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ANALYSIS OF THE PROPOSED RESOLUTION OF THE UNITED STATES TOBACCO LITIGATION

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On July 16, 1997, we released a detailed analysis of the analysis of the proposed resolution to the tobacco litigation without citations or bibliography and requested comments and criticisms. Several people provided technical comments, and many people asked that we "repackage" our analysis in to a series of 2-3 page "briefing papers" on different issues related to the tobacco deal. We are now releasing these draft "briefing papers" to again solicit comments. We anticipate finalizing both these briefing papers and the detailed analysis in early September and would appreciate any comments you have to offer. (We will publish the final report in two volumes.) If you would like to provide us with comments, please send them to Stanton A. Glantz, PhD, Box 0124, University of California, San Francisco, CA 94143 or email glantz@cardio.ucsf.edu, with copies to Brion Fox (email fox@cardio.ucsf.edu) and Jim Lightwood (email lightwo@itsa.ucsf.edu).

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EXECUTIVE SUMMARY

On June 20, 1997 a group of attorneys general presented to the public a proposed resolution, which would resolve their lawsuits against the tobacco industry and establish a national tobacco policy for the United States. This deal, which had been negotiated with the tobacco industry, was widely anticipated. It became possible as a result of the intense pressures the tobacco industry has faced in the past few years from regulatory authorities and from the threat posed by civil litigation against it.

Because of these pressures, the tobacco industry was willing to come to the negotiating table and develop a deal acceptable to it and to a group of attorneys general who had sued it. As conditions for settlement the tobacco industry wanted protection from the threat of lawsuits and restrictions on regulatory control. In return the attorneys general wanted concessions which would provide the states reimbursement for the excess medical expenditures and would improve the public's health.

In the months leading up to the publication of the deal, many commentators discussed the relative merits of entering into a negotiated resolution. 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 about making a deal which would guarantee tobacco industry profitability, would require Congressional action because of the influence the tobacco lobby in national politics, would preempt stronger state, local and regulatory efforts to control tobacco and would preclude broad based public health efforts to control tobacco in the future.

With the publication of the deal it is possible to analyze its merits directly. Within the Preamble to the document are many strongly worded claims that the deal will strengthen the federal and state government's regulatory arsenal, reaffirm individual's right of access to the courts, ensure FDA and state regulatory flexibility to affect youth access, hazardous components of tobacco products, and other tobacco related issues, and fund various programs to compensate those who have suffered loss due to tobacco products. When the terms of the deal are analyzed directly, it is clear that the deal does not measure up to the promises made.

An analysis of the individual terms of the deal discloses three facts.

First, the deal is far from complete. In many parts terms are left undefined, there are ambiguities and inconsistencies. The legislation that is drafted with this as a basis will need to make assumptions which may or may not be consistent with the drafters' intent. In most cases the ambiguities are in areas emphasizing the public health implications of the deal, whereas the portions of the deal which provide protection to the tobacco industry are more well-defined.

Second, the deal fails to live up to its billing. Close scrutiny of the likely policy implications of the individual terms of the deal disclose that the disadvantages outweigh the advantages.

The advantages purported in the deal could be obtained without the necessity of incurring the disadvantages attendant with giving the tobacco industry special treatment.

As a result, we conclude that the deal fails as a public health tool.

The Funding Provisions Are Inadequate

The money in the deal is large in absolute terms but small when compared against the damage done by tobacco products. Therefore, with a careful analysis it becomes clear that there will be insufficient funds to satisfy all claims. The amount of medical damages against the industry for the settled claims are out of proportion to the actual money that will be available resulting in a great under-funding. Moreover, the financial portions of the deal are structured in such a manner that they will guarantee industry profits and will be insufficient to cause a dramatic drop in demand or create incentives for industry reform.

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 incentives to the industry and a cost shifting to American taxpayers. Taxpayers will absorb 30-40% of the cost of the deal.

The Industry Will be Protected From Most Threats of Litigation

The civil liability protections will strongly protect the tobacco industry. They will increase the barriers to litigation and provide perfect security to the industry in the way of capping exposure. The limitations on litigation may deprive injured smokers from receiving just compensation. The caps will eliminate the incentives civil justice system by reducing any threat for failing to act in a responsible manner.

Regulatory Controls are Unnecessary and Insufficient

Specifically, the claims of that the deal results in new regulatory authority are exaggerated. The FDA already 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, or like the advertising restrictions, be regulated by another agency. Furthermore, the claims regarding the benefits attendant with many of the regulatory changes are exaggerated. 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 also adds intensive rollbacks to the FDA authority that currently exists. The Agency will face additional regulatory hurdles before it can regulate tobacco constituents and will have specific restriction on how and when it can regulate nicotine. These hurdles will preclude much of the potential for reform towards safer products.

Similarly, the environmental tobacco smoke provisions represent a rollback of the current ability to regulate broadly. The ETS provisions within the deal would exclude a large number workplaces such as in the hospitality industry. These restrictions are not a part of the proposed OSHA regulations currently under review.

The Lookback Provision Is Inadequate

There are provisions in the deal designed to hold the industry accountable for not implementing programs to decrease youth smoking, by exacting penalties for not meeting specific targeted reductions. These targets, however, are based upon faulty analysis of youth prevalence rates, and the penalties imposed are not sufficient to create industry incentives to eliminate youth smoking.

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 towards 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 industry.

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

If one assumes that there are beneficial aspects to this deal, but one is nevertheless concerned with the negative aspects of the deal, much of the same legislation could be, and arguably should be passed independently. For example, the public health measures could be funded by an increase in the tobacco excise tax. The Congress could give the FDA and OSHA more direct authority over tobacco products, and could ensure full funding for the programs. The States could enter into individual legal settlements with the tobacco industry in the same way that Mississippi did. The absence of such political will may be indicative of how the Congress is still a pro-tobacco institution and also how the deal will fare in Congress.

Conclusion

When weighing the advantages with the disadvantages of the deal it becomes clear that the costs far

outweigh the benefits, and that it is unnecessary to view the deal as a whole. The deal removes all incentive for the tobacco industry to change its behavior by limiting regulatory, civil liability and market controls. As a result, we conclude that the public health would be better served if the deal is rejected on its merits.

The Tobacco Deal: Political Issues

The original premise for the deal was that, while public health advocates had rarely been able to overcome opposition from the tobacco industry in Congress 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,¹ 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) assured people that they had private assurances from President Clinton and Senate Majority Leader Trent Lott (Scruggs's brother-in-law) that if the attorneys general, public health groups, and tobacco companies could come to an agreement, that they would see that the deal went through Congress unchanged. As a result, the deal was presented as a take it or leave it proposition, with various proponents arguing that it is both necessary to do everything in the deal, and that it is impossible to separate out the individual provisions of the deal.

The Boards of Directors of Philip Morris and Lorillard tobacco have endorsed the deal as it is written.

In contrast, no public health organization has embraced the deal as written.² Therefore, 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 so as to avoid the likelihood that the tobacco industry will dominate the Congressional decision making process. In order 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 credit against the costs of the deal based on the fact that the tobacco excise tax (paid by smokers) was increased by 15¢.

1. One wonders if this was ever a realistic expectation. It is hard to imagine the image of John Seffrin (CEO of the American Cancer Society), Dudley Hafner (CEO of the American Heart Association), Geoffrey Bible (CEO of Philip Morris), and Steven Goldstone (CEO of RJ Reynolds) appearing at a witness table together, stating under oath that they all supported any piece of legislation.
2. The American Cancer Society, American Heart Association, and American Medical Association, 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 continued support of some public health groups for the process of a negotiated settlement 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. Moreover, if the public health community is to go to Congress as opponents of the tobacco industry, it should be to implement the positive aspects of the deal legislatively independent of the concessions that had been made to the tobacco industry regarding liability and regulatory relief.

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

OSHA is developing a rule which would restrict secondhand smoke throughout workplaces across the country. The deal is not required for OSHA action.

Mississippi entered into a separate settlement of its litigation against the tobacco companies. Under the terms of this settlement it recovered more of its damages than it would recover under the terms of the deal. It is believed that many of the other states and private litigants could achieve more favorable terms by settling independently with the tobacco companies than by supporting the deal.

Several states (California, Massachusetts, Arizona and Oregon) have large tobacco control efforts. Massachusetts and Minnesota have laws requiring ingredient disclosure.

Even if it were a valid policy gesture to settle the Medicaid lawsuits, there is no reason that other private litigants should have their rights restricted.

The primary effect of the deal on tobacco consumption has been assumed to be through the price increase associated with the passthrough provision. As constructed, this situation essentially taxes smokers to pay for the tobacco industry's legal liability (just as Congress' recent action to give the industry a \$50 billion credit against the cost of the deal did). It would be simpler and more just to simply increase the tobacco tax.

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The Tobacco Deal: Funding the Settlement

There are three parts to the settlement 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 equal to \$10 billion with no allocation provided for in the deal is not incorporated into the analysis. This payment is presumably to compensate for past damages. 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 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 consumption.

The civil liability fund is inadequate. According to some estimates as much as \$70 billion dollars worth of recoverable damages are incurred 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 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 woefully insufficient even before the class actions are considered.

This under-funding 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 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. For example, there is a 20-30 year lag in the development of smoking related diseases after smoking initiation. Thus, the tobacco companies would be able to reduce its payments immediately even though health care costs won't 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 1.7 per cent per year. The second is a high cost cases 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.

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 \$223 billion, for the high cost it is \$306 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 74 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 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 tax-payers. 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 profits to as much as \$30 billion domestically. 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.

Table 2. Inadequacy of funds in settlement , assuming Medicaid priority on unallocated funds(Years 1-10) (Percent of budget met by settlement)		
	low medical inflation	high medical inflation
Average Medicaid reimbursement	76%	64%
Average Civil liability reimbursement	<5%	<5%
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%

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The Tobacco Deal: Funded Public Health Measures

The deal signatories suggest two specified budgets for public health programs within Title VII of the deal. One 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. The second 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 projected budgets (in \$ billions prior to inflation adjustments) for the Title VII programs are:

Year	1	2	3	4	5	6	7	8	9
Public Health Trust Fund (Medical Research)	2.5	2.5	3.5	4.0	5.0	2.5	2.5	2.5	0.0
Public HealthA Funds (Tobacco Control)	2.100	2.175	2.200	2.325	2.825	2.825	2.825	2.825	2.825

The deal creates the impression that the funds under this document for public health monies necessitate granting immunity to the industry and otherwise restricting public health controls. This is not true. As is shown by the NCI's ASSIST program and the large scale public education campaigns funded by higher tobacco taxes in California, Massachusetts, Arizona and Oregon, providing money for these public health programs is simply a matter of political will. In addition, there is a ready mechanism for raising the funds by raising the national tobacco tax. The effect on the market would be the same (or, perhaps, more predictable) as in the deal. The only separate opposition than would come from using this funding mechanism as opposed to the one in the deal would be from the tobacco companies. The only difference between funding these programs from an excise tax and funding them through the deal, is that the deal offers substantial benefits to the tobacco industry in exchange for passing these costs along to its consumers.

