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Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

THE NEED FOR DISCLOSURE BEFORE CONSIDERING A TOBACCO DEAL

In a famous line from Lewis Carroll's Alice In Wonderland, the Queen announces, "Sentence first, verdict afterwards." It is precisely that reversal of the ordinary order of business that constitutes perhaps the most basic flaw in the proposed tobacco deal. The supporters of the deal trumpet the disclosure provisions, claiming that they would force the industry to come clean with the public. But in fact, not a single document would come to light unless and until Congress approved the deal--in other words, until it is too late for Congress to know what the tobacco industry is peddling. Moreover, as is clear from an examination of the actual terms of Appendix VIII of the agreement--mislabelled "Public Disclosure of Past and Future Tobacco Industry Documents and Health Research"--even if Congress blessed the deal, almost nothing of significance would be disclosed for years to come, if ever.

At the outset, it is important to understand that the insistence on disclosure is not simply a desire to know the whole truth about what the tobacco industry has done. Disclosure is vital because, without it, Congress cannot make an informed judgment about whether to approve all or part of the deal and cannot know what kind of protections should be built in to guard against industry efforts to end run any restrictions imposed. Equally significant, if the Food and Drug Administration is to regulate tobacco products in an effective way, it must know what the industry knows. Because the agency does not have subpoena power, disclosure through the settlement or in litigation is the only realistic means of gathering the necessary information.

To be sure, the proposed deal contains numerous problems that are apparent even without review of industry documents. Among the deal's most egregious flaws are (1) serious impediments to the FDA's ability to regulate nicotine levels in tobacco products; (2) inadequate penalties and overly generous time periods related to requirements for reductions in under-age tobacco use; (3) major concessions to the industry on liability issues, such as cumulative annual caps, elimination of all class action and other aggregation devices, and abolition of punitive damages for previous conduct; (4) no effort to prevent the industry from doing abroad what it would be prohibited from doing in this country; and (5) guarantee of tax deductibility for every dollar that is paid out, thereby reducing the deal's cost to the industry by about 40 percent. Almost certainly, disclosure of the documents would prove these problems to be even worse than they seem.

Ralph Nader, Founder

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THE NEED FOR PRIOR DISCLOSURE

Numerous areas of the proposed deal cannot be adequately evaluated without prior disclosure of industry documents.

Regulation of nicotine and other components of tobacco products: Congress is being asked to impose a strict regime on the FDA that may make it impossible as a practical matter for the agency ever to reduce nicotine content. Prior disclosures establish that the industry knows a great deal about nicotine and that it uses its knowledge to manipulate the addictive quality of tobacco products. Indeed, the disclosures of recent years played a significant role in the FDA finding that tobacco products are drug-delivery systems. Without question, the industry has a great deal more in its files on that subject which, if known, would have a major impact on how Congress wrote any nicotine control provision. Liggett, for example, is being sued by the other major tobacco companies to prevent it from making such disclosures.

Among the areas of concern in this aspect of the agreement is the anti-contraband provision, which requires FDA to prove that reducing levels of nicotine would not result in black market products containing enough nicotine to maintain addiction. Most public health advocates are very skeptical of that provision, and it would be irresponsible for Congress to accept it unless the industry's files provided some reason to believe that no such problems would arise.

Similarly, before legislating any limits on the FDA's ability to regulate tobacco products, Congress must know much more about the various additives and components. The deal would allow the industry five years to submit petitions seeking approval for the additives in its products. The industry maintains that the ingredients in its products are confidential and has refused to disclose what it knows about the harmful effects of tobacco components and cigarettes additives. The deal does not address this issue, and the lack of disclosure impedes Congress' ability to analyze the proposed provision regarding additives, including whether they present an imminent hazard to public health.

Youth smoking: Information on what rates of reduction in underage smoking can be achieved over what periods of time is essential to setting appropriate levels of penalties for failing to achieve those goals. The industry surely has some pretty good ideas on that topic. After all, it has focussed much research and advertising on capturing the youth market.

Counter-advertising: The industry has achieved remarkable success in seducing kids into trying tobacco products. The deal provides money and legal authority to counteract both the initial attraction and the ultimate addiction, but those in the tobacco control movement do not know whether their ideas will work in practice. In particular, they do not know whether they can devise marketing strategies that will appeal to teens and persuade them never to start using tobacco products. The best way to beat the other team is to get hold of its playbook, which here means industry documents that lay out how tobacco

companies attract kids (and other targeted populations, such as women and some minority groups). Counter-advertising is useful only if it works. Getting the industry's marketing plans may not guarantee success, but it will greatly improve the chances.

Punitive damages: The proposal would immunize the industry from punitive damages for prior wrongful conduct. Before consenting to such a radical provision, Congress must know what wrongs the industry committed. Congress must know the extent of the industry's knowledge of the harmful effects of tobacco use and secondhand smoke, its efforts to conceal that knowledge, its manipulation of nicotine, and its programs for marketing its products to kids. Before even considering whether to absolve the industry of civil penalties for deceit and concealment, Congress must know specifically what was done, when, and by whom.

An analogy may help to highlight this problem. Suppose a man were convicted of a serious crime, and the President were asked to pardon him. Would it be rational for the President to say, "Tell me why I should pardon you, but you don't have to tell me all the bad things you've done, and I won't complete my investigation or even read the trial transcript."? The industry is in effect asking for a pardon for liability from punitive damages. While we believe that the answer should be "never," no one should even consider such a request until the industry has come clean and fully disclosed its sordid past.

Smoking cessation programs: Disclosure is likewise central to developing effective smoking cessation programs. If Congress and the FDA are to do their jobs properly, the industry must make available its documents on nicotine and its addictive impact, as well as any information it has on programs that do and do not work.

NON-DISCLOSURE UNDER THE PROPOSED DEAL

Under the deal, millions of documents would be put into a warehouse, accessible to the public. Thousands of other allegedly privileged documents, however, would be withheld from Congress, the FDA, and the public, for many years and perhaps forever. Although the deal provides a procedure for challenging privilege claims, that procedure is woefully deficient. Thus, the secrecy provisions are inadequate both because they do not initially disclose numerous significant documents and because they establish barriers ever to accessing those documents.

The deal limits the documents that will be public to those "produced to the other side" in certain lawsuits, but the tobacco companies have refused to produce important material in those suits. The industry has successfully resisted discovery for decades on two principal grounds: (1) that the information sought is covered by the attorney-client privilege or work-product protection, or (2) that the information sought contains trade secrets, even where known by others in the industry or ascertainable through chemical analysis. As Appendix VIII to the agreement makes clear, those claims would remain alive and well under the deal, with no concessions by the industry. Thus, this portion of the agreement

would be more accurately entitled "Provisions Authorizing Continued Non-Disclosure of Vital Tobacco Industry Documents."

