campaigns designed to discourage and de-glamorize the use to tobacco products. To carry out such efforts, an independent non-profit organization with a Board made up of prestigious individuals and the leaders of the major public health organizations shall be created which shall contract or make grants to non-profit private entities who are unaffiliated with tobacco manufacturers or tobacco importers, who have a demonstrated record of working effectively to reduce tobacco product use and expertise in multi-media communications campaigns. The independent body shall be authorized to contract with state health departments, where appropriate, to run campaigns for their states and communities. In creating the program the Secretary or independent body shall also take into account the needs of particular populations. The goal shall be the reduction of tobacco product usage, both by seeking to discourage the initiation of tobacco use by persons under the age of 18 and by encouraging current tobacco users to quit.

(D) Tobacco Use Cessation - For the first 4 years, \$1 billion, and thereafter, \$1.5 billion of the total amount paid by the tobacco industry shall be paid into a Trust Fund to be used to assist individuals who want to quit using tobacco to do so.

Within 12 months the Secretary shall promulgate regulations to govern (1) the establishment of criteria for and a procedure for the approval of cessation programs and devices for which payment may be made under the program, (2) the eligibility requirements for individuals seeking to use moneys from the trust to fund the tobacco cessation efforts, and (3) the procedures to govern the tobacco cessation program.

The goal of the tobacco cessation program shall to enable the most tobacco users possible to receive assistance in their effort to quit using tobacco by providing financial assistance and identifying the programs, techniques, and devices that have been shown to be safe and effective. Benefits to individuals should not be limited to a single effort, but should be tailored to the needs of individual smokers according to standards established by the Secretary using the best available scientific guidelines.

(E) Public Health Trust Fund Presidential Commission - A Presidential commission will be appointed to include representatives of the public health community, Attorneys General, Castano attorneys and others to determine the specific tobacco-related medical research for which the \$25 Billion Public Health Trust Fund will be used.

TITLE VIII: Civil Liability

The following provisions would govern actions for civil liability related to tobacco and health.

A. General

1. Present Attorney General actions (or similar actions brought by or on behalf of any governmental entity), parens patriae and class actions are legislatively settled. No future prosecution of such actions. All "addiction"/dependence claims are settled and all other personal injury claims are reserved. As to signatory States, pending Congressional enactment, no stay applications will be made in pending actions, based upon the fact of this resolution, without mutual consent of the parties.
2. Third-party payor (and similar) actions pending as of 6/9/97 are not settled, but governed by provisions regarding past conduct set forth in Section B below.

B. Provisions as to Civil Liability for Past Conduct

The following provisions apply to suits for relief arising from past conduct - i.e., suits by persons claiming injury or damage caused by conduct taking place prior to the effective date of the Act.

1. All punitive damages claims resolved as part of overall settlement. No punitive damages in individual tort actions.
2. Individual trials only: i.e., no class actions, joinder, aggregations, consolidations, extrapolations or other devices to resolve cases other than on the basis of individual trials, without defendant's consent. Action removable by defendant to federal court upon receipt of application to, or order of, state court providing for trial or other procedure in violation of this provision.
3. Except as expressly provided in the Act, FCLAA and applicable case law unchanged by the Act.
4. Provided that the five negotiating companies enter into the Protocol: Protocol manufacturers to enter into joint sharing agreement for civil liability. Protocol manufacturers not jointly and severally liable for liability of non-Protocol manufacturers. Trials involving both protocol and non-Protocol manufacturers to be severed.
5. Permissible parties:
Plaintiffs -
 - a. Claims of individuals, or claims derivative of such claims, must be brought either by person claiming injury or heirs.
 - b. Third-party payor (and similar) claims not based on subrogation that were pending as of 6/9/97.
 - c. Third-party payor (and similar) claims based on subrogation of individual claims; no extrapolations, etc.

Defendants

- a. maintained only against companies, their assigns, any future fraudulent transferee, and/or entity for suit designated to survive defunct manufacturer. Actions may be manufacturing successors and
 - b. Manufacturers of agents agencies and liable vicariously for acts (including advertising attorneys).
6. No removal except under paragraph 2 above.
 7. The development of "reduced risk" tobacco products after the effective date of the Act is neither admissible nor discoverable.
 8. Statute of limitations: for all actions, individual state laws governing time periods from injury, discovery, notice or contamination/violation.

9. Annual aggregate cap for judgments/settlements: 33% of annual industry base payment (including any reductions for volume decline). If aggregate judgments/settlements for a year exceed annual aggregate cap, excess does not have to be paid that year and rolls over.

Any judgments/settlements run against defendant? but give rise to 80-cent-on-the-dollar credit against annual payment in year paid. Suitable provision for settlement consultation and permission. Manufacturers control insurance claims, and any insurance recovery obtained by manufacturers (net of cost) on account of judgment and/or settlement covered by above sharing arrangement allocated 80% to annual payments. Manufacturers retain any insurance proceeds on account of defense costs.