Moreover, because of the passthrough requirements of the deal, the cost of the programs will ultimately be borne by cigarette consumers under the deal or an increase in the excise tax. In many ways, the deal has the same effect as the recent (and heavily criticized) action by Congress to give the tobacco industry a credit of \$50 billion towards the cost of the deal to offset the increase in the tobacco tax (which is paid by smokers). In both cases, the smokers are expected to bear the full cost of the deal even though the benefits accrue to the tobacco industry.

Furthermore, because there would be no anti-trust protections with an increased excise tax, there is a strong possibility that an increased tax would have a greater impact on tobacco industry profits which would create an incentive to innovate. If there is an absence of political will to pass such a program because of tobacco industry opposition, one must be skeptical about any the ability of the Congress to implement this deal in a manner which improves the public health at the expense of the tobacco industry.

Furthermore it is not clear how the funding for these programs is guaranteed. For example it is not specified from what account the Public Health Funds are to be allocated. Because the Public Health Trust moneys are fully accounted for in Subsection E to Title VII, presumably the Public Health Funds would come from the Base Amounts described in Title VI. This policy places the public health funds in direct competition for medical cost reimbursement, since the deal does not contain enough money to fully fund both. Based on the experience of California and other states that have tobacco taxes dedicated to public health programs, there will probably be pressure to eliminate the public health funds.

There are also limitations to the programs proposed. The programs are designed around specific goals such promoting cessation, de-glamorizing tobacco use and discouraging initiation by persons under 18 years of age. By doing so the programs may become self-limiting. For example, in some jurisdictions around the country efforts to produce anti-tobacco education campaigns have been limited to advertisements targeted directly towards children. This is true despite evidence which indicates that tobacco education programs aimed at broad audiences and those highly critical of the tobacco industry are more effective. To prevent these limitations from occurring in any of the public health programs designed under the deal, extraordinary care should be taken to provide broad discretion to program coordinators.

There are also problems with the money allocated in Title VI for the Public Health Trust Fund, presumably the same fund described within Subsection E to Title VII for which a Presidential Commission is established to distribute this \$25 billion fund for "specific tobacco-related medical research." First, it terminates after a period of eight years when it is highly unlikely that there will be no need for additional research after that time. Second, the Commission is to be comprised of public health officials, the Attorneys General and attorneys representing the Castano classes. Yet the funds are to be

used for medical research. This dichotomy should be resolved and the Commission should be restricted to professionals in the field for which the funds are to be used. Third, the scope of the research should be expanded to include applied and policy research. Many of the reductions in morbidity and mortality due to tobacco has resulted from advances in policy and public health not biological factors in health improvement rather than medical advances.

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The Tobacco Deal: Tax Issues

Subparagraph D to Title VI of the deal deems that all of the moneys paid pursuant to the deal will be deemed ordinary and necessary business expenses for the purposes of tax treatment. The present discounted value of the tax deduction over the first 25 years of the settlement is \$97.6 billion dollars at a 2.5% real discount rate and 35% tax rate. As a result, taxpayers will absorb 30-40% of the cost of the deal.

All payments by the tobacco industry, including those made "in lieu of" punitive damages (which, in many cases, are not tax deductible), are tax deductible which results in a decrease in incentives to the industry and a cost shifting to American taxpayers. Although there has been much rhetoric that the goal of the deal is to compensate victims and not to penalize the industry, this greatly oversimplifies the issue. The claim that the deal is not intended to penalize the industry is also contrary to the preamble which implies that a fraction of the moneys collected in the deal is to offset the prevention of punitive damages for cases involving past conduct. Yet under many circumstances punitive damages, as with fines and penalties, are not tax deductible. Thus, this makes clear the artifice of "resolving" past punitive damages.

Other than as a necessary concession to the industry for the sake of getting its approval for the deal, there appears to be no public health benefit to this provision. The disadvantage is that this provision substantially changes the financial impact of the settlement for the industry. Tax deductibility will reduce the financial pressures on the industry and consumers. For example, the lookback provisions are based upon a disgorgement of the profits of the addicted youth smokers. Because the payments would be tax deductible, this would allow the industry to, in effect, keep some of the profit it was supposed to disgorge.

In addition, the deal envisions benefits as a result of the "passthrough" of industry costs to the consumer, to increase the price of tobacco products and decrease demand. This demand decrease will be blunted because of the costs incurred by the industry will be reduced by the tax deductibility. The before tax cost per pack is between 36 and 59 cents (an 18-30% price increase) over the first ten years, the tax deduction reduces this to between 23 and 39 cents (an 11-19% price increase). Alternatively, if the industry passes through the entire before tax cost of the deal, the tobacco companies will have a profit windfall.

This provision is sufficiently broad that an argument could be made that any fines resulting from the enforcement of any violation of the regulations or laws would also be deemed a payment under this deal and therefore tax deductible. This argument is even more persuasive when the deal establishes special treatment for the tobacco industry, such as the \$10 million fine for violating the FDA disclosure requirements (Title III.A). Furthermore, this provision could weaken the enforcement of other state and federal laws by allowing the tobacco industry to deduct the cost of any civil fine levied against it.

This provision also gives rise to large collateral effects. First, a deal which implicates the tax system could restrict future efforts to increase the tax on tobacco products. (Indeed, the recent decision by Congress to give the tobacco industry a "credit" against the cost of the deal equal to the increase in the cigarette excise tax shows that this tradeoff already has been made.) Similarly, a settlement fund would

not provide the flexibility to account for future understanding of the economic toll tobacco has on society. As a result, restricting future economic flexibility by entering into a global settlement would limit our ability in the future to apply economic incentives to modify the tobacco companies' behavior. Second, all of the money paid by the tobacco industry is accounted for in payouts, this deal could be internally revenue neutral. The industry will, however, be able to deduct the payments, so that there will be a net loss in general tax revenues. This shortfall, which could rise to as much as 40% of the annual payments (i.e. between \$3.4 billion and \$6 billion annually) is approximately twice the amount of the Public Health Funds. This money will need to be made up by either reducing spending for other public programs or by raising revenues on other taxpayers. This cost shifting is another way the industry will be able to externalize the costs related to its product to others.

It would be cheaper for the Congress to simply appropriate funds for the public health programs from general revenues or a dedicated tobacco tax.

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The Tobacco Deal: Effects of the Passthrough Provision

The passthrough provision 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, this results in a mandated price increase. This 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. This may reinforce the current market and pricing structure and limit competition.

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

Depending on the assumptions on what costs are subject to a pass-through, the price per pack of cigarettes will increase from between 15 to 25 per cent on average over the first 10 years of the settlement. This will reduce volume of adult sales by an average of 6 to 10 per cent. Revenue will increase as result of this by 4 to 6 per cent on average. It must be remembered, however, that because of the volume adjustment provisions 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 pass-through provision on youth consumption and uptake is controversial because estimates of youth price elasticity of demand are very uncertain. Some studies indicate that it is one or even higher, others that it is close to zero. The measurement is difficult because youth smoking is illegal, youth themselves purchase only one half to two-thirds of the tobacco they consume, and new smokers often consume sporadically. Secondly, 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 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. This analysis will look at the case of a 0.6 price elasticity, 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 one third of the initial 30% youth daily smoking reduction and about 15% 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.) Finally, 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.

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The Tobacco Deal: 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, 40% 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 any 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, 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.

Rebate for Good Behavior. 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. Brand preference of the youth market can be observed, so each firm could be penalized for its individual sales to youth. It is also not clear how the industry's "good faith compliance" could be assessed, particularly since the industry is well practiced in developing "anti-smoking" programs that subtly promote smoking.

Daily Smoking Prevalence is the Wrong Measure. The settlement language indicates that the goal is to reduce youth smoking. However, the measure used is the prevalence of daily smoking, and this is only a portion of youth consumption. By the age of eighteen, only 75% of adult smokers have started daily smoking, but around 90% have already initiated *some* smoking. The gap between daily smoking and first use is larger for 13 to 16 year olds. Therefore, this measure misses 25% of youth smoking that leads to an adult habit. In addition, the measured daily smoking prevalence may fall while less intense youth consumption remains about the same, so changes in daily smoking will overestimate the actual reduction. Almost as many frequent smokers have symptoms of addiction as daily smokers. If the industry can keep frequent smoking rates relatively high while delaying daily smoking for just a year or two, they will evade the surcharges completely, with little change in the overall number of people who initiate smoking as youth and go on to become addicted smokers.

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The Tobacco Deal: 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 protections in Subparagraph A to Title VIII by eliminating all Attorney General actions, and similar actions brought on behalf of governmental entities, 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 payor 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.

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. Therefore, the settlement amounts would need to be divided among all possible claimants. 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 to sue 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. The possibility of a conflict of interest has been raised for these attorneys because they eliminated the rights of many entities who are their clients without guaranteeing any recovery. Furthermore, the fact that the negotiating attorneys will be so richly rewarded highlights the need for health groups with no involvement in the negotiations to insist that the provisions of any agreement (whether federal or with individual states) be in the public interest.

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The Tobacco Deal: Added Protections Against Most Civil Liability for the Tobacco Industry

The tobacco industry desired complete protection from all lawsuits; 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 a fund to be set aside from the industry payments to pay for damages in future cases. The size of the fund, begins at \$2 billion in year one and rises to \$5 billion in year nine. 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, including:

- no punitive damages
- no 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 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
- 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.

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 barriers to filing suit against the tobacco industry are extremely high. The industry uses extremely 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. 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 for the spread of risk and increase the likelihood of higher damages.

Through this deal the barriers to litigation are raised, which 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 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 likelihood that lawsuits will be filed will be reduced dramatically. 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 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. Finally, in some cases it may be possible to use epidemiological evidence of large groups to prove causation. This minimizes the ability of the tobacco industry to "blame the smoker" and may prove to be a more effective legal strategy. By eliminating class action lawsuits, fewer plaintiffs are likely to sue and recover damages against the industry, and attorneys may be less likely to represent individuals.

One of the reasons the tobacco industry has not paid money damages in a personal injury lawsuit, 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. 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. Suits are either third party payor claims or "claims of individuals." 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 per suit/per year basis, and the tobacco companies will be shielded by an aggregate cap for all lawsuits. These financial barriers will also 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.

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 of the expansion of many Statutes of Limitation, modifying the law of a jurisdiction which uses the discovery rule. 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 payors. 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 enormous barrier to payors 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 during 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 near complete immunity from future litigation. The right to sue is a right in name only.

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.

This deal removes essentially all of the incentives for the tobacco companies to act more responsibly. 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 payor 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 in which this is phrased creates ambiguities which makes 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. In the worst case scenario, assuming that each company pays pro rata into the settlement fund, and that the fund represents 100% of the money available for civil judgements the companies will have no incentive to improve their behavior or their products. If the tobacco companies behave in a responsible manner and avoid all litigation, they will pay 1/3 of the base amount into a civil liability fund. If they behave irresponsibly and lose all litigation, they will pay 1/3 of the base amount into a civil liability fund. But even if these figures are adjusted upwards by 25%, or an individual company could be responsible for the full amount of the cap, the risk to 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. This raises issues of justice, because it could deny the ability to fully recover judicially appropriate damages. It may also result in inadequate compensation for injured persons, and may deny recovery to different people who are otherwise similarly situated.