The problem with maintaining the industry's non-disclosure defenses is that the tobacco industry has a very expansive view of the law of privilege. Generally, attorney-client privilege in the corporate context covers communications between a company and its lawyers regarding a case or legal advice. But tobacco companies assert a new version of the privilege: They run much of their research, including that done by their contractors and front groups, past their lawyers; then they claim that all of the information about or derived from the research is privileged. Similarly, they have taken an expansive view of work-product protection. Although this protection generally covers only documents prepared by a lawyer in anticipation of or in connection with actual litigation, the tobacco companies claim that it includes anything which a lawyer, or anyone working with that lawyer, might use in some way in some litigation that might be brought some day by some body. Taken together, these privilege claims extend to virtually everything that a tobacco lawyer wrote or received (including copies sent for information purposes).

Under the deal, before anyone can challenge a privilege claim, the industry will conduct a re-review of its withheld documents. The deal does not require that the re-review result in any additional disclosures. The re-review process has no deadline, and the industry obviously has no incentive to finish it quickly.

After the re-review, challenges to privilege claims could be brought. The deal would not, however, allow claims to be resolved as they arise in individual cases. Instead, the deal would require that all privilege claims be sent to a three-judge panel of federal judges, appointed by the Judicial Conference (which means Chief Justice Rehnquist). Federal law, as augmented by the ABA/ALI Model Rules--a highly pro-corporate regime--would replace all state law, supplemented by the Uniform Trade Secrets Act, which is also unlikely to produce neutral, let alone pro-disclosure, results. The panel's ruling would be reviewable only by permission in the Supreme Court, which is not likely to hear the case, let alone overturn the panel decision. At that point, the decision would be binding on every court and everyone. The only possible means of change would be to apply to the three-judge court itself, on some kind of motion for reconsideration.

Aside from the substantive bias referred to above, this scheme has serious structural flaws. First, it would allow anyone to come in and challenge a claim of secrecy. The deal contains no requirement that the first person to sue over the documents be qualified in any way (such as being a designated class representative, a state Attorney General, or an FDA Commissioner), that the challenger's lawyer have knowledge of the industry and its pattern of privilege claims, or that others participate to fill legal and factual voids. Accordingly, the industry, which does not suffer from any handicaps in terms of resources or expertise, would likely prevail in many cases and never have to deal with the issue again. Indeed, even an industry ally could raise a challenge, weakly pursue it, and bind everyone else to the decision.

Making the process even worse, no federal judge (let alone three of them) would view this assignment with anything short of extreme annoyance. Judges never like this kind of issue, particularly where, as seems inevitable, the industry will insist on a document by document, page by page, and/or line by line review of its claims. And making three judges pass on each claim will slow the process down, thereby increasing their frustration. The real fear is that the panel will take the path of least resistance: uphold industry claims on a broad-brush basis and be done with the matter.

This secrecy scheme would be bad enough if it were devised solely for litigation purposes. However, the deal purports to bind everyone, from the FDA to Attorney General Reno, to state legislatures and law enforcement officials, to Congress, even though, as demonstrated above, the withheld documents directly bear on many of the vital decisions that public entities are being asked to make now or will have to make in the future.

Thus, in all likelihood, most of the industry's key documents will never become public if the agreement becomes law. As a result, the FDA and others trying to achieve meaningful reductions in tobacco use will be handicapped.

DISCLOSE BEFORE CONSIDERING ANY TOBACCO DEAL

Given the numerous and complex issues addressed in the proposed deal, enacting or even evaluating the deal prior to full disclosure of industry documents is premature. Congress should require full disclosure of industry documents before considering the proposed deal. Such disclosure should include

- Full disclosure of the files of the Tobacco Institute and the Council for Tobacco Research;
- Waiver of attorney-client privilege and work-product claims for all documents created prior to the filing of the first Attorney General's lawsuit;
- Renunciation of claims of trade secrets for information shared with, or available to, another tobacco company;
- Renunciation of privilege claims for information relating to technical data, health or safety, marketing to minors, and the effects of secondhand smoke; and
- Inclusion in the public document depository of all pleadings, privilege logs, motions, memoranda, and depositions in all past or pending tobacco cases.

Only after Congress and the public have the necessary information should discussion of a legislative resolution proceed.

July 11, 1997



Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

July 10, 1997

The Honorable William J. Clinton
The President
The White House
Washington, DC 20500

Dear Mr. President:

On behalf of Public Citizen, a national consumer organization with over 125,000 members nationwide, I am writing to express our appreciation for your decision to reject provisions in the recently proposed tobacco settlement that would restrict FDA authority. We share your concerns over this provision. Public Citizen has long been in the vanguard in advocating stricter controls on the regulation, sale and promotion of tobacco products generally, and we have fought hard to force the tobacco industry to cease its cynical efforts to hook children on their products.

However, having carefully reviewed the settlement document, we are extremely troubled by many other provisions as well. I recognize that both you and Congress will review the proposal thoroughly and that both Houses will hold hearings to explore the merits and the pitfalls of the proposal. But I want to take a moment to highlight the core problems with the proposal so that you may have the benefit of our analysis as you further consider the deal.

In reviewing the proposal, it is important to keep in mind certain key questions: Will it advance the public health? Will it preserve the FDA's ability to regulate both nicotine and harmful additives? Will it force the tobacco companies to make public the research, including research on health effects, safer products, and marketing to minors, that they have undertaken and concealed over the years? Will it leave current and future victims of tobacco--including those exposed to second-hand smoke--with meaningful redress in the courts? Unfortunately, in our view, the answer to each of these questions is "no." Let me point out the key deficiencies of the settlement.

FDA Jurisdiction: In announcing the settlement, the negotiators claimed that the settlement preserved the FDA's authority to regulate nicotine, and to regulate, if need be, other additives to cigarettes and smokeless tobacco products. That claim is wrong.

Ralph Nader, Founder

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In the first place, the settlement divests the FDA of its current authority to regulate the nicotine in tobacco products as a drug, an authority upheld by the North Carolina court in the tobacco companies' litigation against the FDA.

Equally troubling, the settlement sets up two insuperable hurdles to the FDA exercising its authority to regulate the nicotine in tobacco products through its authority over medical devices: *First*, the agency must use "formal rulemaking." Unlike "notice and comment" rulemaking, which can be concluded within a year or so, formal rulemaking requires a full-scale evidentiary proceeding that can take many years to conclude. *Second*, in addition to the procedural obstacles, the settlement erects a substantive hurdle to FDA action by requiring the agency to prove that lowering nicotine levels will not create a black-market demand for tobacco products with higher nicotine yields. Proving that negative will be impossible for the agency since addicted cigarette smokers will very likely want access to products that better maintain their addiction.

Moreover, even if the FDA could actually overcome these hurdles -- and former FDA Commissioner David Kessler has stated publicly that the agency cannot -- the deal forbids the FDA from acting to eliminate nicotine from tobacco products for the first twelve years following the settlement -- it can only propose reductions in nicotine levels. Although the settlement theoretically permits the FDA to consider nicotine elimination after the year 2009, as a practical matter, even then it would not be able to do so because it still could not surmount either the formal rulemaking hurdle or prove that there will be no significant demand for high-nicotine products.