Provision with respect to individual judgments above \$1 million: amount in excess of \$1 million not paid that year unless every other judgment/settlement can be satisfied within the annual aggregate cap. Excess rolls forward without interest and is paid at the rate of \$1 million per year, until the first year that the annual aggregate cap is not exceeded (at which time the remainder is paid in full). For purposes of this provision, a third-party payor (or similar) action not based on subrogation is treated as having been brought by a single plaintiff and is subject to the \$1 million rollover on that basis.

10. In the event that the annual aggregate cap is not reached in any year, a Commission appointed by the President will determine the appropriate allocation of the amount representing the unused amount of the credit. The Commission will be entitled to consider, among public health, governmental entities, and other uses of the funds, applications for compensation from persons, including nonsubrogation claims of third party payors, not otherwise entitled to compensation under the Act.

11. Defense costs paid by manufacturers.

C. Provisions as to Civil Liability for Future Conduct

The following provisions apply to suits for relief arising from future conduct - i.e., suits claiming injury or damage caused by conduct taking place after the effective date of the Act.

1. Paragraphs 2, 3, 5, 6, 7, 8, 9, 10 and 11 in Section B apply.
2. No third-party payor (or similar) claims not based on subrogation.

TITLE IX: Board Approval

The terms of this resolution are subject to approval by the Boards of Directors of the participating tobacco companies.

Appendix I - Warnings in Advertisements

The space in press and poster advertisements for tobacco products that is to be devoted to the warning and, where relevant, the "tar," nicotine and any other constituent yield statements will be 20% of the area of the advertisement. The size of the printing of the warning and the yield statements shall be pro rata to the following examples:

- a) Whole page broadsheet newspaper - 45 point type
- b) Half page broadsheet newspaper - 39 point type
- c) Whole page tabloid newspaper - 39 point type
- d) Half page tabloid newspaper - 27 point type
- e) DPS magazine - 31.5 point type
- f) Whole page magazine - 31.5 point type
- g) 28 cm X 3 columns - 22.5 point type
- h) 20 cm X 2 columns - 15 point type

FDA may revise the required type sizes within the 20% requirement.

Appendix II - Retail Tobacco Product Seller Penalties

1. The sale of tobacco products to consumers by an unlicensed seller shall be a criminal violation, and be subject to minimum penalty of \$1,000, or imprisonment, for 6 months, or both, if an individual, or in the case of a corporation, by a maximum penalty of \$50,000. Any State or local jurisdiction may provide by statute or code more severe penalties.
2. In addition to any criminal penalties which may be imposed under any applicable state or local law, a tobacco product licensee may be subjected to civil sanctions, including penalties, or license suspension or revocation (on a site-by-site basis), or a combination thereof, for any violation of the provisions of the State licensing laws regarding sales to minors. Such sanction shall not exceed the following:
 - (a) For the first offense within any two year period, \$500 or a 3 day license suspension or both.
 - (b) For the second offense within any two year period, \$1,000 or a 7 day license suspension or both.
 - (c) For the third offense within any two year period, \$2,000 or a 30 day license suspension or both.
 - (d) For the fourth offense within any two year period, \$5,000 or a 6 month license suspension or both.
 - (e) For the fifth offense within any two year period, \$10,000 or 1 year license suspension or both.
 - (f) For the sixth and any subsequent offenses within any two year period, \$25,000 or a revocation of license with no possibility of reinstatement for a period of three years.
 - (g) Permanent license revocation is mandatory for the tenth offense within any two year period.

Each state must enact a statutory or regulatory enforcement scheme that provides substantially similar penalties to the minimum federal standards for a retail licensing program.

[Source/Precedent: Washington State Alcohol Licensing Act]

Appendix III - Application to Indian Tribes

A. Application Of Act

1. The provisions of the FDCA, the regulations of the FDA, and the Act relating to the manufacture, distribution and sale of tobacco products shall apply on Indian lands as defined in 18 U.S.C §1151 and on any other trust lands subject to the jurisdiction of an Indian tribe. To the extent that an Indian tribe engages in the manufacture, distribution or sale of tobacco products, the provisions of this Act shall apply to such tribe.
2. Any federal tax or fee imposed on the manufacture, distribution or sale of tobacco products shall be paid by any Indian tribe engaged in such activities, or by persons engaged in such activities on such Indian lands, to the same extent such tax or fee applies to other persons under the law.

B. Tribal Programs And Authority

1. For the purposes of the provisions of this Act, FDA is authorized to treat any federally-recognized Indian tribe as a state, and is authorized to provide any such tribe grant and contract assistance to carry out the licensing and enforcement functions provided by this section.
2. Such treatment shall be authorized only if:
 - (a) the Indian tribe has a governing body carrying out substantial governmental powers and duties;
 - (b) the functions to be exercised by the Indian tribe under this section pertain to activities on trust lands within the jurisdiction of the tribe; and
 - (c) the Indian tribe is reasonably expected to be capable of carrying out the functions required under this Act.