The restrictions on future lawsuits will create the same barriers to suit that exist as the restrictions on suits for past damages. The only difference 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 the damages caps will still be in place, as will the other procedures which protect the industry from the risks of civil litigation, and the increased barriers to suit.

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The Tobacco Deal: Protecting the Oligopoly

Few people would disagree that there is some form of market failure at work 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. As an oligopoly the current tobacco companies enjoy large profits.

The deal would memorialize many of the 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 from 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, and 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.

But 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 pattern.

Ultimately, it may not be bad to eliminate new market entrants, but there are problems with this structure. First, it is such a blatant power grab by the tobacco companies, one is skeptical of its benefits other than to preserve the profitability of the those tobacco industries we know are culpable. Second, the restrictions are so broad that they may implicate Constitutional issues. For example, the specific application of the user fee if a new entrant does not voluntarily forfeit its rights to a trial before a jury or its First Amendment rights, raises multiple due process issues (takings, separate application of the laws, etc.), and many First Amendment issues. Third, much of the consideration for the deal is based upon relieving the tobacco companies 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.

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

In addition, there are other provisions within the deal which will protect the current tobacco company's oligopoly. The provision that requires all costs of the deal to be passed through will simply memorialize the market failure. First, the passed through costs are sufficiently small, that the effect on demand will be small. Second, 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. Third, it is unclear how closely the passthrough will reflect the true costs of the deal. 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 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.

Similarly, the joint liability provisions and the industry cap on civil liability damages provides an additional opportunity to share information among the tobacco companies.

The tobacco companies will be guaranteed excess profits and will have no incentive to modify their behavior or to innovate. Instead of requiring a passthrough, the market failure should be repaired by eliminating anti-competitive behavior and the cost of the deal will more closely be reflected in the market price. Additionally, this would likely free up substantially more room to negotiate for more money under the deal.

In addition, despite the possible benefits to allowing the tobacco companies 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.

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.

Another provision which has the potential to be anti-competitive is section E(1) 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. Furthermore it erects market barriers for new market entrants by restricting the cross-licensing requirement of new technologies to these entities.

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 failure is memorialized by preserving the oligopoly pricing structure and failing to remove the information inequities within the market. In addition, it provides opportunities for further conspiring. 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.

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The Tobacco Deal: Access to Tobacco Industry Information

It appears that 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. 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 companies would also not have to release their studies related to secondhand smoke.) 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 the Rules of Evidence. In addition, there is a belief that the tobacco companies may be "hiding" additional documents overseas.

Therefore, it is highly unlikely that with the tobacco companies, still vulnerable to attacks on their corporate character in the media and still defending lawsuits in other countries, that they 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 them from in judges who are familiar with the industry's recalcitrance and exposes them to essentially 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 incentive to sue, make it unlikely that anyone would seriously challenge industry claims of privilege, making it unlikely that these documents would ever be made public. Finally, 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.

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.) Thus, it is quite disturbing that many are advocating giving a special deal to the tobacco companies before the documents are fully reviewed. Before any grants of immunity or other protections are given to the tobacco companies, all of their internal documents should undergo a thorough public review and be made widely available, such as via the Internet.

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, 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. The disclosure of documents alone, even if complete, is insufficient.

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The Tobacco Deal: Limitations on 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 would be unacceptable. Subparagraph B of Title V provides for the authority of 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) limits state and local control for the sake of having national warning labels and national performance standards for tobacco products. After five years, however, states can apply for a special exemption related to the disclosure of ingredients. The deal preempts or complicates state and local action for tobacco control and will benefit the tobacco industry.

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 Administration 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.

Furthermore, 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. The 5 year stay on granting exemptions for listing ingredients will similarly preempt existing state regulatory authority. There is no public health reason for this restriction.

The terms of the deal may explicitly preempt many state enforcement activities. For example, the deal restricts state enforcement actions such 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.

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 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. Third, the comprehensive regulatory scheme could be used as a potential defense to criminal actions. 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. Similar arguments could be made as a defense to other criminal

law actions. Fourth, the delays in state regulatory authority, such as the five year delay in disclosure requirements will buy the tobacco industry time to influence state politics and to see that current public health officials are replaced.

Another way in which the deal limits state authority is by providing for penalties for failing to meet youth access requirements. These provisions deem that the states will forfeit money for failing to meet compliance rates on retailer sales. This is a misplaced program and a mechanism to weaken state oversight over tobacco control. First, there is at best a loose connection between youth access laws and youth consumption. 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 would be forced to reallocate substantial resources away from effective youth consumption programs into compliance checks.

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The Tobacco Deal: General Enforcement

As with any law there needs to be an effective enforcement mechanism to ensure obedience. 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. These contractual agreements are intended to the possibility of a Constitutional challenge of the laws by the tobacco companies. The deal would be subject to the penalties of the statutes which will be enacted or amended as part of the deal, including the Food Drug and Cosmetic Act. States would not be able to go beyond the scope of penalties established within the legislation. 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. The enforcement scheme in the deal would preempt all of these enforcement mechanism for any matters covered by the Act or the Protocol. The Act and the Protocol are so broad, however, that it incorporates most if not all of industry behavior effectively barring enforcement. Moreover, the deal would not provide for citizen enforcement of the laws or the Protocol. If there is to be a comprehensive national solution, it is vital that individuals have an independent right to enforce the terms of the deal.

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 no longer 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 that this 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 authors of the deal are asking people to make a blind horse trade.

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, it is axiomatic that the Congress will be able to void the terms of the Consent Decrees.

Second, the Consent Decrees as constituted are weak. There is no Consent Decree which 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 forum shops to find a weak interpretation of the Consent Decrees and forces that interpretation upon other jurisdictions. Finally, the Consent Decrees appear to be duplicative of the Protocol, and it is not clear which would take priority.

The Consent Decrees would also 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 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 FDA should be protected from these influences.

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The Tobacco Deal: Disclosure of Tobacco Ingredients

The deal the tobacco companies would be required 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 the favor of the tobacco industry, and will actually slow the process of ingredient disclosure under existing state laws.

Two states -- Massachusetts and Minnesota -- have enacted ingredient disclosure laws. While the industry is challenging these laws in court, it is likely that these states will be able to force ingredient disclosure through simpler procedures than those proposed in the deal. The deal would preempt these laws for five years and then establish cumbersome procedures for enforcing them.

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. These safety tests could fall into the same traps, leaving heavily addicted smokers subjected to risks from additives, which the industry could now claim that they are simply meeting the federal requirements. Past experience has shown that the tobacco companies will take advantage of any opportunity to slow the regulatory process. This provisions 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 should be reversed. The tobacco industry should have a much shorter time frame in which to prove that the additives when used in a reasonably expected manner are safe. If the tobacco industry fails to meets 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 its 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 burdens on the industry, which already has (or should have) the scientific data on the safety of it 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 arises 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. (Although 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 for 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 products 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. The FDA, and the states, should have the flexibility to design a disclosure requirement which can take into account the unique status of tobacco products. Consumers should have full disclosure so that they can better understand the risks.

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The Tobacco Deal: The Reformation of the Tobacco Industry

It is clear that 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 and require that any reconstituted trade group be subject to governmental supervision, would protect whistle blowers, and would provide for enforcement of the changes in the changes of 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 the one 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 bucket 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. The CEOs appeared in Congress Waxman's hearing 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.

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 their product all through the stream of commerce. While the deal seeks to hold 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 Tobacco Institute and 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, there are new organizations, such as the Center for Indoor Air Research and Project 99, that now promote the tobacco industry's goals. The deal is silent about how these new organizations would be modified.

Finally, despite the possible benefits to allowing the tobacco companies 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.

In sum, the attempts to provide for corporate reformation will not be effective. The Tobacco Industry will continue to be an enemy to the public's health and must be viewed as such. Holding the companies accountable through the civil and criminal legal system, and the attendant economic incentives, has a greater chance of forcing changes in corporate behavior.

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The Tobacco Deal: 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 embraces this model by legislatively investing 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. If the Congress is going to codify FDA regulatory authority, it should give the FDA full authority.

Under Section E(1) to Title I of the deal tobacco products are defined as they are in the current FDA rule. 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 treating tobacco products with special controls, this decision should be left in the hands of the FDA.

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. No restrictions should be placed on FDA regulatory authority in the deal, and the FDA should be left to resolve the ambiguities created by having to regulate a hazardous product in a scheme designed to regulate safe products.

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 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) 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 12 mg. 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.

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 any type of modification 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 constituent 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 be welcoming a prohibition on the use of some of the hazardous products currently on the market. (For an analogous example one can look to market replacements which facilitated the banning of environmental toxicants such as PCBs and DDT.) 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) 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 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," an extremely burdensome requirement. Even after the 12 year period the standard will be "preponderance of the evidence" standard which is still over and above what is necessary in other regulatory contexts and will prove to be a hindrance to agency action. These heightened burden 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 incorrect assumption that the gradual reduction of nicotine will benefit smokers. It is unclear whether there is a threshold below which nicotine loses its addictive properties. Until that threshold is met, 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 the increase in health risks at least over the short term. This creates a dilemma which could possibly prohibit the regulation of nicotine. If it is true that the gradual reduction of nicotine will make it easier to eliminate nicotine entirely, then this will be 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. (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 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 the nicotine 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 development 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, 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. Product availability will ensure that a demand could be satisfied. (This can be seen when adjoining states or countries have greatly dissimilar taxing structures.) The tobacco companies, would even have an incentive to feed that demand. 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 restrictions placed on FDA oversight of tobacco products will place consumers at risk.

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The Tobacco Deal: 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. 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 much 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 as 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. 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 advertising restrictions are also unlikely to significantly reduce the pervasiveness of tobacco imagery in society. Many countries throughout the world have more restrictive advertising policies 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. 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.

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The Tobacco Deal: 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 adopt a licensing scheme for retailers of tobacco products.

Section C of Title I codifies much 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, there is the concern that these programs have a limited effectiveness. First, there is not good evidence that youth access programs reduce teen smoking prevalence or consumption, with the evidence that does exist speculative at best. 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. 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. 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. Therefore, the advantages claimed by advocates of the deal are exaggerated, and need to be tempered. Effective anti-smoking campaigns must be aimed at all age groups.

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 are exaggerated.

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

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The Tobacco Deal: 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 imbued with the authority to require that such products be brought to market.

Many people view safer cigarettes as the holy grail towards improving the health of smokers. 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. Some people believe that 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, 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 create could actually 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.

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. No market has been demonstrated to exist. Second, due to the market failure extant within the current tobacco industry there is no profit motive to create a safer product. 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 "develope[d] 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 actually stifle research

within the industry. (It is unclear how this requirement segues 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. Many people believe that because of the barriers within the industry, if a safer product is to be developed it will come from outside the industry. By erecting higher barriers for new market entrants, the deal may slow or prevent the introduction of a safer product.

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. This could be done for example, by adopting a requirement that all nicotine be eliminated from cigarettes within a set time period. Similarly, by providing research money, capital market incentives and capital to new market entrants who would produce a safer product would more likely result in market penetration by a safer product and create a competitive atmosphere by which the existing tobacco companies would be induced to develop their own safer products.