As to the additives in cigarettes, the companies would have five years to submit to the FDA a safety assessment for each additive. The FDA would then have only 90 days to review industry claims that the additives posed no risk. If the agency missed the 90 day deadline, the additive would be deemed approved. It is intolerable that the FDA should be given so short a time to review the massive submissions that the tobacco industry would file.

Ingredient Disclosure: For years, public health advocates have argued that the public--and especially users of tobacco products--have a right to know what additives the companies put in tobacco products. The agreement does nothing to rectify this problem; indeed, it ratifies the tobacco companies' position. The agreement provides that the industry will disclose ingredients to the FDA, but allow it to designate any ingredient as a confidential trade secret--a designation the FDA would have to accept.

Document Disclosure: Congress should not enact any broad-based legislation addressing tobacco issues before it has had an opportunity to review the industry documents regarding prior research and marketing. Such review is imperative in order to knowledgeably assess the merits of any proposal regarding tobacco issues. In the areas of liability, regulation, and advertising, no concessions should be made to the industry until it has disclosed all relevant information regarding its past practices.

The proposed deal does not require the industry to disclose a single document that it has not already released in litigation. To the contrary, the deal allows the industry to continue to press the same overblown privilege and confidentiality arguments that it has used to stonewall discovery in litigation. The agreement provides that industry lawyers will conduct a document-by-document review of the records withheld as privileged in litigation to reconsider whether they should be released. Although the agreement would not place any time deadline on the industry review, only after the review is completed would any independent assessment of the validity of privilege claims be allowed to take place.

For example, the tobacco industry will still be able to claim privilege for documents relating to the effect of nicotine and whether lower levels produce less addiction and less harm to users. Yet Congress is being asked to enact highly favorable protections for industry regarding nicotine, and FDA is burdened with special requirements for regulating it, all based on a wholly incomplete record, which was prepared entirely by the industry. Similar concerns arise for other additives in cigarettes and smokeless products and for the effects of secondhand smoke.

Further, the settlement creates an elaborate and almost certainly unworkable system for having a three-judge federal court review the documents one by one, in response to challenges raised by people who will have reviewed only an industry-generated index. As described in the agreement, the process would be heavily stacked in the industry's favor.

Payments: The multi-billion dollar payment proposed in the settlement is better for the industry than for tobacco users. First, the agreement specifies that all payments pursuant to the settlement would be tax-deductible. Given the 40 percent marginal tax rate paid by RJR (and presumably by the other tobacco companies), the tax deduction would mean that the American people would underwrite about \$150 billion of the settlement. Second, nothing in the settlement forbids the industry from raising prices to offset the payments. Thus, consumers--not the industry--would pay for the settlement. Although higher prices may have the benefit of reducing teen smoking, no one should fool themselves

that the payments set forth in the agreement would harm the industry financially.

Civil Liability: The settlement agreement deals a body blow to our nation's system of civil justice. For one thing, it provides that "no punitive damages [may be imposed] in individual tort actions." The rationale for this provision is that some portion of the settlement money has been "designated" as punitive damages; but punitive damages are not tax deductible, whereas all the payments required under the settlement would be. Thus, contrary to the claims of the settlement's proponents, the agreement does not require the payment of any punitive damages, let alone any payment that serves the same deterrent and punitive function. In fact, the agreement insulates the industry from paying any penalty for its past wrongdoing. Yet if any industry ever deserved to be liable for punishment through punitive damages, surely it is the tobacco industry.

The settlement agreement also strips away the right of plaintiffs to band together to bring class action cases. Many cases, however, are not economically feasible as individual actions. The agreement would therefore eliminate an important tool for victims to seek redress in the courts and allow tobacco victims fewer rights than people injured by other consumer products.

The settlement also places strict caps on the amount of damages a tobacco company would have to pay in a given year and on the amount an individual could recover in one year. We oppose any cap or limitation on the actual damages any individual can recover within a year, or any tobacco company would have to pay. Bending the civil justice system to benefit a corporate wrongdoer is unjustified, and sets a dangerous precedent that every irresponsible corporation will want to follow. Setting a precedent here would be particularly unwise, in light of the sordid history of corporate abuse by the tobacco industry and the fact that neither the Congress nor the public has been fully informed as to the extent of the tobacco's industry's past wrongdoing.

Attorneys' Fees: The payment of fees to the numerous lawyers who represent the states and the plaintiffs in proposed class actions is not addressed in the agreement. We have heard that attorneys' fees are or will be subject to a separate agreement that will be kept confidential. That would be intolerable. The American people have a right to know just how much the lawyers are seeking in payment. And any settlement of fees for the class action lawyers should be subject to public judicial review, as required in any class action settlement. Public Citizen has used this authority to reduce fees in a number of cases. This settlement was negotiated on behalf of the American people, and the

July 10, 1997
Page 5

lawyers who assumed this responsibility should not be permitted to cut a secret deal on the critical issue of attorneys' fees.

International Consequences: The tobacco industry talks about "global peace," yet the deal completely ignores its practices abroad. The Fifth Commandment does not say "thou shalt not kill Americans." There is no moral basis for anyone truly concerned about public health to close their eyes to American tobacco companies' promotion around the world of death through tobacco use while making some concessions to limit the carnage in this country.

The tobacco industry has made this agreement only in the U.S. in order to avoid the citizen-based judgments of our U.S. civil justice system. But the rest of the world will continue to pay the consequences.

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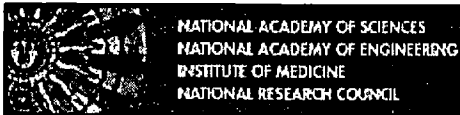
This list of problems with the settlement is not intended to be exhaustive. The settlement document is nearly 70 pages long and quite complex. Although many parts of the agreement are not clear, it is clear that the deal is fraught with problems and dangers. We urge that you and your staff consider these points as you deliberate on the merits of the settlement.

We look forward to working with you as this proposal is considered in Congress.

Sincerely,

A handwritten signature in cursive script, appearing to read "Joan Claybrook".

Joan Claybrook
President, Public Citizen



National Cancer Policy Board

Letter on Tobacco Control

Sent to the following members of the Executive Branch and Congress: Donna Shalala, William Corr, Bruce Reed, Newt Gingrich, Richard A. Gephardt, Trent Lott, Tom Daschle, Henry A. Waxman, Orrin G. Hatch, Ron Wyden, Tom Bliley, John D. Dingell, James M. Jeffords, Edward M. Kennedy, William V. Roth, Jr., Daniel P. Moynihan, Bill Archer, Charles B. Rangel, Patrick J. Leahy

July 18, 1997

Dear <salutation>,

Tobacco use is the Nation's largest cause of preventable disease and disability, killing over 400,000 people per year in the United States and claiming the lives of one in three smokers. The best long-term strategy to reduce this enormous health toll and its costs to society is to prevent the initiation of tobacco use and addiction to tobacco products among children and youths. Unfortunately, as you know, tobacco use among young people has increased consistently over the past several years. The Nation is losing ground, despite growing public awareness and renewed federal action. Action by local, state, and federal governments, along with action in the private sector will be necessary to reverse this trend, and reverse it we must if we are to reduce the health impacts of tobacco use. As you review tobacco control policies <in the executive branch><in Congress>, we wish to call to your attention the following five points, based on the 1994 report from the Institute of Medicine (IOM), *Growing Up Tobacco Free*, as updated by data presented at a July 15, 1997 IOM workshop and considered by the National Cancer Policy Board at its meeting on July 16.