[Source/precedent: Clean Air Act, 42 U.S.C. §7601(d)]

3. FDA regulations which establish a retail licensing program shall apply on Indian trust lands, and each tribe's program shall be no less strict than the program of the State in which the tribe is located.
4. If FDA determines that an Indian tribe does not qualify for treatment as a state, FDA will directly administer the retailer licensing program, or may delegate such authority to the state.

C. Tobacco Compensation And Public Health Grants

1. A portion of the settlement funds to which a state is otherwise entitled shall be paid to HHS for distribution to the Indian tribes which have been certified by FDA for treatment as states. The funds to be paid for such purposes on behalf of Indian tribes shall be determined by the proportion of registered tribal members resident on the reservation to the total population of the state in which the tribe is located. The funds to be distributed to Indian tribes shall be used for the same purposes as those funds are to be used by the states and be subject to the same compliance requirements for retail sales to minors as are the states under the Act.
2. The Department of Health and Human Services will annually pay to the governing body of each Indian tribe its share of the funds for use under an FDA-approved plan after annual certification by FDA, under the same standards that apply to the States, that the Indian tribe is in compliance with the requirements of the Act and any applicable regulations.
3. If HHS does not distribute all, or a portion, of an Indian tribe's share of the funds in any given year because the tribe has not qualified under the terms of this section or has not met the compliance requirements for retail sales to minors, those funds will be distributed to other qualified tribes in the same state for the same purposes and on the same proportional basis, less the non-qualified tribe's population, as other settlement funds are to be distributed to the tribes.

D. Obligations of Tobacco Manufacturers

1. Tobacco manufacturers shall not engage in any activity on Indian lands subject to this Act which activity the manufacturers may not otherwise do within a State.
2. Tobacco manufacturers also agree not to sell tobacco products for manufacture, distribution, or sale to an Indian tribe, or to a manufacturer, distributor, or retail seller subject to the jurisdiction of an Indian tribe, except under the same terms and conditions as the tobacco manufacturers impose under other manufacturers, distributors and retail sellers under the Act, or any applicable regulations.

Appendix IV - Industry Associations

Within 90 days of the effective date of the Act, the tobacco product manufacturers shall disband and dissolve the Council for Tobacco Research, U.S.A. and the Tobacco Institute. In addition, with respect to any new trade associations:

A. Tobacco product manufacturers may form or participate in any new tobacco industry trade association. Any such new trade association shall have an independent board of directors, in accordance with the following requirements. For at least 10 years after the formation of the new association, a minimum of 20 percent of the directors, but at least one director, shall be other than a current or former director, officer or employee of any association member or affiliated company. No other director of a new trade association may be, at the same time, a director of any association member or affiliated company. The officers shall be appointed by the board and shall be employees of the association, and during their term shall not be employed by any association member or affiliated company. Legal counsel for any such association shall be independent and not serve as legal counsel to any association member or affiliated company while counsel to the association.

B. Any new tobacco product manufacturers' trade association shall adopt by-laws governing the association's procedures and the activities of its members, board, employees, agents and other representatives. The by-laws shall include, among other things, provisions that:

- (1) members who are competitors in the tobacco industry shall not meet on the association's business except under sponsorship of the association;

- (2) every board of directors meeting, board sub-committee meeting, general association or committee meeting, and any other association sponsored meeting, shall proceed under and strictly adhere to an agenda, approved by legal counsel and circulated in advance; and
- (3) minutes describing the substance of the meetings shall be prepared for all such meetings, and shall be maintained by the association for a period of 5 years.

C. Moreover, under the new regime:

1. The structure, by-laws, and activities of tobacco industry trade associations shall be subject to continuing oversight by the U.S. Department of Justice and by state antitrust authorities. For a period of 10 years from the creation of a new trade association, such authorities may, without limitation on whatever other rights to access they may be permitted, upon reasonable prior notice:

- (a) have access during regular office hours to inspect and copy all books, records, meeting agenda and minutes, and other association documents; and
- (b) interview the association's directors, officers and employees, who may have counsel present.

The inspection and discovery rights provided in (a) and (b) above shall be exercised through a multi-state States' Attorneys General oversight committee. Any documents and information provided to any state pursuant to (a) and (b) above shall be kept confidential by and among the states and shall be utilized only for governmental purposes of enforcing the Act and ancillary documents.

2. 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. Approval or non-approval of a plan shall not be grounds for abatement of any surcharge to a manufacturer for failure to meet the reductions in underage tobacco use contemplated in this resolution and the Act.