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 August 20, 1997 DRAFT

The Tobacco Deal: Secondhand Tobacco Smoke

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

The greatest strides towards clean indoor air has been occurring 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 and would 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 for two reasons. First, it is based on a faulty premise that smoking prevalence will stay constant. To the contrary, many expect consumption patterns to change, resulting in a large demographic shift to non-smokers. Second, research has shown repeatedly that the in communities which pass strict clean indoor air legislation, the restaurants do not suffer economically from the change.

Second, it is not necessary to enter into a deal in order to reduce exposure to environmental tobacco smoke. OSHA is currently reviewing and preparing to issue final regulations governing environmental tobacco smoke. Although it is true that no regulations have been promulgated to date, that is due to the slowness of the regulatory process not a lack of motivation. In addition, with the science becoming so clearly established, with for example the Surgeon General's report on secondary smoke, the EPA declaring environmental tobacco smoke carcinogenic, and the California EPA report, 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 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.

Moreover, as mentioned above, states and localities have been the focus of much of the clean indoor air efforts with great success. There are some in the tobacco control community who see immeasurable 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. Whichever approach is better, national or local, it can be and is being enacted without the need for the deal.

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August 19, 1997

Gerold Mander
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Washington, DC 20502

Dear Mr. Mander,

Elizabeth Drye asked me to send you this material. We are updating this analysis; I will send that along in a couple of weeks.

If I can be of further assistance, please contact me.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Stanton A. Glantz".

Stanton A. Glantz, PhD
Professor of Medicine
Institute for Health Policy Studies

encl

Commentary

Tobacco Litigation

Issues for Public Health and Public Policy

JAMA made international news in July 1995 when it published a series of 5 articles presenting the first academic analysis of about 10 000 pages of previously secret tobacco industry documents, known as the Brown and Williamson documents.¹⁻⁵ These documents demonstrated that, as long ago as the 1960s, the tobacco industry knew nicotine was an addictive drug and smoking caused cancer and other disease, and that it developed a sophisticated legal and public relations strategy to keep this information away from the public, public health authorities, and the courts. An accompanying Editorial⁶ identified 14 steps to pursue regarding its opposition to tobacco use, including “All avenues of individual and collective redress . . . through the judicial system.” Fueled in part by publication of the Brown and Williamson documents, there has been an explosion of litigation against the tobacco industry since then.

Today the tobacco industry faces a wide variety of legal challenges: product liability lawsuits filed by individuals harmed by smoking; product liability lawsuits filed by individuals harmed by secondhand smoke; class-action lawsuits filed on behalf of people addicted to nicotine; lawsuits by various states to, among other things, recover Medicaid expenditures incurred for the increased costs for caring for indigent smokers; and lawsuits by municipalities and private insurers seeking the recovery of health-related expenditures.

In the past, individual plaintiffs’ firms brought product liability suits on a contingency fee basis. The tobacco industry prevailed by simply grinding these firms down with a policy of dragging out litigation and appeals until the plaintiff’s firm was exhausted. Today, that situation is dramatically different; there is a large network of public and private legal resources arrayed against the tobacco industry. A consortium of more than 60 major products liability firms have mounted a series of state class action suits regarding nicotine addiction.⁷ More recently, the state attorneys general of 21 states, as well as 14 cities and counties, have, with the cooperation of the private bar, brought suits designed to recover the costs to taxpayers of treating tobacco-induced illness. These actions have shifted the focus of tobacco policymaking out of Washington, DC, and back to states and cities, where the chances of a favorable outcome are much higher. These actions for the first time present the tobacco industry with legal opposition with sufficient resources to thwart its war-of-attrition tactics.

The theories on which these cases are being brought make it much harder for the tobacco industry to mount its usual de-

fenses. When an individual smoker sues, the industry works to discredit the individual and argues that it is impossible to be sure that it was smoking that caused the particular disease that injured or killed the plaintiff. The cases seeking reimbursement for health expenditures, however, are not subject to the tobacco companies’ causation argument because they are based on epidemiologic evidence. Indeed, the Brown and Williamson documents show that in 1976, S. J. Green, head of British American Tobacco’s research and development and a member of the board of directors, understood this situation. In a thoughtful essay entitled “Cigarette Smoking and Causal Relationships,” he stated,⁸

The public position of the tobacco companies with respect to causal explanations of the association of cigarette smoking and diseases is dominated by legal considerations. In the ultimate companies wish to be able to dispute that a particular product was the cause of injury to a particular person. By repudiation of a causal role for cigarette smoking in general they hope to avoid liability in particular cases. . . . The industry has retreated behind impossible demands for “scientific proof” whereas such proof has never been required as a basis for action in the legal and political fields. Indeed if the doctrine were widely adopted the results would be disastrous. I believe that with a better understanding of the nature of causality it is plain that while epidemiological evidence does indicate a cause for concern and action it cannot form a basis on which to claim damage for injury to a specific individual.^{8(p1)}

Green, however, then goes on to conclude with an opinion that makes the very point upon which state lawsuits seeking recovery of medical care costs are based:

In summary, for social policy purposes it is sensible and totally relevant to use the experimental evidence pertaining to large groups and also to select the simplest hypothesis. It may therefore be concluded that for certain groups of people smoking causes the incidence of certain diseases to be higher than it would otherwise be.^{8(p1)}

In addition, the lawsuits designed to recover medical costs of smoking borne by taxpayers or private insurance companies deprive the tobacco companies of their favorite tactic of blaming the smoker. In product liability lawsuits brought by smokers, the tobacco companies use defenses such as assumption of risk and comparative negligence to blame the smoker for choosing to smoke and refusing to stop. They seek to eliminate the plaintiff as a sympathetic individual in the eyes of the jury. In contrast, when the issue is state or local taxpayer liability or the liability of private insurance ratepayers for the costs of smoking, the individual smoker’s responsibility is moot.

These lawsuits are beginning to have an effect. The smallest US tobacco company, the Liggett Group, settled the cases against it brought by 5 states under terms that awarded these states (and others that chose to enter the settlement) up to 5% of its pretax revenues to help offset the costs of smoking-

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induced illness paid by these states.¹⁰ Liggett also reached a tentative settlement of the private national class action *Castano v American Tobacco Company*, but the *Castano* class was ultimately decertified by the Fifth Circuit Court of Appeals, thus voiding the settlement.

While the Liggett settlement—which was the first time any tobacco company settled any litigation against it—was hailed as a major political breakthrough, the terms of the settlement were not very good from the perspective of the actual costs of smoking. As it stands, the Liggett settlement will only reimburse the 5 initial settling states for about 8% of the Medicaid costs attributable to Liggett cigarettes; if the entire country joined the Liggett settlement, only about 1% of Medicaid costs attributable to Liggett cigarettes would be covered for the remaining states. These calculations are based on the most recently available numbers. Liggett's annual pretax income from US sales was approximately \$24.6 million in 1995.¹¹ The total US Medicaid costs due to tobacco were \$6.3 billion (4.8% of Medicaid expenditures due to smoking times \$130.8 billion total Medicaid expenditures) in 1993.^{12,13} Liggett's market share was 2.3% in 1994.¹⁴ Increasing medical costs and declining Liggett market share will make the percentage recovery of medical costs in 1996 lower than we estimate. Indeed, 1 state, Minnesota, refused to join the settlement because it deemed the settlement inadequate.¹⁵ Likewise, the proposed *Castano* settlement was advantageous to Liggett, only amounting to a small fraction of the actual costs incurred by smokers addicted to Liggett cigarettes.

For its part, Liggett agreed to the settlements as part of a strategy to reduce its liability exposure in an (unsuccessful) effort to convince RJ Reynolds stockholders to agree to merge with Liggett.¹⁶ This decision represented the first time that such business considerations of limiting liability through settlement rather than a litigation war of attrition played a role in a tobacco company's legal strategy. Despite some controversy about the benefits of the Liggett settlement, the fact that it dealt only with 5 states and that Liggett is the smallest tobacco company made the downside risks relatively small compared with the value of obtaining the first break in the tobacco industry's united opposition to settlement.

The stakes of settlement discussion increased dramatically in August 1996, when the press reported that there were discussions under way on a congressionally sanctioned global settlement, which was weaker than the heavily criticized one proposed by Kluger.¹⁶ The proposed global settlement would have encompassed not only all litigation surrounding the tobacco industry,^{17,18} but also the Food and Drug Administration (FDA) regulations finding that tobacco products were nicotine delivery devices and imposing modest restrictions on tobacco advertising and promotion.¹⁹

Though never finalized or released for public review, the proposal reportedly called for the payment by the tobacco companies of \$6 billion in 1997, escalating to \$10 billion per year in the fourth year continuing for the next 11 years. Much of this money was to be paid to the states to reimburse them for Medicaid costs, and some was to be paid toward individual compensation for sick smokers and to fund tobacco control programs, primarily aimed at children. The tobacco companies were to voluntarily adopt most of the proscriptions in the FDA regulations, and the FDA would forfeit jurisdiction unless certain targets regarding the reduction in youth smoking were met. In exchange, the tobacco companies were to gain protection from most lawsuits.¹⁷ This proposal attracted considerable criticism from the public health community, and the attorney general of Minnesota released a statement condemning the proposed settlement on the same day it was reported on by the *Wall Street Journal*.¹⁸

While this proposal was not implemented, it reemerged in a modified form in December 1996, accompanied by expres-

sions of interest in a legislative settlement by leaders of the tobacco industry, including Steven F. Goldstone, chief executive officer of RJR Nabisco Holdings.²⁰⁻²² While Philip Morris has been reported to deny any interest in a settlement in its statements to the media,²⁰ its consolidated financial statement filed with the Securities and Exchange Commission states that management "will explore all reasonable measures that may be in the best interests of its shareholders."^{23(p23)}

The prospects of a possible global resolution raise several important issues that require consideration by the public health community, related to the question of what, if any, nonjudicial resolution of the broad range of law suits now confronting the tobacco industry would be in the interests of public health.

First, given the progress that is occurring on multiple fronts, it is clear that any talk of a legislative resolution is grossly premature. Important information is coming out of the discovery process associated with the litigation and we do not even know the full extent of the industry's wrongdoing or liability. A resolution at this time would stop this important process.

Second, any discussions of a legislative resolution need to be conducted with a full understanding of the history of how the tobacco industry uses Congress and federal preemption to evade responsibility for its actions. There is a strong potential to repeat the mistakes made by the health community in the 1960s.²⁴ There are many parallels with the situation today. The first surgeon general's report on smoking and health²⁵ had just been released, there was broad public interest in issues surrounding tobacco and its promotion, and several federal agencies and states were actively engaged in the tobacco issue. The industry responded by going to Congress and, in exchange for some concessions, including weak warning labels, obtained federal legislation preempting state action on cigarette advertising. The issue all but disappeared from the public agenda. At the time, many in the public health community thought that they had secured a victory. In hindsight, most now think that the tobacco industry outsmarted them.