1. Goals for reducing rates of youth initiation and tobacco use must be explicit, and failure to achieve them must be penalized sufficiently to build strong incentives for compliance by the tobacco industry.

Any long-term solution to the problem of tobacco-related disease will require incentives for private firms to be in alignment with public health goals. The proposed settlement is one opportunity to create such incentives, but even without a settlement federal policy should establish appropriate incentives.

2. The price of tobacco products must be increased substantially and immediately.

The first recommendation of the 1994 report was to increase the federal excise tax to \$2 per pack (or its equivalent for other tobacco products), depressing domestic demand and making the U.S. price comparable to that in other developed economies. The federal excise tax on tobacco is proportionately lower than it was in 1955, and prices to consumers are considerably lower than in other developed economies. Price increases, especially when combined with public education, are the best demonstrated public health interventions to reduce demand, and have the added benefit of generating revenue for tobacco control and other purposes. The proposed settlement among state attorneys general and tobacco firms is estimated to entail price increases in the range of 50 to 75 cents per pack, and these could be introduced gradually, lessening their effect. Studies of past price increases domestically and abroad suggest this magnitude of price increase would reduce consumption far less than the goals adopted by the federal government in *Healthy People 2000* or goals specified in the proposed settlement itself. To achieve a more powerful public health impact and to match the intervention to its stated goal, state and federal excise taxes over and above any settlement must be increased immediately by at least the \$2 increment recommended in 1994, and thereafter continually adjusted to match or exceed inflation.

3. The federal preemption of state and local regulation of advertising and promotion must be repealed.

The most successful efforts to curb tobacco use in this country have grown from mobilization at the state and community levels, entailing collaborations among private health organizations and federal, state, and local governments. Federal legislation currently prohibits state and local governments from regulating any form of advertising and promotional activities based on smoking and health, even if the activity occurs exclusively within the jurisdictional borders. Some state and local governments have indicated that their tobacco control efforts would be more powerful with such regulation, so removing the federal preemption remains critical. Building capacity for other state and community tobacco control measures is also important. States such as California and Massachusetts have mounted effective public education campaigns funded by state excise tax increases, but similar efforts in other states require sustained funding at levels well above those involved in federal tobacco control efforts to date. Federal support to states and local communities should be increased.

4. FDA regulation of tobacco products must be strengthened.

We applaud the actions of the Food and Drug Administration to regulate tobacco products as nicotine-delivery devices. The FDA regulation proscribing sale of tobacco products to those under 18 and limiting distribution pathways, as recommended in IOMs 1994 report, is an important first step but will require funds sufficient to ensure adequate enforcement. Despite the steps taken by FDA, federal regulation of advertising, promoting, labeling, packaging, and contents of tobacco products is incomplete. Federal regulatory efforts through FDA, the Federal Trade Commission, and other agencies must be strengthened to approach the full range of actions recommended in 1994.

5. The federal government must study, monitor, and evaluate tobacco control measures.

The federal government should continue to support research, monitoring, and evaluation, regardless of whether a settlement is implemented. New knowledge is needed to guide policy choices. Youth initiation rates have risen in recent years, for example, but the reasons are not fully understood, nor are the factors that underlie substantial differences in tobacco use among population subgroups. The 1994 report noted the importance of research to understand and improve behavioral and public health interventions. Generating new knowledge will become even more important as tobacco control activities escalate. Supporting research, monitoring and evaluation is a federal responsibility.

We appreciate your consideration of this letter. We will make this letter public on July 21, 1997.

Sincerely,

Peter M. Howley, Chair, National Cancer Policy Board

Joseph V. Simone, Vice-Chair

John C. Bailar

Norman Daniels

Joseph M. Davie

Robert W. Day

Kathleen M. Foley

Bertha A. Ford

Ellen R. Gritz

Elizabeth A. Hart

John Laszlo

Daniel Nathans

Diana B. Petitti

Amelie Ramirez

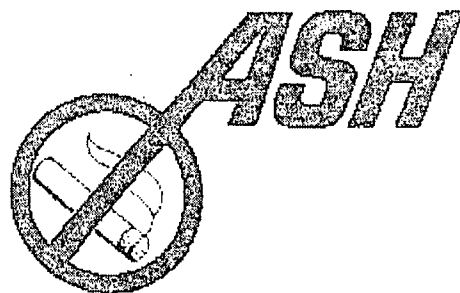
John R. Seffrin

Ellen L. Stovall

Frances M. Visco

Judith L. Wagner

Robert C. Young



ACTION ON SMOKING AND HEALTH
A National Legal-Action Antismoking Organization

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NATIONAL CANCER ADVISORY BOARD CRITICIZES DEAL [7.23.3]

Read the Text of Their Letter

The National Cancer Advisory Board has written a letter to key members of the Administration as well as selected members of Congress criticizing the proposed tobacco deal. The text is reprinted below.

The letter was sent to Donna Shalala, William Corr, Bruce Reed, Newt Gingrich, Richard A. Gephardt, Trent Lott, Tom Daschle, Henry A. Waxman, Orrin G. Hatch, Ron Wyden, Tom Bliley, John D. Dingell, James M. Jeffords, Edward M. Kennedy, William V. Roth, Jr., Daniel P. Moynihan, Bill Archer, Charles B. Rangel, Patrick J. Leahy. [Please note that the words "in the executive branch" in line 9 of paragraph 1 were changed to "in Congress" in the letters to members of Congress.]

Donna Shalala
Secretary Department of Health and Human Services
Room 638G 200 Independence Avenue, SW Washington,
DC 20201

Dear Secretary Shalala:

Tobacco use is the Nation's largest cause of preventable disease and disability, killing over 400,000 people per year in the United States and claiming the lives of one in three smokers. The best long-term strategy to reduce this enormous health toll and its costs to society is to prevent the initiation of tobacco use and addiction to tobacco products among children and youths. Unfortunately, as you know, tobacco use among young people has increased consistently over the past several years. The Nation is losing ground, despite growing public awareness and renewed federal action. Action by local, state, and federal governments, along with action in the private sector will be necessary to reverse this trend, and reverse it we must if we are to reduce the health impacts of tobacco use. As you review tobacco control policies in the executive branch, we wish to call to your attention the following five points, based on the 1994 report from the Institute of Medicine (IOM), Growing Up Tobacco Free, as updated by data presented at a July 15, 1997 IOM workshop and considered by the National Cancer Policy Board at its meeting on July 16.