Appendix V - "Lookback"

A summary of the "look-back" provision is as follows:

A. The Reduction Requirements.

1. The required reductions in underage tobacco use are measured against a base percentage. For underage use of cigarettes, the base percentage is the average weighted by relative population of such age groups in 1995 as determined by the U.S. Census Bureau, of (a) the average of the percentages of 12th graders (ages 16 and 17) from 1986 to 1996 who used cigarette products on a daily basis; (b) the average of the percentages of 10th graders (ages 14 and 15) from 1991 to 1996 who used cigarette products on a daily basis; and (c) the average of the percentages of 8th graders (age 13) from 1991 to 1996 who used cigarette products on a daily basis. The percentages are those measured by the University of Michigan's National High School Drug Use Survey "Monitoring the Future" or by such comparable index using identical methodology as is chosen by FDA after notice and hearing. For underage use of smokeless tobacco products, the base percentage is the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Census Bureau, of (a) the percentage of 12th graders (ages 16 and 17) in 1996 who used smokeless tobacco products on a daily basis; (b) the percentage of 10th graders (ages 14 and 15) in 1996 who used smokeless products on a daily basis; and (c) the percentage of 8th graders (age 13) in 1996 who used smokeless tobacco products on a daily basis. These percentages are to be derived from the same source as are the percentages with respect to use of cigarette products.

2. After the fifth year after enactment of the Act and annually thereafter, the FDA will calculate the incidence of daily use of tobacco products by those under 18 years of age as follows:

For cigarette product use, the FDA will calculate the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Bureau of Census, of the percentages of 12th graders (ages 16 and 17), 10th graders (ages 14 and 15) and 8th graders (age 13) who used cigarette products on a daily basis during the preceding year. The percentages used in this calculation are to be those measured (a) by the University of Michigan Survey; or (b) by such comparable index using identical methodology as is chosen by the FDA after notice and hearing. If the methodology of the University of Michigan Survey is hereafter changed in a material manner from that employed in 1986-96 (including by changing the states or regions on which that Survey is based), the FDA shall use the percentages measured by an index chosen by it after notice and hearing having a methodology identical to that employed by the University of Michigan Survey in 1986-96.

For smokeless tobacco product use, the FDA will calculate the average, weighted by relative population of such age groups in 1995 as determined by the U.S. Bureau of Census, of the percentages of 8th (age 13), 10th (ages 14 and 15) and 12th graders (ages 16 and 17) who used smokeless tobacco products on a daily basis during the preceding year. This calculation is to be made using the same methodology as with respect to cigarette product use.

Any data underlying the University of Michigan Survey shall be available by request from FDA.

3. The reduction requirements (expressed as reduction from the base percentage) for cigarette products are as follows:

Year After Enactment Reduction Requirement

years 5-6: 30% reduction
years 7-9: 50% reduction
year 10: (and 60% reduction thereafter)

The reduction requirements (expressed as reduction from the base percentage) for smokeless tobacco products are as follows:

Year After Enactment Reduction Requirement

years 5-6: 25% reduction
years 7-9: 35% reduction
year 10 (and thereafter): 45% reduction

B. The Surcharge

Where the FDA's calculation (per the procedure set forth above) shows that the reduction requirements with respect to underage use of cigarette products were not met in the preceding year, the FDA will impose a surcharge on the manufacturers of cigarette products. Where the FDA's assessment shows that the Reduction Requirements with respect to underage use of smokeless tobacco products were not met in the preceding year, the FDA will impose a surcharge on the manufacturers of smokeless tobacco products.

1. The surcharge with respect to the cigarette industry will be calculated as follows:

(a) The FDA will determine the percentage point difference between:

(i) the required percentage reduction applicable to a given year, and
(ii) the percentage by which the percent incidence of underage use of cigarette products for that year is less than the base incidence percentage. (In the event that the FDA's calculation of the percent incidence of underage use of cigarette products for that year is greater than the base incidence percentage, the number of percentage points used will be (i) the required percentage reduction for that year plus (ii) the percentage by which the actual percent incidence for that year is greater than the base incidence percentage.)

(b) The surcharge will be \$80 million for each percentage point derived per the above procedure. This amount reflects an approximation of the present value of the profit the cigarette industry would earn over the life of underage smokers in excess of the required reduction (at current levels of population and profit). This calculation will be subject to the following:

(1) the \$80 million will be adjusted proportionately for percentage increases or decreases compared with 1995 in the population of persons resident in the United States aged 13-17, inclusive.

(2) the \$60 million will be adjusted proportionately for percentage increases or decreases compared with 1996 in the average profit per unit (measured in cents and weighted by annual sales) earned by the cigarette industry. (The average profit: per unit in 1996 will be derived from the industry's operating profit as reported to the SEC; and the average profit per unit for the year in which the surcharge is being determined will be calculated and certified to the FDA by a major, nationally recognized accounting firm having no existing connection to the tobacco industry using the same methodology as employed in deriving the average profit per unit for 1996.)

(3) 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 (to the extent that there were not underage smokers of comparable age in those previous years on whom a surcharge was not paid because of the cap set forth in paragraph (d) below).

(4) the surcharge may not exceed \$2 billion in any year (as adjusted for inflation).

2. The surcharge with respect to the smokeless tobacco industry will be derived through a comparable procedure based upon a base per-percentage point amount and a cap specific to that industry.