Third, special concerns are raised with the involvement of Congress. Decentralized approaches to tobacco control have been more effective than a single national approach.²⁶ If the Congress is actively involved in the negotiations toward a resolution, there is a greater likelihood that the tobacco companies will sculpt the agreement to suit their interests rather than the public interest. Historically, Congress has been more beholden to tobacco interests than to states, localities, or public health concerns.^{27,28}

Fourth, while the proposed settlement involved \$10 billion per year, this amount is only a small fraction of the \$50 billion in direct medical costs and \$100 billion in total costs smoking imposes on society every year.¹² In addition, there needs to be careful consideration of how much money would be available from the tobacco industry to finance a settlement. Harris²⁹ estimates that current tobacco industry annual profits are around \$8 billion, but that, under monopoly pricing, the industry could raise prices to \$4 per pack, which would generate approximately \$30 billion in profits that could be applied to a settlement. (In addition to raising money, the associated price increase would reduce total cigarette consumption by 47%, with the attendant public health benefits.) More money could be generated (on a 1-time basis) if the industry were to liquidate some of its capital, particularly in light of the fact that a settlement would remove significant litigation risks now faced by the industry and would probably double the value of its stocks.³⁰ The increase in stock value has been estimated to be at least \$60 billion for Philip Morris alone, and the total "litigation discount" in stock value for the entire industry could be \$100 billion to \$200 billion, more than the value of the previously proposed settlement.

Fifth, any global resolution of tobacco litigation would represent one of the most significant public policy decisions on a public health issue in the last half of the 20th century. This decision calls for a broad public discussion over what things would and would not be acceptable as part of a nonjudicial resolution, including whether any such resolution would be in the public interest.

Several important public policy issues require discussion:

- How can the public health community actively influence any nonjudicial resolution, including influencing whether or not such a resolution occurs?
- What are the public health priorities for a settlement?
- What role should tobacco control advocates and public health organizations play in any possible settlement?
- How should a settlement be structured to reimburse public and private agencies for both past and future damages?
- Should the financial portion of any settlement seek to fully reimburse society for the costs of smoking or should it be linked to tobacco industry profitability?
- Should any of the substantial increase in stock value that would accompany a settlement be recaptured for public purposes as part of the settlement?
- What are the public costs and benefits of having a global solution that would preempt evolving local solutions?
- What opportunities are lost by preempting private cost recovery lawsuits?
- What opportunities are lost by preempting private product liability lawsuits?
- What other judicial opportunities are lost by preempting all suits, including those under theories not yet developed?
- What are the implications of not obtaining full disclosure of internal tobacco industry documents, including those currently in the hands of plaintiffs but under protective orders as well as documents still in the industry's hands?
- What effect would incomplete disclosure have on ongoing criminal investigations of the tobacco industry and its officers?
- Does it make sense to involve issues outside the scope of the litigation, such as the fate of the FDA regulations, in the discussion of a global solution?
- Should any antitobacco education program be focused on children^{30,31} or should it be designed to include adults, where the short-term public health benefits will be realized more quickly?
- What are the legal and ethical implications of selecting a single industry for special consideration in avoiding application of the law?
- How can a settlement best be administered to avoid capture or other future manipulation by the tobacco industry?

While these questions are raised in the context of a potential global resolution, the issues they raise are equally relevant to potential settlements of the individual attorney general actions and the private class action suits.

Finally, there needs to be a special awareness of the potential conflicts of interest between the private attorneys involved in this litigation and the public interest. While there is no question that the entry of the private bar has transformed this issue, it is also an unfortunate fact that there is tremendous pressure on these law firms to accept an agreement that would permit them to reap substantial fees today rather than continue to incur substantial expenses as litigation drags on. While this tension is understandable, it heightens the importance of the need for the attorneys general, as well as the public health community, to insist that the public interest be protected.

To rush into a settlement without adequately considering these issues could allow the tobacco industry to capitalize on the public health community's mistakes as it has done in the past. For example, Annas³² recently suggested that it is time to work out "reasonable terms" in a global settlement built around "strategies to discourage children from smoking and in produc-

ing a safer and less addictive cigarette." There is significant debate within the tobacco control community whether focusing tobacco control efforts on children will serve the tobacco companies' interests³⁰ and whether the phenomenon of "smoker compensation" described in the Brown and Williamson documents² may preclude "safer and less addictive" cigarettes. Moreover, this suggestion ignores the full scope of tobacco control activities. Annas would trade only "limited immunity" for his limited goals, but this limited immunity could prove to be too high a price if it is given away without fully exploring all of the policy ramifications attendant with a global settlement.

Given the substantial progress that has occurred in the 20 months since *JAMA* published the original reports on the Brown and Williamson documents, the best short-term decision is for the states and others to resist pressure for a global political settlement and to stay the course and continue the litigation.

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Removing the Incentive to Sell Kids Tobacco

A Proposal

THE TOBACCO companies have a strong financial incentive to recruit children as new smokers. Every day 1200 smokers die and another 3500 stop smoking. Once a smoker is addicted, he or she can be expected to generate a daily revenue stream for the tobacco industry for 20 or more years. Since very few people begin smoking after they reach adulthood, the tobacco industry must recruit children. Tobacco advertising should not be viewed as a current expenditure but as a long-term investment. It is worth the high cost of advertising because it generates future profits.^{1,2} As a result, these children-smokers are crucial to the industry's long-term health. The tobacco companies regularly and emphatically assert that "We don't want kids to smoke," yet they spend billions on advertising campaigns featuring cowboys and cartoon characters. Not surprisingly, Marlboro and Camel are the brands most commonly smoked by kids; in California, 59% of 12- to 17-year-old smokers smoke Marlboros and 23% smoke Camels.³ These figures are typical.

Arrayed against this potent economic force are state laws making sales of tobacco to youth illegal. These laws are weak and poorly enforced; 60% to 90% of children report buying their own cigarettes.^{4,5} While improving enforcement does have some short-term benefits, it is expensive and requires continuous vigilance. A better approach would be to remove the economic incentive that the tobacco companies have to see children smoking.

I suggest an assessment that eliminates the economic incentive to get children to smoke or use other forms of tobacco. This assessment on tobacco companies would be twice the revenues generated by sales to children younger than 18 years of age. This amount would be about equal to the discounted present value of the long-term profits generated by new smokers.² The assessment would not be on smokers but the tobacco companies. Prices would only have to go up if the tobacco companies refused to pay the assessment out of profits, which have increased rapidly in recent years to exceed \$8.3 billion in the first 9 months of 1992. More important, this assessment would be avoidable if the tobacco companies simply made good on their claim that they do not want kids to

smoke and revised their marketing and distribution systems to reduce consumption by children.

There are several ways they could do this. The Marlboro and Camel campaigns^{6,7} clearly appeal to children. The tobacco companies could drop these campaigns. Advertising could be moved away from schools and publications read by teens. Sponsorship of events that appeal to kids could be ended. The companies could include language in their distribution agreements canceling the agreements if distributors are caught, by company representatives, selling to kids. The tobacco companies already enforce many restrictions on their vendors; this simple step would put the tobacco industry's considerable economic clout behind reducing access to cigarettes by minors, which remains a continuing serious problem.⁵

This assessment would be determined by the states based on sales to kids. National surveys issued by the Office of Smoking and Health or by the individual states would be used to determine the prevalence of teen smoking and the quantity, the brand, and the revenues generated by tobacco sales. These surveys would be conducted annually, and the tobacco manufacturers would be sent a bill, much as the property tax assessor sends homeowners and business operators a bill.

There are about 5 million teenaged smokers in the United States,⁸ and they each smoke about 0.6 pack per day or about 1.1 billion packs of cigarettes a year. At \$1.60 per pack, this amounts to about \$1.7 billion in annual sales.

The assessment would be \$3.4 billion, allocated according to teenagers' smoking patterns. The \$3.4 billion is a lot of money but is less than the \$3.6 billion the cigarette companies spent on advertising and promotion and less than half their profits in 1992.

For example, in 1990 in California,³ Philip Morris sold 61% of all cigarettes smoked by kids (virtually all Marlboros), RJ Reynolds, 25% (virtually all Camels), and Lorillard, 8% (Newport), with the remaining 5% distributed among other brands. If these numbers are typical nationwide, Philip Morris' annual bill would be \$2 billion, RJ Reynolds, \$850 million, Lorillard, \$272 million, and the others, a mere \$170 million.

These assessments could be levied at the national or state level, where industry performance could be closely monitored. In California, for example, it would yield \$400 million for the state.

This assessment has several advantages: The tobacco companies would have a difficult time objecting to the tax in principle because of their public posture that they don't want

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kids to smoke; if kids don't smoke, they don't pay the assessment. It splits the tobacco companies from the smokers, since the smokers will only have to bear the assessment if the tobacco companies refuse to absorb it out of profits. The assessment is based on actual smoking behavior of kids rather than where they buy the tobacco; this procedure avoids problems of interstate purchases and smuggling, which are potential concerns when there are large differences in state excise taxes. Such an assessment provides an economic incentive for the tobacco companies to reduce marketing to children. The annual public release of statistics on brand preference by children would put public pressure on the tobacco companies to change their marketing efforts, much as the recent controversy about RJ Reynolds' Joe Camel campaign has. The survey used to assess the tax will also provide ongoing surveillance of tobacco use by youth, which can guide planning and implementation of tobacco control progress. Assessing the tobacco companies based on sales price avoids the need for complicated accounting rules based on profits. It is easy and inexpensive to implement, and it will generate increasing revenues as the tobacco companies continue to increase the price of cigarettes. Should the tobacco companies pass the price on to their victims, the price increases will discourage some of them from smoking.⁸

Enacting this proposal will not be easy. Despite the fact that most states are desperate for funds and looking for new sources of revenue, the tobacco industry has generally been successful in keeping excise taxes low in the United States. (By world standards tobacco taxes in the United States are very low—in Canada a pack of cigarettes costs about US \$5.40, compared with only about \$1.60 in the United States.⁹) The tobacco industry has kept taxes low through campaign contributions to politicians¹⁰ and the industry's successful public relations campaign to blame government and taxes for

the increasing price of cigarettes, when, in fact, price increases by the tobacco companies themselves (to increase profits) have increased more than three times faster than the tax on cigarettes. By presenting the tobacco tax as a tax on smokers, the tobacco industry is able to mobilize its victims to keep taxes down, making more room for managed price and profit increases by the industry itself. The proposed assessment would bypass this argument by charging the *tobacco companies* based on consumption by children at the same time they are taking a public posture of being opposed to smoking by children. This refocusing of the issue of tobacco taxation might be enough to make it politically feasible.

Most important, this assessment may create a situation in which the tobacco companies really do not want kids to smoke.

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**ANALYSIS OF THE PROPOSED RESOLUTION OF THE
UNITED STATES TOBACCO LITIGATION**

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This is a preliminary draft analysis of the proposed resolution to the tobacco litigation without citations or bibliography. The deal is extraordinarily complex and filled with multiple ambiguities. Because of the intense interest in the issue and the artificial time deadlines created in the policy realm, we have decided to release this preliminary draft now in an effort to inform others and to request comments and criticisms. We believe that there is a public interest in obtaining the most complete and informed analysis possible, and are therefore opening our analysis to public comments. If you would like to provide us with comments, please send them to Stanton A. Glantz, PhD, Box 0124, University of California, San Francisco, CA 94143 or Email glantz@cardio.ucsf.edu, with a copy to Brion Fox, Box 0936, University of California, San Francisco, CA 94143 or Email fox@cardio.ucsf.edu.