1. Goals for reducing rates of youth initiation and tobacco use must be explicit, and failure to achieve them must be penalized sufficiently to build strong incentives for compliance by the tobacco industry. Any long-term solution to the problem of tobacco-related disease will require incentives for private firms to be in alignment with public health goals. The proposed settlement is one opportunity to create such incentives, but even without a settlement federal policy should establish appropriate incentives.
2. The price of tobacco products must be increased substantially and immediately. The first recommendation of the 1994 report was to increase the federal excise tax to \$2 per pack (or its equivalent for other tobacco products), depressing domestic demand and making the U.S. price comparable to that in other developed economies. The federal excise tax on tobacco is proportionately lower than it was in 1955, and prices to consumers are considerably lower than in other developed economies. Price increases, especially when combined with public education, are the best demonstrated public health interventions to reduce demand, and have the added benefit of generating revenue for tobacco control and other purposes. The proposed settlement among state attorneys general and tobacco firms is estimated to entail price increases in the range of 50 to 75 cents per pack, and these could be introduced gradually, lessening their effect. Studies of past price increases domestically and abroad

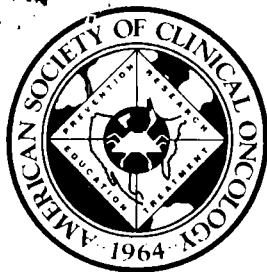
suggest this magnitude of price increase would reduce consumption far less than the goals adopted by the federal government in Healthy People 2000 or goals specified in the proposed settlement itself. To achieve a more powerful public health impact and to match the intervention to its stated goal, state and federal excise taxes over and above any settlement must be increased immediately by at least the \$2 increment recommended in 1994, and thereafter continually adjusted to match or exceed inflation.

3. The federal preemption of state and local regulation of advertising and promotion must be repealed. The most successful efforts to curb tobacco use in this country have grown from mobilization at the state and community levels, entailing collaborations among private health organizations and federal, state, and local governments. Federal legislation currently prohibits state and local governments from regulating any form of advertising and promotional activities based on smoking and health, even if the activity occurs exclusively within the jurisdictional borders. Some state and local governments have indicated that their tobacco control efforts would be more powerful with such regulation, so removing the federal preemption remains critical. Building capacity for other state and community tobacco control measures is also important. States such as California and Massachusetts have mounted effective public education campaigns funded by state excise tax increases, but similar efforts in other states require sustained funding at levels well above those involved in federal tobacco control efforts to date. Federal support to states and local communities should be increased.

4. FDA regulation of tobacco products must be strengthened. We applaud the actions of the Food and Drug Administration to regulate tobacco products as nicotine-delivery devices. The FDA regulation proscribing sale of tobacco products to those under 18 and limiting distribution pathways, as recommended in IOMs 1994 report, is an important first step but will require funds sufficient to ensure adequate enforcement. Despite the steps taken by FDA, federal regulation of advertising, promoting, labeling, packaging, and contents of tobacco products is incomplete. Federal regulatory efforts through FDA, the Federal Trade Commission, and other agencies must be strengthened to approach the full range of actions recommended in 1994.

5. The federal government must study, monitor, and evaluate tobacco control measures. The federal government should continue to support research, monitoring, and evaluation, regardless of whether a settlement is implemented. New knowledge is needed to guide policy choices. Youth initiation rates have risen in recent years, for example, but the reasons are not fully understood, nor are the factors that underlie substantial differences in tobacco use among population subgroups. The 1994 report noted the importance of research to understand and improve behavioral and public health interventions. Generating new knowledge will become even more important as tobacco control activities escalate. Supporting research, monitoring and evaluation is a federal responsibility.

We appreciate your consideration of this letter. We will make this letter public on July 21, 1997.



American Society of Clinical Oncology

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October 10, 1997

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JRM - FYI

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Barbara L. Weber, MD

William C. Wood, MD

Executive Vice President

John R. Durant, MD

The Honorable Bruce Reed
Domestic Policy Council
1600 Pennsylvania Ave., NW
Washington, DC 20500

RE: ASCO Position on the Proposed Tobacco Settlement

Dear Mr. Reed:

The American Society of Clinical Oncology (ASCO) is a medical organization representing nearly 12,000 physicians who specialize in clinical cancer research and patient care. As front-line witnesses to the devastating toll from tobacco use and as the Nation's experts in the treatment of cancer, ASCO members advocate, in the strongest terms possible, that the best way to reduce the incidence of cancer is to prevent people--particularly children--from ever using any tobacco products, especially cigarettes and smokeless tobacco. In addition, to save lives, our Nation must invest in clinical research to improve diagnosis and treatment of tobacco-related diseases.

We believe our organization brings a unique and important perspective to the debate over the proposed tobacco settlement. Attached is a copy of ASCO's official position on the issue. Our organization strongly supports a national settlement with the tobacco industry, provided that the resulting agreement approaches or meets ASCO's policy goals and furthers the public health. A comprehensive, global settlement is the preferred way to address this complex medical and social issue rather than piecemeal litigation that could lead to unpredictable and inconsistent results.

Overall, ASCO is encouraged by the provisions of the settlement that (1) place strict limits on tobacco advertising and promotion; (2) attempt to eliminate access by children and teenagers to tobacco products; (3) provide significant funds for a national anti-tobacco public education campaign; and (4) create a \$25 billion Public Health Trust Fund.

However, there are a number of critical flaws in the settlement agreement that must be corrected by the President and Congress in order for the agreement to provide effective prevention and intervention mechanisms and to

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October 10, 1997

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receive ASCO's support. Without strengthening the terms of the settlement, the cycle of addiction, disease and death associated with tobacco use will not be broken.

As detailed in the attached position paper, ASCO calls for the following key changes that should apply equally to all tobacco products including cigarettes and smokeless tobacco:

- ▶ allow the Food and Drug Administration to regulate nicotine as a "drug" and tobacco products as "devices" with no procedural or substantive strings attached;
- ▶ structure the penalty for industry failure to meet its underage "look-back" targets as automatic excise tax increases, in addition to limited cash payments;
- ▶ ensure that funds in the Public Health Trust Fund are distributed through a scientific peer-review process, with research focusing on basic disease processes, development of effective early diagnostic tests, chemoprevention and other preventative approaches, and improved therapeutic interventions for tobacco-related diseases; and
- ▶ identify United States's trade policies and programs that actively promote tobacco exports, particularly to underdeveloped countries, as immoral and unwise, and institute a system of tight controls over tobacco exports.

We stand ready to work with you and other members of Congress to craft legislation to address these issues in the settlement agreement. We are willing to testify at hearings on this issue and our organization's policy staff will be available to you and your staff to provide additional assistance or information. We look forward to working with you on this matter of critical importance.