3. The surcharge payable by cigarette manufacturers will be the joint and several obligation of those manufacturers, allocated by actual market share. The surcharge payable by smokeless tobacco product manufacturers will be the joint and several obligation of those manufacturers, as allocated in the same manner. Within each such respective product market, the FDA will make such allocations according to each manufacturer's relative market volume in the United States domestic cigarette or smokeless tobacco markets in the year for which the surcharge is being assessed, based on actual federal excise tax payments.

4. The surcharge for a given year, if any, will be assessed by the FDA by May 1 of the subsequent calendar year. Surcharge payments will be paid on or before July 1 of the year in which they are assessed by the FDA. The FDA may establish, by regulation, interest at a rate up to (sentence incomplete)

5. After payment of its share of the surcharge, a tobacco product manufacturer may seek return of up to 75% of that payment through the abatement procedures described below.

C. Use of the Surcharge

The Surcharge funds would be used in a manner designed to speed the reduction of the levels of underage tobacco use. Upon final completion and review of any abatement petition, the FDA would transfer as grants to state and local government public health agencies, without further appropriation, 90% of all monies paid as Surcharge amounts. As a condition of such transfers, the recipients of the transferred funds would be required to spend them on additional efforts by state and local government agencies, or by contract between such agencies and private entities, to further reduce the use of tobacco products by children and adolescents. The FDA may retain up to 10 percent of such Surcharge amounts for Administrative Costs - the administration of the Surcharge provisions of the Act and related proceedings, and for other administrative requirements imposed on the FDA by the Act. If 10 percent of the Surcharge amounts exceeds the Administrative Costs, the FDA may (1) transfer any portion of the excess to other federal agencies, or to state and local government agencies, to meet the objective of reduction of youth tobacco usage, or (2) may expend such amounts directly to speed the reduction of underage tobacco use.

D. Abatement Procedures

Upon payment of its allocable share of any Surcharge, a tobacco product manufacturer may petition the FDA for an abatement of the surcharge, and shall give timely written notice of such petition to the attorneys general of the several states.

1. The FDA shall conduct a hearing on an abatement petition pursuant to the procedures set forth in sections 554, 556 and 557 of Title 5 of the United States Code.

2. The attorneys general of the several states shall be entitled to be heard and to participate in such a hearing.
3. The burden shall be on the manufacturer to prove, by a preponderance of the evidence, that the manufacturer should be granted an abatement.
4. The FDA's decision on whether to grant an abatement, and the amount thereof, if any, shall be based on whether:
 - (a) The manufacturer has acted in good faith and in full compliance with the Act, and any FDA rules or regulations promulgated thereunder, and all applicable federal, state or local laws, rules or regulations;
 - (b) In addition to full compliance as set forth in (a) above, the manufacturer has pursued all reasonably available measures to attain the required reductions;
 - (c) There is evidence of any action, direct or indirect, taken by the manufacturer to undermine the achievement of the required reductions or other terms and objectives of the Act; and
 - (d) Any other relevant evidence.
5. Upon a finding by the FDA that the manufacturer meets the grounds for an abatement under the standards set forth above, it shall order an abatement of up to 75% of the Surcharge with interest at the average United States 52-Week Treasury Bill rate for the period between payment and abatement of the surcharge. The FDA may consider all relevant evidence in determining what percentage to order abated.
6. Any manufacturer or state attorney general aggrieved by an abatement petition decision of the FDA may seek judicial review thereof within 30 days in the United States Court of Appeals for the District of Columbia Circuit. Unless otherwise specified in this Act, judicial review under this section shall be governed by sections 701-706 of Title 5 of the United States Code.
7. Notwithstanding the foregoing, a tobacco product manufacturer may neither file an abatement petition or seek judicial review of a decision denying an abatement if it has failed to pay the surcharge in a timely fashion.
8. No stay or other injunctive relief enjoining imposition and collection of the surcharge amounts pending appeal or otherwise may be granted by the FDA or any court.

[Source/precedent: 5 U.S.C. Sections 554, 556-57, 701-06]

Appendix VI: State Enforcement Incentives

The details of the state enforcement incentives are as follows:

In addition to FDA and other federal agency, state attorney general and other existing state and local law enforcement authority under current law, the proposed Act requires the following:

- A. States must have in effect a "no sales to minors" law providing that it is unlawful for any manufacturer, retailer or distributor of tobacco products to sell or distribute any such products to any persons under the age of 18. (42 U.S.C. §300X-26(a)(1); 45 C.F.R. §96.130(b)). This state statutory requirement remains in addition to the federal regulatory prohibitions on retail sales of tobacco products to children and adolescents (also defined as persons under the age of 18) adopted by the FDA in its August 28, 1996 Final Rule (to be codified at 21 C.F.R. §897.14 et seq.);
- B. States must conduct random, unannounced inspections at least monthly, and in communities geographically and statistically representative of the entire state and its youth population to ensure compliance with the "no sales to minors" law, and implement "any other action which the state believes are necessary to enforce the law." (goes further than 45 C.F.R. §96.130(c), 96.130(d)(1), (d)(2);
- C. States must conduct at least 250 random, unannounced inspections of retailer compliance with the "no sales to minors" law per year for each 1 million of resident population, as determined by the most recent decennial census. In the case of tribes, tribes must conduct no fewer than 25 such inspections per location of point of sale to consumers per year, conducted throughout the year.