EXECUTIVE SUMMARY

On June 20, 1997 a group of attorneys general presented to the public a proposed resolution, which would resolve their lawsuits against the tobacco industry and establish a national tobacco policy for the United States. This deal, which had been negotiated with the tobacco industry, was widely anticipated. It became possible as a result of the intense pressures the tobacco industry has faced in the past few years from regulatory authorities and from the threat posed by civil litigation against it.

Because of this pressure, the tobacco industry was willing to come to the negotiating table to develop a deal acceptable to it and to the attorneys general. As conditions for settlement the tobacco industry wanted protection from or predictability from the threat of lawsuits. In return the attorneys general wanted concessions which would provide the states reimbursement for the excess medical expenditures and would improve the public's health.

In the months leading up to the publication of the deal, many commentators discussed the relative merits of entering into a negotiated resolution. 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 about making a deal which would guarantee tobacco industry profitability, would require Congressional action because of the influence the tobacco lobby in national politics, would preempt stronger state, local and regulatory efforts to control tobacco and would preclude broad based public health efforts to control tobacco.

With the publication of the deal it is possible to analyze its merits directly. Within the Preamble to the document many strongly worded claims that the deal will strengthen the federal and state government's regulatory arsenal, reaffirm individual's right of access to the courts, ensure FDA and state regulatory flexibility to affect youth access, hazardous components of tobacco products, and other tobacco related issues, fund various programs to compensate those who have suffered loss due to tobacco products. When the terms of the deal are analyzed directly, it is clear that the deal does not measure up to the promises made.

An analysis of the individual terms of the deal discloses two facts.

- First, the deal is far from complete. In many parts terms are left undefined, there are ambiguities and inconsistencies. The legislation that is drafted with this as a basis will need to make assumptions which may or may not be consistent with the drafters' intent. In most cases the ambiguity can serve to work against the public health community, whereas the well-defined portions of the deal are those which provide protection to the tobacco industry.
- Second, the deal fails to live up to its billing. Close scrutiny of the likely policy implications of the individual terms of the deal disclose that the disadvantages outweigh the advantages.

As a result, we conclude that the deal fails to meet the standards established in the Preamble and

fails as a public health tool.

The Funding Provisions Are Inadequate

The money in the deal is large in absolute terms but small when compared against the damage done by tobacco products. Therefore, with a careful analysis it becomes clear that there are insufficient funds to satisfy the claims made against the payments. The amount of medical damages against the industry for the settled claims are out of proportion to the actual money that will be available resulting in a great under-funding. Moreover, the financial portions of the deal are structured in such a manner as to guarantee industry profits and will be insufficient to cause a dramatic drop in demand or create incentives for industry reform.

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 incentives to the industry and a cost shifting to American taxpayers. Taxpayers will absorb 30-40% of the cost of the deal.

The Industry Will be Protected From Most Threats of Litigation

The civil liability protections will strongly protect the tobacco industry. They will increase the barriers to litigation and provide perfect security to the industry in the way of capping exposure. The limitations on litigation may deprive injured smokers from receiving just compensation. The caps will eliminate the incentives civil justice system, by reducing any threat for failing to act in a responsible manner.

Regulatory Controls are Unnecessary and Insufficient

Specifically, the claims of that the deal results in new regulatory authority are exaggerated. The FDA already 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, or like the advertising restrictions, be regulated by another agency. Furthermore, the claims regarding the benefits attendant with many of the regulatory changes are exaggerated. 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 also adds intensive rollbacks to the FDA authority that currently exists. The Agency will face additional regulatory hurdles before it can regulate tobacco constituents and will have specific restriction on how and when it can regulate nicotine. These hurdles will preclude much of the potential for reform towards safer products.

Similarly, the environmental tobacco smoke provisions represent a rollback of the current ability to regulate broadly. The ETS provisions within the deal would exclude a large number workplaces such as in the hospitality industry. These restrictions are not a part of the proposed

OSHA regulations currently under review.

The Lookback Provision Is Inadequate

There are provisions in the deal designed to hold the industry accountable for not implementing programs to decrease youth smoking, by exacting penalties for not meeting specific targeted reductions. These targets, however, are based upon faulty analysis of youth prevalence rates, and the penalties imposed are not sufficient to create industry incentives to eliminate youth smoking.

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 towards safer products. Furthermore, by closing the market new companies will find it more difficult to compete. this will further guarantee excess profits for the industry.

Conclusion

When weighing the advantages with the disadvantages of the deal it becomes clear that the costs far outweigh the benefits and that the claims in the Preamble are exaggerated. Furthermore, when the terms of the deal are compared against public health benchmarks it is clear that the deal does not even meet the minimum standards for an acceptable resolution. As a result, we conclude that this deal should be rejected on its merits.

I. Introduction

On June 20, 1997, a number of state attorneys general reported that they had reached an historic agreement with the tobacco industry to change the way in which it does business. The agreement referred to by the negotiators as an "Agreement in Principle" or resolution defies simple definition. As presented by the AGs would affect the regulation of the industry, the ongoing tobacco litigation and many public health measures. For the sake of simplicity, it will be referred to within this report as "deal" or "agreement." The deal was presented as a boon for the public health, and it would provide the tobacco industry predictability which is lacking so long as it is subject to continued litigation. This report will analyze the terms of the deal in the context of whether it will indeed meet these goals.

II. The Legal Background

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 more risk than the tobacco industry had seen before. This increased risk created an atmosphere in which the tobacco industry was willing to consider negotiating a solution. In addition, the large number of attorneys prosecuting the actions against the tobacco companies provided a broad set of experiences from which creative solutions could arise. This recent wave of cases, can be organized into four main groups: individual product liability actions, nicotine dependency actions, health care reimbursement actions and personal injury class-action lawsuits.

A. The Lawsuits

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 would have helped consumers make informed choices. By concealing this information, the argument goes, the tobacco industry prevented the smokers from making truly informed decisions regarding the dangers of smoking. Similarly, nonsmokers who did not assume the risk have sued the tobacco companies for injuries caused by passive smoke. 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. Although a more recent case was unsuccessful, some plaintiffs attorney believe that the majority of the cases filed against the tobacco industry are winnable. There has also been a growth in personal injury lawsuits related to environmental tobacco smoke ("ETS"). These cases eliminate the assumption of risk defense, because the non-smokers never made the conscious choice to smoke. A case between the tobacco industry and a class of non-smoking airline flight attendants who allegedly suffered health problems as a result of passive smoking is currently being tried in Florida. 420,000 smokers and 53,000 non-smokers die each year as a result of diseases caused by tobacco products, and these terminal illnesses/deaths form the basis of most of the lawsuits filed. There are, however, many more theories being explored by attorneys by which injured parties may sue the tobacco companies to recover their damages. There are deaths related

to indirect use of tobacco such as house fires. Active and passive smoking are also related to an increase in illnesses such as bronchitis, asthma and childhood ear infections. Attorneys are also beginning to look at the property damage that is caused by tobacco smoke, such as soot build-up on sensitive property.

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. 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 the risk of nicotine dependency class actions for each state and territory of the United States. These cases have a potential for success against the industry because they represent a risk of smoking that was known by the industry but concealed. Therefore, the industry will have a tougher time blaming the smokers.

The health care reimbursement lawsuits, commonly referred to as the Attorneys General lawsuits or the Medicaid lawsuits, seek to recover those excess medical costs incurred because of the increased cost of treating smokers. The increased health care costs due to smoking are in excess of \$50 billion a year. The theory behind these cases is that these costs are often borne by society which should, therefore, recapture the costs from the tobacco companies. Besides the 40 state attorneys general, medical reimbursement suits have also been filed by the Commonwealth of Puerto Rico, one private insurer, a small number of pension funds, and more than a dozen cities and counties. These suits are believed to have great potential promise because the states have sufficient resources to match the tobacco companies war of attrition tactics. The lawsuits are founded in equitable principles regarding disgorgement of profits and unjust enrichment, common law legal claims such as fraud and breach of warranty, and a number of civil statutes, such as consumer protections acts, antitrust laws and racketeering laws. In addition, because these suits rely upon epidemiological evidence applied to large populations rather than individuals, the issues of causality and proximate causality are made much simpler. As a result of this deal Mississippi entered settled its case on July 3, 1997, less than a week before it was scheduled to go to trial. Under the terms of that deal, Mississippi is to receive, \$170 million, on July 15, 1997 and thereafter, Mississippi will be paid: 1998 - \$68 million; 1999 - \$76.5 million; 2000 - \$85 million; 2001 - \$110.5 million; 2002 - \$136 million; and for 2003 and beyond \$136 million adjusted for inflation annually.

The fourth category of lawsuits are the personal injury class-action lawsuits. Although these lawsuits are simply an extension of the individual personal injury claims, they represent a separate threat to the industry. In theory, these cases will present causation according to a large scale epidemiological model and will make the filing of lawsuits more affordable and efficient. The lawsuits also present a graver threat to the industry because of the risk of much larger damage awards.

B. The Desired Relief

The personal injury plaintiffs intend to hold the tobacco companies liable for the damages they have incurred as a result of either passive or active smoking. Through the lawsuits, plaintiffs hope to force the tobacco companies to create a safer environment. Theoretically, large jury verdicts in product liability suits with both compensatory and consequential damage components will create economic incentives in the tobacco industry to create safer products and disclose the dangers of smoking.

The private plaintiffs in the nicotine addiction lawsuits seek the disclosure of information related to the addictiveness of nicotine and seek monetary damages in order to fund a smoking cessation programs for addicted smokers.

The health care reimbursement actions seek to force the tobacco industry to internalize the health related costs of smoking which are currently being borne by society. This will create incentives for the tobacco companies to fully disclose information regarding the health effects of tobacco and nicotine and will prevent deceptive advertising practices. The attorneys general actions 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.

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. Finally, many of the actions are based upon laws which have provisions for treble damages, such as many of the antitrust and racketeering laws.

III. The Pro and Con of Negotiating a Deal With the Tobacco Industry

Well before the terms of the deal were actually published,, an extensive dialogue had been conducted by which individuals debated the merits of conducting discussions with the tobacco industry. Although difficult to separate support for or opposition to the actual terms of any given deal from the support for or against the deal making process it is useful to review some of the arguments made by the proponents and opponents of making a deal with the tobacco industry.

A. Reasons Given for Negotiating a Deal With the Tobacco Industry

With the new 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 in Fall 1996. 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. As a result of this deal, 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.

When the remaining tobacco companies showed a willingness to sit down and negotiate with the attorneys general many viewed it as an opportunity. This opportunity could result in a negotiated solution which would remove the uncertainty of litigation and provide additional public health benefits otherwise unobtainable in litigation.

1. Eliminate Risks

The litigation presents either risky or novel theories of relief which are undeveloped. Except for the Liggett and Mississippi settlements, the tobacco industry has not paid a dime to a plaintiff in a smoking related lawsuit. 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 will add even more time on to the equation. A settlement can be enforced immediately and will therefore, remove the delays.