Sincerely,

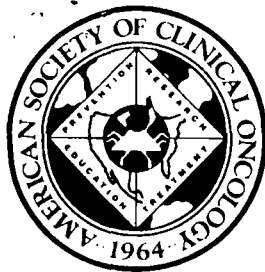


Robert J. Mayer, M.D.
President



Lowell E. Schnipper, M.D.
Chair, Public Issues Committee

Attachment



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ASCO POSITION ON THE PROPOSED TOBACCO SETTLEMENT

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Regrettably, ASCO members all too often see the deadly consequences of tobacco use--there are more than 139,000 annual deaths in the United States from lung cancer alone.¹ Even persons who have successfully stopped smoking remain at high risk of developing lung cancer for the rest of their lives. For example, 50% of all new lung cancers are diagnosed in former smokers. But deaths from highly addictive tobacco products are not limited to lung cancer. Tobacco use also is responsible for cancers of the mouth, pharynx, larynx, esophagus, pancreas, uterine cervix, kidney and bladder, resulting in another 35,000 annual deaths from tobacco use.² In the face of such daunting statistics, the Society, in 1996, adopted a policy statement calling for the elimination of tobacco products along with a number of strong intermediate steps to further that goal.³ That policy statement serves as ASCO's benchmark for assessing the settlement agreement reached by 40 State Attorneys General and the tobacco industry.

In an attempt to limit its legal liability, the tobacco industry has negotiated an agreement with the Nation's Attorneys General that includes increased regulation of tobacco as a drug, and a substantial financial settlement. ASCO strongly supports a national settlement with the tobacco industry, provided that the resulting agreement approaches or meets ASCO's policy goals and furthers the public health. A comprehensive, global settlement is the preferred way to address this complex medical and social issue rather than piecemeal litigation that could lead to unpredictable and inconsistent results. We recognize and emphatically support holding a public debate on the details of the proposed settlement and we urge Congress and the President to give these deliberations top priority so that they conclude as expeditiously as possible.

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- 1 According to the 1997 edition of the American Cancer Society's "Cancer Facts & Figures," there will be an estimated 160,400 lung cancer deaths, 87 percent of which are caused by tobacco use, and an estimated 178,100 new lung cancer cases in 1997.
- 2 "Cancer Facts & Figures - 1997."
- 3 American Society of Clinical Oncology--Tobacco Control: Reducing Cancer and Saving Lives. *J Clin Oncology* 14:1961-1963, 1996.

Overall, ASCO finds that a number of the provisions of the proposed settlement represent positive developments. In particular, this organization is encouraged by the provisions that (1) place strict limits on tobacco advertising and promotion; (2) attempt to eliminate access by children and teenagers to tobacco products; (3) provide significant funds for a national anti-tobacco public education campaign; and (4) create a \$25 billion Public Health Trust Fund.

However, there are a number of critical flaws in the settlement agreement that must be corrected by the President and Congress in order for the agreement to provide effective prevention and intervention mechanisms and to receive ASCO's support. Without strengthening the terms of the settlement, the cycle of addiction, disease and death associated with tobacco use will not be broken.

In particular, ASCO calls for the following key changes that should apply equally to all tobacco products including cigarettes and smokeless tobacco:

- ▶ allow the Food and Drug Administration (FDA) to regulate nicotine as a "drug" and tobacco products as "devices" with no procedural or substantive strings attached;
- ▶ structure the penalty for industry failure to meet its underage "look-back" targets as automatic excise tax increases, in addition to limited cash payments;
- ▶ ensure that funds in the Public Health Trust Fund are distributed through a scientific peer-review process, with research focusing on basic disease processes, development of effective early diagnostic tests, chemoprevention and other preventative approaches, and improved therapeutic interventions for tobacco-related diseases; and
- ▶ identify United States's trade policies and programs that actively promote tobacco exports, particularly to underdeveloped countries, as immoral and unwise, and institute a system of tight controls over tobacco exports.

FDA Authority

The settlement agreement accepts FDA authority to regulate nicotine as a drug and tobacco products as devices, but with severe restrictions for the first 12 years, then certain limits thereafter. ASCO is on record supporting a strong national tobacco regulatory program.

FDA has a longstanding tradition of establishing rigorous standards and procedures for regulating drugs and devices. The pharmaceutical and medical device industries, which make products that save lives, are required to meet those standards. The tobacco industry, which sells products that cause disease and death, should not be given special treatment. FDA should be allowed to regulate nicotine and tobacco products as it would any other drug or device. ASCO calls for the removal of any substantive or procedural limits on FDA's regulatory authority in this area.

As a public health matter, ASCO recognizes that an immediate ban on nicotine could pose great problems for the 77-92% of adult tobacco users who are addicted to nicotine. Thus, ASCO acknowledges there may have to be a phase-in period for full FDA authority over tobacco. That period, however, should be no more than 6 years, during which time there should be more research and other funds directed toward expediting the development and distribution of more effective smoking cessation products and therapies.

Look-Back Penalties

ASCO's policy statement advocates a substantial increase--in the range of \$2.00 per pack--in the federal excise tax on cigarettes or other tobacco products. That policy is based on the economic evidence that price increases lead to decreased consumption, particularly among underage tobacco users. The settlement agreement calls for "look-back" provisions to set targets for reduced youth smoking. As of the fifth year of the settlement, the industry must show a 30% reduction in underage smoking and a 25% decline in underage use of smokeless tobacco, with additional targets thereafter. If the industry fails to meet such targets, there is an \$80 million penalty for each percentage point below the goal, up to a cap of \$2 billion annually, with the possibility of significant rebates.

ASCO's overriding goal is to prevent children from using tobacco and the look-back targets help accomplish that goal. But ASCO is concerned that the proposed penalties are insufficient incentives to achieve the desired reduction. Therefore, in addition to a capped monetary penalty, the settlement agreement should also rely on excise tax increases, which have a track record in reducing consumption, as the fail-safe mechanism. The significant health risks associated with tobacco use outweigh any concerns that such taxes may be perceived as regressive.

The excise tax program should be implemented consistent with the approach adopted for the look-back provisions. For every percentage point below the goal, there should be an automatic increase, in the range of 10 cents, in the federal excise tax on tobacco and smokeless tobacco products. For example, if there is only a 15% reduction in underage smoking in the fifth year, there will be an additional \$1.50 federal excise tax on tobacco products in the sixth year. This same formula would be applied to smokeless tobacco products. The total tax may be more if a state or local government decides to impose its own excise tax on tobacco. Thus, if the tobacco industry reaches the reduction targets, there will be no automatic federal tax increase but if they fail, the tax will be added in order to achieve reduced consumption. Monies from both the look-back penalties and the excise tax should be used to supplement the Public Health Trust Fund.

Research Funds

ASCO members know all too well how difficult it is to treat cancer, particularly the cancers associated with tobacco use. The key to improving this situation is research on basic mechanisms involved in cancer; identification of susceptibility genes and current and former smokers at highest risk for cancer; and development of effective chemoprevention, new diagnostic tests, and improved treatment options for tobacco-related diseases. That is why ASCO is encouraged that the settlement agreement funds a \$25 billion Public Health Trust Fund. But it is essential that the trust fund establish a rigorous, science-based, peer review system to award research grants. Otherwise, we run the risk of wasting valuable research dollars on projects that do not expand the current state of knowledge. Scientific expenditures through the trust fund should be patterned after the existing grants program administered by the National Institutes of Health (NIH); one possibility is that it be administered by the NIH.