Annual State Reporting Requirements

As a condition to receiving any moneys due and payable pursuant to the Act, States must annually submit a report to the FDA and the States must make their reports public (except as provided in (C) below) within the state. Such state reports must include at least the following:

- A. A detailed description of enforcement activities undertaken by the state and its political subdivisions during the preceding federal fiscal year;
- B. A detailed description of the state's progress in reducing the availability of tobacco products to individuals under the age of 18, including the detailed statistical results of the mandated compliance checks;
- C. A detailed description of the methods used in the compliance checks, and in identifying outlets which were tested, with the FDA providing the state appropriate confidentiality safeguards for information provided to the agency regarding the timing and investigative techniques of state compliance checks that depend for their continued efficacy upon such confidentiality;
- D. A detailed description of strategies the state intends to utilize in the current and succeeding years to make further progress on reducing the availability of tobacco products to children and adolescents; and
- E. The identity of the "single state agency" responsible for fulfilling the Synar Amendment and the Act's requirements, including the coordination and report of state efforts to reduce youth access to tobacco products sold or offered for sale in the state. (strengthens and extends beyond 45 C.F.R.

§96.130(e) by adding greater detail to the requirements and transferring reporting obligation of states to FDA from HHS)

Required Attainment Goals for State Enforcement

The FDA is required to make an annual determination, prior to allocating any moneys allocated to the states under the proposed Act for the purposes of defraying public health care program expenditures (but not including or conditioning moneys made available under the Act for the payment of private claims), as to whether each state has "pursued all reasonably available measures to enforce" the prohibition on sales of tobacco products to children and adolescents.

In addition to the criteria set forth in 45 C.F.R. §96.130, the proposed Act will require the FDA to find presumptively that the state has not "pursued all reasonably available measures to enforce" the "no sales to minors law" unless the state has achieved, in the following years, the following compliance rate results for the retail compliance checks required by the Act:

Federal Fiscal Year Retail Compliance Check Under Review Performance Target

5th Year after year of 75%
enactment of Act

7th Year after year of 85%
enactment of Act

10th Year after year of 90%
enactment of Act and annually thereafter

These compliance percentages are expressed as the percentage of the random, unannounced compliance checks conducted pursuant to the Act for which the retailer refused sale of tobacco products to the potential underage purchaser. (note: these performance targets are far more stringent on the states than those in the Synar Amendment, which sets as a "final goal" a target of no less than 80% (i.e., an inspection failure rate of no more than 20%) within "several years. See 45 C.F.R. §96.130. In addition, the proposed Act's targets are mandatory, uniform national minimum performance requirements, while the Synar Amendment calls for HHS simply to "negotiate" an "interim performance target" beginning in 1998).

Reduction of Money Allocated to State Not Meeting Performance Targets

If a state does not meet the Act's "no sales to minors" performance targets for retail compliance checks, then the FDA may refuse to pay to that noncomplying state certain moneys otherwise payable to that state under the proposed Act. No state shall be held responsible for sales to underage consumers outside that state's jurisdiction. Specifically, the FDA may withhold from such state an amount equal to 1% of moneys otherwise payable to that state under the Act to defray health care expenditures of public programs of medical assistance for each percentage point by which the state's performance on its mandatory compliance checks fails to meet the required performance targets for that year. In no event may the FDA withhold more than 20% of the money otherwise allocable to such state under the Act for such purposes.

The FDA shall reallocate any Withhold Amounts, once final, to states that exceed the Act's Performance Targets, in amounts and by an allocation formula determined by the agency to reward those states with the best record of reducing youth access to tobacco products.

Appeal Following Withhold

Upon notice from the FDA of a withhold of moneys (the "Withhold Amount") allocable to the state under the Act, a state subject to such notice of withhold may petition the agency for a release and disbursement of the Withhold Amount, and shall give timely written notice of such petition to the attorney general for that state and to all tobacco product manufacturers. The agency shall hold, and invest in interest bearing securities of the United States government or its agencies, any Withhold Amounts subject to a pending petition for release and disbursement or related appeal until final disposition of such petition and appeal.

In the case of petition by a state for a release and disbursement of a Withhold Amount, the agency's decision on whether to grant such a petition, and the amount thereby released and disbursed, if any, shall be based on whether:

- (1) the state has acted in good faith and in full compliance with the Act, and any agency rules or regulations promulgated thereunder;
- (2) the state has pursued all reasonably available measures to attain the Retail Compliance Check Performance Targets and Youth Smoking Reduction Goals of the Act;
- (3) there is evidence of any action, direct or indirect, taken by the state to undermine the achievement of the Retail Compliance Check Performance Targets and Youth Smoking Reduction Goals or other terms and objectives of the Act; and
- (4) any other relevant evidence.