If all of the lawsuits are greatly successful, this also presents risks. The industry could be driven into bankruptcy, which would shield it from additional lawsuits. Though bankruptcy may prove beneficial from a public health point of view, it could result in a skewed recovery of damages. More money can be obtained from the tobacco industry if it is kept an ongoing enterprise than if it is liquidated. This will aid those who are seeking reimbursement of large sums of money from the industry, and it will aid those whose cases come later. Rather than reward those few cases brought initially, a settlement could better compensate more injured parties. Bankruptcy could also have the secondary effect of leaving tens of millions of nicotine addicted smokers without a means for acquiring nicotine. By allowing the tobacco industry to keep in business, the consumers will not be subjected to such a dramatic result. Through a deal, incentives could also be given to the tobacco companies to market a safer product.

Finally, there is the realization that the tobacco industry has substantial influence in Congress and would likely seek to obtain legislation which would shield it from the litigation, in the same way the asbestos industry sought protections in the early 1980's. If such Congressional legislation was considered, the plaintiffs and the public health community may have been shut out of the political process. By negotiating a settlement prior to Congress considering such legislation allows the anti-tobacco forces to have substantial input into the contents of the deal.

2. Provide Additional Public Health Benefits

Advocates for a deal also feel that much more can be gained by negotiating with the tobacco industry than could be obtained through the litigation. For example, tobacco control advocates favor many restrictions on advertising which may implicate the First Amendment. A court decision or regulation could not force the tobacco industry to comply with a restriction of its Constitutional rights. However, the tobacco industry could voluntarily avoid certain advertising practices, which it could decide to do in support of a deal. Similarly, the tobacco industry could choose to throw its weight behind other tobacco control efforts such as merchant licensing schemes, youth access restrictions and workplace smoking restrictions.

In addition, not every state or injured smoker has sued the tobacco industry. Therefore, even if the lawsuits are successful not all of those injured will be compensated by current suits. Even if Mississippi, who filed the first lawsuit, wins its case and obtains damages and various marketing restrictions, these benefits will not carry-over to Alabama who has not filed a lawsuit. A negotiated deal could provide a national solution which will come more closely to remedying all injured parties.

Finally, the advocates argue that there is a value to having a discussion about a national tobacco policy. By placing tobacco control at the center of the public agenda, industry misdeeds can be disclosed and public will become better educated. The magnitude of the problem related to tobacco means that positive policy results necessarily follow effective education. Therefore, by merely going through the negotiation process attention will be focused and resources allocated for change. Presenting a resolution to Congress will accelerate this process giving a national stage to the discussion and forcing a public debate in the halls of Congress.

B. Reasons Given for Opposing a Negotiated Deal With the Tobacco Industry¹

Critics of the process of negotiating a deal with the tobacco industry almost exclusively have come from the public health community. Most of the criticisms focus on how a deal would hinder the public health efforts. (See for example, Glantz, SA, Fox, BJ and Lightwood JM. Tobacco Litigation: Issues For Public Health and Public Policy, *JAMA*, March 5, 1997, vol. 277, pp. 751-753.) Treating the hazards of tobacco as a disease, the tobacco industry is often viewed as the vector for the disease. Thus, in order to reduce the death and disease related to tobacco the tobacco industry and its actions must be addressed directly. Any deal which would allow the tobacco industry to continue in its normal course of business would necessarily be bad for the public health. In order to truly reduce tobacco disease, the vector of the disease, the industry, must be sufficiently dealt with. By negotiating a deal which the industry approves of, the deal makers will implicitly give credibility to the industry, and will ultimately develop a policy which the industry can live with. Thus the process will result in a deal which will advance the industry's

¹Much of this section was presented in a slightly different form by Brion J. Fox at the 12th Annual Tobacco Products Liability Conference, May 9-11, 1997.

1. A national solution presents unique risks

The state attorneys general do not have the authority to give the tobacco industry protection from all lawsuits, nor can they negotiate on behalf of the parties who have not yet filed. As a result, for any deal that is negotiated, federal legislation will need to be written, approved and passed to enact its terms. This action of going to Congress will enable the tobacco industry to lobby for changes in the negotiated deal. The tobacco industry is one of the largest contributors to both the Republican and Democratic parties and has extraordinary lobbying influence in Congress. As a result, many public health professionals feel that past Congressional efforts at tobacco control have benefitted the tobacco industry. For example, the cigarette labeling law has 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. Presenting a deal to the Congress is presenting an open door to the tobacco industry.

But even if a deal is accepted in the form presented to Congress, there are risks inherent in any national approach. 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. Replacing federalism in the context of tobacco control will weaken tobacco control efforts.

Critics worry that a federal deal would restrict regulatory controls. A global settlement is more likely to commit all regulatory authority in a single agency than the natural evolution of regulatory behavior. Such preferential treatment creates certain regulatory hazards. First, it sets up a single agency for capture. Second, protections against agency hegemony and corruption are removed. Third, the efforts to regulate behavior through injunctive relief and market based incentives is more flexible and can be better enforced in a political structure friendly to tobacco interests.

Congressional action may also create protections from criminal immunity which would be inappropriate under any circumstance. This can be done either explicitly, or unintentionally through legislation which creates special privileges for the tobacco industry. Given the extent of known wrongdoing, and that which may yet be uncovered if the discovery process is allowed to continue, any possibility of criminal immunity should be avoided. In short, the only protection from liability which should be given to the tobacco industry is that which they gain by settling individual lawsuits. There exist few wholesale grants of immunity to product manufacturers. The tobacco industry has not earned any special privileges and should not be given any.

2. Advocates for a deal are under-estimating the public health value of the litigation

The estimates of damages caused by the tobacco companies are enormous. 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. 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. Critics argue that with the extraordinary amount of damages at stake in these lawsuits, only a few victories will be necessary to secure huge public health advantages. And that to sacrifice these lawsuits will be to eliminate the chance for these advantages.

To enter into an agreement that the tobacco industry finds acceptable will mean that the tobacco industry will be able to continue its profitable course of action. Otherwise, it would be an irrational economic actor.

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 front page headlines regarding its misdeeds. As a result, the public health community is in a good position to demand substantial change in other venues in society. Entering into a global settlement removes tobacco from the headlines and could result in complacency.

3. Advocates of the deal are overestimating the public health benefits and under-estimating the public health risks

Critics of the deal also fear that by entering into a deal with the tobacco industry would limit the public health tools. The negotiators of any deal will necessarily choose some public health tools to the exclusion of others. For example, youth issues related to tobacco is the "trendy" issue and one which many people believe could promote the ultimate goal of a healthful society. Although it is clear that most smokers begin smoking when they are minors, and that most of them will become addicted some feel that youth-centered approaches are misguided and could result in unchanged smoking rates. Given the uncertainty as to what approach is the best, it could be a mistake to commit to a single approach which emphasizes youth. Public health efforts are successful when they are multi-disciplinary and provide flexible approaches to problems. The public health community is not prescient and does not know what tools will be most needed five years from now, so it should not sacrifice any of the current tools at our disposal.

Critics also worried that a deal would either be predicated upon, or completely exclude the development of new technologies. For example, some believe that we will approach a healthier society by developing technologies, such as nicotine replacement therapies, nicotine free cigarettes, and "safe" cigarettes. Such a proposal may be useful, but it would be foolish to trade away any of the public health tools currently in hand on the faith of an unproven technology. Similarly, a deal which sacrificed the development of these tools could prove equally foolish.

4. Rushing into a deal will eliminate significant opportunities

Critics are also concerned that a deal would likely trade away future liability for limited gains today. This grant of future immunity could be in the form of specific immunity for the tobacco industry or by increasing the barriers to litigation which would make filing new lawsuits much more difficult. Critics believe, such special treatment and protections to the industry which

is causing the public health problems is antithetical to creating a healthier society. Similarly, critics are concerned that the protections from liability are not matched closely with those who have been fairly reimbursed.

Critics of the deal feel that limitations on liability are not necessary and should not be granted. It is obvious why the tobacco industry craves protection from lawsuits. Every large product manufacturer in the country desires the same thing, it provides valuable financial security. This value, however, is given at the expense of individuals. There is no reason to give the tobacco industry these protections. If, as discussed above, the tobacco industry can resolve its disputes and settle with individual parties it will be protected from those lawsuits. But to sacrifice a person's right to recover damages against the tobacco industry without fair compensation violates the tenets of justice. Nevertheless, that is what the global settlement seeks to do.

Individuals who have suffered damages as a result of the tobacco industry's behavior, face many obstacles to actually recovering from the tobacco industry. The settlement would place additional obstacles in the way of these individuals which would serve to be an absolute bar against future lawsuits. For example, filing individual suits is an expensive and risky proposition. It is one that frightens many a potential plaintiff, and even more attorneys. Through class action lawsuits and consortiums of attorneys working together, however, it is possible to spread the risk and reward to increase the number of individuals who will be able to recover. Without the ability to file class actions, many attorneys would refuse to take these cases and individuals would have a hard time finding anyone to represent them. Similarly, placing caps on damages or eliminating punitive damages will make it less appealing to file a lawsuit, and harder to find representation if an individual were to find the courage to file a lawsuit. Thus, it would be perfectly consistent to protect a person's "right" to sue, yet still make the cases rare and impossible to win.

Critics also worry that a deal would be built upon static economic assumptions. A deal based upon current economic status of the industry, or on linking damages to tobacco industry profits, or on models which predict what the market could bear, are all static views of the economic reality. Such a view presents the dangers of gravely underestimating the amount to be paid by the tobacco industry and eliminating future flexibility. For example, it is likely a proposal will underestimate the stock benefits that would be obtained by the tobacco companies by settling, and could not account for the potential insurance contributions to the tobacco companies. In addition, any financial deal that would be agreeable to the tobacco companies, will necessarily guarantee their future profitability. (Assuming that the tobacco companies are rational actors.) Thus, a deal necessarily would have an economic cap which does not exist in litigation.

Critics would prefer an economic model based upon the actual damages caused by the industry and one that did not sacrifice future economic flexibility. For example, a deal which implicates the tax system could restrict future efforts to increase the tax on tobacco products. Similarly, a settlement fund would not provide the flexibility to account for future understanding of the economic toll tobacco has on society. As a result, restricting future economic flexibility by entering into a global settlement would limit our ability in the future to apply economic incentives to modify the tobacco companies' behavior.

IV. Analysis of the Proposed Deal

This section will go through and analyze the deal Title by Title seeking to interpret the deal as if legislation were drafted in a manner which would best exemplify the deal as written. The deal, unlike the way it is characterized, is not a traditional legal settlement, in which the parties resolve the issues as between themselves through a negotiated process. This deal includes many issues collateral to the underlying suits, and the legal rights of parties not represented at the negotiation. Even then, it does not present a complete solution. Rather, it is a series of proposed legislative changes upon which a group of attorney generals and the tobacco industry have agreed they would support in principle, and would provide private enforcement mechanisms for, should the suggested legislation be passed. Despite the fact that the deal requires legislation, there is no specific legislative language proposed, thus providing much room for interpretation. The Congress, should it choose to consider the proposals contained in the deal, will need to interpret the deal and design legislation to enact it. As we interpret the deal, if there are contradictions, ambiguities or inconsistencies we will attempt to define the spectrum of possibilities based upon the deal as it is written.