Research priorities must be sufficiently defined in order that an expanded scientific effort be focused and well coordinated:

- ▶ Preventive strategies are needed to interrupt the process of carcinogenesis that is initiated by exposure to carcinogens in tobacco smoke. This will require an understanding of the

biologic consequences that follow from the interaction between these cancer causing chemicals and human DNA.

- ▶ There is critical need for the development of diagnostic assays that will permit detection of tobacco-related cancers at, or as close to, their inception as possible. This need is underscored by the relatively good survival rates for the minority of patients who present with early lung cancer, and the high fatality rates observed in the majority of patients who present at a late stage of the disease.
- ▶ Novel therapeutic approaches are intensely needed, since tobacco-related cancers are among the most refractory to standard medical interventions. These can only emerge from a redoubled effort at basic research into the fundamental processes that govern the cancer cell, which in turn will lead to the identification of molecular targets for new therapeutic interventions. Lastly, and most emphatically, these funds should be allocated to clinical research, whereby the research advances that have been made can be extended to new therapies that are offered to the patient.

Export Controls

According to the World Health Organization, smoking kills approximately 3 million people worldwide each year. If current trends continue, that figure will grow to 10 million deaths annually by the year 2025. The enormity of this problem is exacerbated by United States' trade policies that encourage the export of tobacco products, particularly to less developed countries. ASCO believes these policies are unconscionable and perverse. Our Society feels a particular responsibility to address this problem because 20 percent of our members and more than 50 percent of participants in our scientific and educational meetings are from outside the United States.

The settlement agreement omits the tobacco export issue. That silence is morally unacceptable. Tobacco is not just another exported commodity. As evidenced by the settlement itself, it is an highly addictive substance that causes pain, suffering and death. Those problems occur whether tobacco is consumed in this country or abroad. ASCO urges that the settlement call for a full-scale Presidential review of all U.S. trade policies that affect tobacco and tobacco products and shift those policies, either by executive order or through legislation, to discourage, rather than encourage, such exports. Moreover, exports can be further discouraged by funding a retraining program for America's tobacco farmers to wean them off this cash crop. In addition, the warning labels and packaging restrictions detailed in the settlement agreement for domestic products should be retained for exported products to foreign markets that have not already developed comparable requirements.

* * * * *

ASCO believes that if the changes outlined above are incorporated into legislation implementing the settlement agreement, then that agreement will further the public health by reducing both the number of new tobacco users and consumption by existing users and by funding research to improve our ability to diagnose and treat tobacco-related diseases. In the absence of these modifications, ASCO will find it difficult to support the settlement.



PUBLIC POLICY

BRIEF

Tobacco Industry Bailout¹ July 21, 1997 (ver. 1)

On June 20, 1997, the nation's biggest tobacco companies and state attorneys general announced a settlement of state tobacco lawsuits aimed at recovering Medicaid money the states spend on treating smoking-related diseases. The complex settlement reaches far beyond the scope of the states' individual lawsuits and will need congressional approval. The settlement proposal addresses a variety of issues including the federal Food and Drug Administration's (FDA) authority to regulate tobacco, tobacco advertising and promotion, youth access to tobacco products, environmental tobacco smoke, and immunity for the tobacco industry from future lawsuits.

The American Lung Association believes the settlement falls considerably short of protecting public health. The proposal is wrought with gaping loopholes that can be manipulated by the tobacco industry.

Following is a summary of the American Lung Association's key concerns about the tobacco settlement.

FDA Authority

The settlement stipulates that the FDA can regulate nicotine as a drug but not ban it from cigarettes until 2009 and only then through a "formal" rulemaking process before an administrative law judge. Before reducing nicotine levels, the FDA must prove that its action will result in "a significant overall reduction of health risks," is technologically feasible and will not create "significant demand" for black market or smuggled cigarettes.

Furthermore, the agreement provides that the industry will disclose ingredients to the FDA, but allows it to designate any ingredient as a confidential trade secret, a designation the FDA would have to accept.

CAVEAT: The settlement document is complex. The document is not a draft of legislative language, rather it is a narrative outline of potential legislation. Some sections are vague or open to differing interpretations. This Public Policy Brief is not a comprehensive analysis of the agreement, rather it is an attempt to highlight many of the questions and problems the American Lung Association has found in reviewing the settlement agreement. As ALA continues its analysis, this document will be revised.

American Lung Association July 21, 1997

ALA position

The FDA's authority to regulate tobacco is sacrosanct. No changes in the agency's current authority or limits on future authority are acceptable. The tobacco settlement would make it almost impossible for the FDA to regulate nicotine.

The settlement sets up two unacceptable hurdles for the FDA to regulate the nicotine in tobacco products through its authority over medical devices. First, the agency would be required to use "formal rulemaking" to get the job done. Unlike "notice and comment" rulemaking, which can be concluded in a year or so, formal rulemaking requires a full-scale evidentiary proceeding that can take many years. Second, the settlement would require the agency to prove that lowering nicotine levels will not create a black-market demand for tobacco products with higher nicotine yields. Meeting the final test on black market or contraband sales will be impossible for the agency. Tobacco executives agree. British American Tobacco CEO Martin Broughton said in the Wall Street Journal about the likelihood that FDA would regulate nicotine: "It is an unlikely prospect. The contraband part gives me the most comfort."

For years, public health advocates have argued that the public, especially users of tobacco products, have a right to know what additives the companies put in their products. The settlement does nothing to rectify this problem.

Immunity from Future Liability

The settlement insulates the industry from paying any penalty for past wrongdoing. It provides that "no punitive damages [may be imposed] in individual tort actions." It also strips away the right of individual plaintiffs to band together to bring class-action cases, thereby affording tobacco victims fewer rights than people injured by other consumer products. The settlement also places strict caps on the amount of damages a tobacco company would have to pay in a given year and on the amount an individual could recover in one year.

ALA position

The American Lung Association is adamantly opposed to any immunity or limits on the tobacco industry's future liability. Damages should not be capped. No limitations should be imposed on punitive damages. There should be no ban on class-action lawsuits. As Joan Claybrook of Public Citizen puts it, "Bending the civil justice system to benefit a corporate wrongdoer is unjustified and sets a dangerous precedent that every irresponsible corporation will want to follow."

Advertising & Promotion

All outdoor tobacco advertising (billboards, etc.) would be banned, as would advertising via the Internet. Sports promotions and in-store displays would be banned. Tobacco ads could no longer feature human images or cartoon characters. The cigarette companies would pay for anti-tobacco advertising campaigns. Cigarette packages would carry stronger warnings covering 25 percent of the front of a package.

ALA position

Limits on advertising must be comprehensive. When faced with restrictions in the past, the industry has found creative and successful ways to market its products. This scenario has been the case in other countries that have imposed advertising restrictions. The creative genius of the industry, coupled with that of its high-paid advertising consultants, will come up with a

brand-new world of tobacco marketing to get around the settlement. Options a tobacco company might use include direct mail marketing, tobacco company "outlets" and paying celebrities to smoke their brands in public.