The burden shall be on the state to prove, by a preponderance of the evidence, that the state should be granted a release and disbursement of the Withhold Amount or any portion thereof. Prior to decision, the agency shall hold a hearing on the petition, with notice and opportunity to be heard given to the attorney general of that state and to all domestic tobacco product manufacturers.

Upon a finding by the agency that the state meets the grounds, as set forth above, and the burden of proof for a release and disbursement of a Withhold Amount, then it shall order a release and disbursement of up to 75% of the Withhold Amount appealed, and it shall so release and disburse to the state that amount, with interest at the average United States 52-Week Treasury Bill rate for the period between notice and release of such Withhold Amount. The agency may consider all relevant evidence in determining that percentage of the Withhold Amount to order released and disbursed.

Any manufacturer or state attorney general aggrieved by a Withhold Amount decision of the agency may seek judicial review thereof within 30 days in the United States Court of Appeals for the District of Columbia Circuit. Unless otherwise specified in this Act, judicial review under this Section

shall be governed by Sections 701-706 of Title 5 of the United States Code.

No stay or other injunctive relief enjoining imposition of the withhold pending appeal or otherwise may be granted by the FDA or any court.

No appeal may be taken from an agency decision denying a petition to release and disburse a Withhold Amount unless filed within 30 days following notice of such decision. No stay or other injunctive relief, enjoining imposition of the withhold pending appeal or otherwise, may be granted, by any court or administrative agency. Appeals filed hereunder shall be made to the District of Columbia Circuit Court of Appeals and, on appeal, shall be governed by the procedural and evidentiary provisions of the Administrative Procedures Act, unless otherwise specified in this Act. The judgment of the District of Columbia Court of Appeals on appeal shall be final.

Appendix VII - Restrictions on Point of Sale Advertising

The details with respect to point of sale advertising restrictions are as follows:

1. There shall be no Point of Sale Advertising of tobacco products, excluding adults-only stores and tobacco outlets, except as provided herein:

A. Each manufacturer of tobacco products may have not more than two separate point of sale advertisements in or at each location at which tobacco products are offered for sale, except any manufacturer with 25 percent of market share may have one additional point of sale advertisement. A retailer may have one sign for its own or its wholesaler's contracted house retailer or private label brand.

No supplier of tobacco products may enter into any arrangement with a retailer that limits the retailer's ability to display any form of advertising or promotional material originating with another supplier and permitted by law to be displayed at retail.

B. Point of Sale advertisements permitted herein each shall be of a display area not larger than 576 square inches (either individually or in the aggregate) and shall consist of black letters on white background or recognized typographical marks.

Point of Sale advertisements shall not be attached to nor located within two feet of any fixture on which candy is displayed for sale. Display fixtures are permitted signs consisting of brand name and price, not larger than 2 inches in height.

2. Except as provided herein, Point of Sale Advertising shall mean all printed or graphical materials bearing the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco, which, when used for its intended purpose, can reasonably be anticipated to be seen by customers at a location at which tobacco products are offered for sale.

3. Audio and video formats otherwise permitted under the FDA Rule may be distributed to adult consumers at point of sale but may not be played or shown at point of sale (i.e., no "static video displays").

Appendix VIII - Public Disclosure of Past and Future Tobacco Industry Documents and Health Research

The legislation would ensure that previously non-public or confidential documents from the files of the tobacco industry -- including the results of internal health research -- are disclosed to the federal government, the States, public and private litigants, health officials and the public. The legislation also would provide for binding, streamlined and accelerated judicial determinations with nationwide effect in the event that disputes remain over the legitimacy of claims of privileges or protections, including attorney-client privilege, and work product and trade secret protections.

1. Under the Act, the manufacturers and CTR and TI would establish a national tobacco document depository that is open to the public and located in the Washington, DC area. This depository would serve as a resource for litigants, public health groups, and anyone else with an interest in the tobacco industry's corporate records on the subjects of smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes and underage tobacco use and marketing. Specifically:

-- The depository would include all of the documents produced to the other side by the manufacturers, CTR and TI in the Attorneys General actions (including all documents selected by plaintiffs from the Guilford, U.K. repository), Philip Morris Companies Inc.'s defamation action against Capital Cities/ABC News, the FTC's investigation concerning Joe Camel and underage marketing, the Haines and Cipollone actions and the Butler action in Mississippi.

-- In the event there are additional existing documents discussing or referring to health research, addiction or dependency, safer/less hazardous cigarettes, studies of the smoking habits of minors and the relationship between advertising or promotion and youth smoking that the manufacturers or trade associations have not yet completed producing as agreed or required in the above actions, such additional documents shall be placed in the depository commencing within 90 days of the effective date of the Act, and concluding as soon as practicable thereafter.

-- Except for privileged and trade secret materials (which shall be exempt from disclosure into the depository), all documents placed in the depository shall be produced without any confidentiality designations of any kind.