A. Preamble

Within the preamble to the deal the parties lay out the scope of the problem and the manner in which the deal is intended to address the problems. It is the charge by which the deal will solve the problems related to the tobacco use in our society.

1. Statement of the problem

The deal characterizes the death and disease related to tobacco as a “pediatric problem.” By doing so the deal is self limiting. It embraces one segment of the public health measures to the exclusion of others, in particular former Surgeon General Koop’s “Smokefree Society.”

The remainder of the preamble does not address the problems related to tobacco. There is no mention of the death, disease and addiction to tobacco products. There is no mention of the property damage caused by tobacco products. There is no discussion of the cost to society of tobacco products, such as the economic cost of death and disease. There is also no discussion of the tobacco companies actions in withholding scientific research related to the hazards of tobacco and actions taken by the tobacco companies to withhold such information.

2. Intent to impose regulatory controls

The preamble embraces regulation as the tool by which it seeks to remedy the problem. It identifies that the current regulatory structure is inadequate. To remedy the problem the preamble suggests that the deal would strengthen FDA authority, regulate smoking in public places and provide new regulatory enforcement tools.

The preamble also indicates that the deal will establish a settlement fund which would finance the recovery of health related expenditures, a smoking cessation program, and a health education campaign.

3. Intent to reform the Tobacco Industry

The preamble ultimately acts as an advocacy piece for the deal's merits. It highlights the limitations of continuing the litigation and argues that reform can best happen through national legislation. It further identifies that the provisions contained within the deal will move the policy of tobacco control forward further and faster than the current course of regulatory action. Finally, the preamble argues that the deal will change the way in which the tobacco industry does business, which will result in fundamental change in the country.

4. Interpretation of the Preamble

Ultimately, the preamble presents a subjective argument in favor of the rest of the document rather than a simple recitation of the deal. In addition, the preamble spends little space describing the scope of the problem, and no space describing tobacco industry wrongdoing or having the tobacco industry accept responsibility/blame for past conduct. The preamble makes a series of positive claims which are to be supported by the actual terms of the deal. Other issues which become evident from the preamble is that the deal does not deal with many tobacco related products other than cigarettes. Cigars, pipe tobacco, and clove cigarettes (except to the extent that they can be deemed cigarettes) are not addressed within the deal. Smokeless tobacco is only dealt with scantily.

B. Title I: Reformation of the Tobacco Industry

Title I of the deal contains the bulk of the regulatory changes to reform the culture of the tobacco industry. In the preamble to Title I it identifies that the Title "incorporate[s] and expand[s] upon FDA regulatory authority." Presumably this means that all of the elements, unless specified otherwise, would be empowered to the FDA. The provisions of the deal would operate only as specified for the first five years, except for extraordinary circumstances. The FDA would be able to review and revise the standards after that time.

1. Restrictions on marketing and advertising

Section A of Title I 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"

Advantages:

To the extent that tobacco use is encouraged by the pervasiveness of tobacco imagery, all of the provisions of the deal are an improvement over the status quo. As is identified in the agreement much of the steps forward are already embodied in the current FDA regulations. While a recent Federal Court judge in North Carolina upheld the ability of the FDA to regulate cigarettes, the Judge disallowed the FDA's ability to restrict advertisement. As a result of this

ruling, the deal would represent a positive step towards embracing FDA authority to regulate marketing and advertisement. Finally, the First Amendment to the Constitution (and similar free speech protections in State Constitutions) can act as a barrier to restrictions on speech. By willingly accepting the speech restrictions, the First Amendment restrictions will not be implicated. In addition, the deal presents significant advantages over the current regulatory regime by going beyond the current requirements.

Disadvantages:

The primary disadvantages to the advertising restrictions are that they are unlikely to accomplish the goal voiced in the Preamble to the deal of "restricting nationwide the sale, distribution, marketing and advertising to persons of legal age." It will not eliminate the pervasiveness of tobacco imagery in our culture nor is it clear that it is necessary to embrace the deal to achieve the marketing and advertisement 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. 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. The FDA or FTC regulatory authority will be subject to a First Amendment challenge. Because advertising is commercial speech it receives less than would political speech. Furthermore, because of the powerful public health interest in restricting advertisement, the need to place extraordinary time, place and manner restrictions on tobacco advertising is well established. Therefore, many of the restrictions are likely to survive.

To the extent that a restriction violates the First Amendment, the fact that the restriction is embodied in Congressional legislation provides no additional protections. Simply because the Tobacco Companies agreed to the restrictions does not provide assurances that the restrictions will be in place. 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 Agreement and will not be bound by an unconstitutional law. Third, to the degree the tobacco companies could voluntarily surrender their First Amendment rights they could do so through individual agreements with the attorneys general and federal legislation is unnecessary.

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 still find that the tobacco imagery is present throughout the country. For example, the restrictions only pertain to domestic enterprises and do not address such actions such as international sponsorship of events. Other countries have shown that the tobacco companies will develop advertisements which are just as effective, albeit in a different style. 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." Other companies have developed similar advertisement styles, for example, the Benson and Hedges anthropomorphization of cigarettes. These attractive advertisements eliminate the need for cartoon characters or human images. The tobacco companies will also be able to use the packaging of cigarettes as a marketing tool.

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. These events appear to have a strong impact on teens, even though they are not allowed in the bars.

Additional advertising and promotion techniques may still be available. For example, direct marketing tools such as direct marketing and establishing distributorship strictures which place the responsibility of marketing on intermediary distributors, could prove to be creative avenues to market tobacco products.

In addition, tobacco imagery is ingrained into our culture. It is not possible to eliminate, for example, 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.

As for the provisions which go beyond the current regulations, many of those could be adopted under the current auspices of the FDA or the FTC. For example, the terms "light" and "low tar" could be deemed false or deceptive advertising and resolved through current procedures, in the same way the FTC reviewed the use of the "Joe Camel" advertising icon.

2. Warnings, labeling and packaging

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. 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.

Advantages:

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 seen to be incomplete and relatively insubstantial. One widely relayed anecdote holds that some women begin smoking during pregnancy on the belief that the current label warning of “low birth weight” refers to the amount of weight the pregnant woman would gain rather than the neonate.

Moreover, the current testing procedures for tar and nicotine have been widely criticized with many advocating that the responsibility be given to the FDA. The deal would do just that.

Disadvantages:

The critiques of this proposal are threefold. First, it is not necessary to adopt the deal to adopt these changes. There are no inherent barriers to adopting these changes. The Congress has on two occasions strengthened the warnings on cigarettes, and could do so again. Furthermore, there is nothing to prevent the Congress from increasing the size of the warnings or the jurisdiction of the testing of cigarettes to the FDA.

Second, the warnings are likely to be of limited effectiveness. Multiple surveys have shown a general awareness of the hazards of tobacco use. There is also current research which indicates that this information has not been translated into personal knowledge of the effect of smoking on one's life expectancy. Thus, there is a widespread belief that the more specific warnings will have little to no effect on consumption rates, because it will not be able to bridge the gap between a person's objective knowledge and the ability to personalize it. Moreover, some research has shown that by preceding a warning with the word “WARNING” simply adds to the weariness many feel towards “warning” overload, thus further minimizing the effectiveness of the message.

Third, the most criticized portion of the Federal Cigarette Labeling and Advertising Act is the fact that it preempts state and local efforts to require stiffer warnings on cigarette packages and that it effectively bars civil lawsuits most civil lawsuits. If one were to embrace substantive changes to the cigarette labeling laws, one would address these provisions. First, one would eliminate the preemptive portions to allow state and local control of adequate warnings. Second, one would ensure that the warnings did not affect one's ability to seek civil relief from the tobacco companies. A defendant could not point to the warning requirement or to the warnings themselves as evidence that it satisfied its duty to its consumers, or that because of the warnings the consumers were adequately informed of the hazards of tobacco use.

3. Restrictions on access to tobacco products

Section C of Title I codifies much 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.

Advantages:

These provisions would clarify the FDA's ability to regulate in this area and would expand

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. What the authors of the deal argue could only be accomplished by the consent of the tobacco manufacturers cannot be thrust upon the 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 are exaggerated.*

5. Regulation of tobacco product development and manufacturing

Section E to Title I describes the regulatory regime under which cigarettes and smokeless tobacco products would be governed. 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 embraces this model by legislatively investing in the FDA the authority to regulate tobacco products.

Advantages:

The advantages to 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 intellectually consistent to treat nicotine as a drug and cigarettes as a drug delivery device. Furthermore, the FDA has already asserted this authority and begun the regulatory process. By codifying the FDA jurisdiction, it removes the threat that an appeals court, or Congress itself, could remove the jurisdiction to regulate nicotine from the FDA.

Disadvantages:

The concerns arising with FDA jurisdiction over tobacco products is that the new legislation would be too extreme. The first extreme is that the FDA would be granted too much authority such that it would not be subject to some form of check on its actions. Without such supervision, the agency could be a ready target for corruption, or alternatively capture by the tobacco industry. Allowing FDA jurisdiction to grow through the normal regulatory process moderates this threat.

The second extreme is that 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/medical device companies. These special protections would ultimately limit the FDA's ability to adequately regulate tobacco products. The current regulatory process appears to be working. 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 forum was specially chosen by the tobacco industry, and many believe it is the most favorable ruling the tobacco industry can get.) This is true in part because 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. The result of regulating tobacco under this scheme could be unintended consequences, such as requiring analysis of suggested use and intended benefits.

• (a) Definition

Under Section E(1) to Title I of the deal tobacco products are defined as they are in the current FDA rule.

Advantages:

The advantages of using the definition already developed is that it uses a definition with which people are already familiar, and has a record developed to support it.

Disadvantages:

The disadvantages of this definition are that it specifically is geared towards cigarettes and smokeless tobacco. The current FDA regulations are not intended to address cigars, pipe tobacco, or possible other forms. 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.

(b) Jurisdiction

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.

Advantages:

By treating tobacco as both a drug and a medical device, this will preserve the maximum amount of authority the FDA can have over a product. In addition, by classifying tobacco products will remove this regulatory burden from the FDA. Finally, care is taken to preserve the FDA's authority to regulate tobacco products as restricted devices.

Disadvantages:

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 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, this decision should be left in the hands of the FDA.*

In addition, it is not clear what effect classifying tobacco products in a new “subcategory” will have on the regulatory process. Presumably it will have no effect, but care should be taken to ensure that special protections are not given with its special status.

(c) FDA Authority

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.

Advantages:

This is the core of the FDA authority. By it, the FDA will be able to regulate the content and distribution of cigarettes to improve health and safety.

Disadvantages:

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, 21 U.S.C. Section 360f allows the FDA to ban a device which “presents substantial deception or an unreasonable and substantial risk of illness or injury”, Section 352(j) 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. This, however, is inconsistent with the provision preventing the FDA from prohibiting tobacco products in their basic form. How these ambiguities are resolved are vital to the continued effectiveness of the FDA as a regulatory authority. The concern is that because the ambiguities are specifically pointed out without resolution, that these rights and other similar regulatory powers of the FDA will be restricted. *No restrictions should be placed on FDA regulatory authority in the deal, and the FDA regulatory*