-- Along with these document collections, the manufacturers and trade associations shall place into the depository all indices (as defined by the court's order in the Minnesota Attorney General action) of documents relating to smoking and health, including all indices identified by the manufacturers in the Washington, Texas and Minnesota Attorney General actions. Any computerized indices shall be produced in both a computerized and hard-copy form. (If reductions of any such indices are required in order to protect any privileged or trade secret information, such reductions shall be subject to the procedures set forth below for adjudicating any disputes over claims of privilege and trade secrecy.)

-- All documents placed into the depository shall be deemed produced for purposes of any litigation in the United States. The court in each underlying action shall retain the discretion to determine the admissibility on a case-by-case basis of any such produced document.

-- The tobacco industry shall bear the expense of maintaining the depository.

2. Immediately upon finalizing a resolution of these litigations with the Attorneys General, without waiting for Congress to embody these requirements in the proposed legislation, the manufacturers, CTR and TI shall:

-- Commence to conduct a good-faith, de novo, document-by-document review of all documents previously withheld from production in tobacco litigation on grounds of privilege. The purpose of this review shall be to identify documents which the reviewer concludes are not privileged. All documents so identified shall be placed in the depository as soon as practicable.

-- Prepare and place in the national depository as soon as practicable a comprehensive new privilege log of all documents that the manufacturers, CTR and TI, based on their de novo review, continue to deem to be legitimately privileged against disclosure.

-- Itemize on this new privilege log all of the descriptive detail that the court has required defendants to furnish document-by-document on their privilege logs in the Minnesota Attorney General action, thereby ensuring that there will be sufficient detail on the privilege logs to enable any interested person to determine whether he or she wishes to challenge claims of privilege or trade secrecy on any particular documents.

3. The Act also would establish a panel of three federal Article III judges, appointed by the Judicial Conference, to hear and decide all disputes over claims of privilege or trade secrets, except for those disputes that already have been determined by other federal or state courts at the time the Act is enacted or are pending in cases prior to the time the Court has had an opportunity to begin to review privilege claims.

-- The three-judge panel shall decide all privilege or trade secrecy challenges asserted by the federal government, the States, public and private litigants, health officials and the public with respect to tobacco industry documents.

-- The Act would vest exclusive federal jurisdiction for the three-judge panel to decide any such disputes in accordance with the ABA/ALI Model Rules and/or principles of federal law with respect to privilege and the Uniform Trade Secrets Act with respect to trade secrecy. Any such adjudication shall be reviewable only in the manner prescribed by 28 U.S.C. [Sec. 125-certiorari].

-- The panel's adjudications shall be binding upon all federal and state courts in all litigation in the United States.

-- The panel shall be authorized to appoint Special Masters pursuant to Fed. R. Civ. P.53, with the cost to be borne by the tobacco industry.

-- Once the Act becomes effective and the three-judge panel is appointed, all disputes that may arise concerning privilege claims by the manufacturers or trade associations relating to smoking and health subjects must be resolved through this process, except for disputes in pending cases that can be resolved prior to the time the Court has had an opportunity to begin to renew privilege claims.

-- If a claim of privilege is not upheld, the three-judge panel shall consider whether the claimant had a good faith factual and legal basis for an assertion of privilege and, if the claimant did not, shall assess against the claimant costs and attorneys' fees and may assess such additional costs or sanctions as the panel may deem appropriate.

4. In order to expedite the process of judicial review and to ensure that the federal government, the States, public and private litigants, health officials and the public no longer need to be concerned that claims of privilege and trade secrecy are being asserted improperly or without legal basis, the legislation would create an accelerated process by which any public or private person or entity, subject to a right of intervention by any other interested person or entity, may challenge any claims of privilege or trade secrecy before the three-judge panel. Under the Act, a person or entity filing such an action to challenge to privilege or trade secrecy will not need to make any prima facie showing of any kind as a prerequisite to in camera review of the document or documents at issue.

5. The manufacturers would also be subject to certain continuing disclosure obligations over and above the aforementioned provisions and whatever further judicial discovery may be required in pending or future civil actions. Specifically, for the first time ever, the manufacturers would be required to disclose all original laboratory research relating to the health or safety of tobacco products, including, without limitation, all laboratory research relating to ways to make tobacco products less hazardous to consumers.

-- Whenever such research is performed in the future, the manufacturers shall disclose its results to the FDA.

-- In addition, all such research (except for legitimate trade secrets) shall be produced to the national document depository described above. In addition, the manufacturers and trade associations shall produce into the depository on an ongoing basis any future studies of the smoking habits of minors or documents discussing or referring to the relationship, if any, between advertising and promotion and underage smoking.

-- No original laboratory research relating to the health or safety of tobacco products shall be withheld from either the FDA or the depository on grounds of attorney/client privilege or work product protection.

6. The tobacco manufacturers' and CTR's and TI's compliance with any of the provisions of this Act shall not be deemed a waiver of any applicable privilege or protection.

7. The Act will also incorporate reasonable and appropriate provisions to protect against the destruction of documents bearing on matters of public health or safety.