Compliance & Corporate Culture --- "Look Back" Provisions

The settlement would fine the industry if youth smoking rates do not drop by 30 percent in 5 years, 50 percent in 7 years, and 60 percent in ten years. There is a penalty of \$80 million per percentage point by which the target is missed. This figure is based on the estimated profit from a lifetime of smoking if the individual began at age 14. The fine is subject to an annual cap of \$2 billion for the entire industry. After paying the fine, however, the industry can petition the FDA to argue that it pursued all "reasonable available measures" to reduce youth smoking and took no actions to undermine that goal. If the FDA accepts that argument, the companies get 75 percent of their money back; if the FDA does not accept the argument, the companies can appeal the matter in court. The fine is tax deductible as a business expense.

ALA position

The financial penalties are much too low and could be recouped by the industry by raising the price of cigarettes just a few cents per pack -- now at 5 to 8 cents per pack. This program is an industry-wide program with no accountability by individual companies. A program that will really change corporate behavior must require individual companies to take responsibility for the sale of their products to children and sanction those companies for failing to resolve the problem. The fine levied against a company must not be tax deductible and must be severe enough to change behavior. These sanctions must place the offenders at severe and escalating disadvantage for their behavior. Additional nonfinancial "penalties" must be added to ensure youth smoking rates are met, such as plain packaging or a total ban on advertising for companies found to be targeting youth. Also, details are needed on what will constitute "reasonable available measures" that the industry can claim were employed to reduce their non-compliance fee.

Environmental Tobacco Smoke (ETS)

Tobacco use in public places, workplaces of 10 or more persons and fast-food restaurants would be prohibited, except for areas with separate ventilation and through which nonsmokers need not pass. Exemptions include bingo parlors, casinos, prisons and tobacco stores. The legislation would not preempt or otherwise affect any federal rules that restrict smoking in federal facilities.

ALA position

The settlement language dealing with ETS position is weaker than current law in many states. Ventilation systems are not an acceptable alternative. The settlement would not protect restaurant, bar and other hospitality workers -- the very people who often work for hours in smoke-filled environments. The agreement appears to continue exemptions for smoking in the Veterans' hospitals and other federal facilities. As we move into the 21st century, our goal should be "zero" tolerance for tobacco smoke.

Public Health Funding

Tobacco companies would pay \$368.5 billion over 25 years for anti-smoking campaigns and public health efforts. Most would be paid in annual installments starting at \$10 billion and rising to \$15 billion. The money would be divided among the states whose attorneys general sued, public health groups, and a new industry fund to pay for damage claims and treatment cost owed to smokers who are ill.

ALA position

The tobacco industry is getting off lightly. Companies can raise prices and write off the settlement payments as tax deductions, pushing payments onto the taxpayer and tobacco consumer. In the meantime, millions of current smokers will continue to use their deadly products and the industry will continue to lure new, young smokers into nicotine addiction. The settlement provides a stable financial situation for the industry for the next 25 years.

Tobacco Industry Documents

The settlement purports to require the tobacco companies to release documents relating to health effects and research, marketing and children. However, the settlement does not require the industry to disclose a single document that it has not already released in litigation. In fact, the settlement allows the industry to continue pressing the same privilege and confidentiality arguments it has used to block discovery in litigation. The settlement provides that industry lawyers will conduct a document-by-document review of all records withheld as privileged in litigation to reconsider whether they should be released. Only after the review is completed would any independent assessment of the validity of privilege claims be allowed.

ALA position

The proposal will perpetuate decades of tobacco industry cover-up. Exempted would be the millions of pages of information now shielded by "attorney-client" privilege. These documents can reveal a lot about the industry's wrongdoing and would be made public through the legal discovery process if the states' lawsuits are pursued in court.

International Impact

Worldwide sales of cigarettes in 1996 reached a total of \$295.8 billion. Approximately 85 percent of the three million tobacco-related deaths occur each year outside the United States. By the year 2020, the World Health Organization predicts that 10 million people will die annually from tobacco-related disease – 70 percent in the developing world.

The U.S. tobacco settlement excludes the rest of the world. Consequently, the U.S. tobacco companies' strategy will be to continue targeting the overseas market, especially the Third World and Eastern Europe, where they already sell a large majority of their cigarettes.

ALA position

The tobacco settlement ignores the rest of the world and condemns children in other countries to avoidable tobacco addiction, resulting in millions of preventable deaths each year. Promoting the export of tobacco-caused addiction, disease and death is unacceptable.

Tax Provisions

Although the industry will pay \$368.5 billion dollars over 25 years, almost every penny will be deemed a business expense and therefore considered tax deductible. Given the 40 percent marginal tax rate paid by RJR (and presumably by other tobacco companies), the tax deduction would be about \$150 billion.

ALA's position

Expenses incurred by the tobacco industry as part of the settlement should not be underwritten by the American people. In order to change the corporate culture of this industry it must pay for the settlement. And while higher cigarette prices may help reduce youth smoking, the payments described in the settlement will not harm the industry financially – in fact the settlement provide financial stability for the industry for 25 years.

For More Information

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or

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Recommended Reading

The text of the tobacco settlement is available via the Internet at:

www.usatoday.com/news/smoke

Additional information can be found via the following web sites:

www.lungusa.org
www.tobacco.neu.edu
www.washingtonpost.com
www.reuters.com
www.nytimes.com
www.ash.org
www.smokescreen.org

NEWS



FOR IMMEDIATE RELEASE

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AMERICAN LUNG ASSOCIATION CALLS PROPOSED TOBACCO SETTLEMENT ADVERTISING PROVISIONS INEFFECTIVE

Organization Recommends Stricter Advertising, Marketing Guidelines

(WASHINGTON -- July 24, 1997) -- Calling the proposed tobacco settlement's advertising provisions "a mere inconvenience to the tobacco industry," the American Lung Association and a volunteer task force of advertising and marketing experts today issued recommendations for ways to end tobacco advertising and marketing to adolescents.

"Joe Camel and the Marlboro Man may be dead, but cigarette advertising still has an impact on encouraging young people to smoke," said John R. Garrison, Chief Executive Officer of the American Lung Association.

The American Lung Association created a Tobacco Advertising Advisory Committee to analyze the proposed tobacco settlement. Based on that analysis, the Lung Association has developed the following guidelines to ensure that cigarette advertising does not reach young people and contribute to their decision to smoke:

- All tobacco advertising visuals accepted by publications with audiences over the age of 18 should be limited to black-and-white ads showing only the product package. No props or scenery of any kind should be allowed. Except for the warning label, no copy should be allowed.
- All publications that accept tobacco advertising should be required to conduct annual readership studies showing the percentage of their readers under the age of 18. Those with an under-18 readership more than 15 percent should be prohibited

(more)

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LUNG ASSOCIATION .. TOBACCO ADVERTISING/2

from running tobacco advertisements or announcements of tobacco marketing or promotional campaigns.

- Direct and indirect payments for tobacco product placement in movies, TV programs and video games should be banned. So should payments to entertainment or sports figures to smoke "in public" or in the course of their professions, such as in live music performances.

"Human images and cartoon characters were banned from cigarette advertising during last month's proposed tobacco settlements, however there are an infinite number of symbols and images that can be used which are meaningful to adolescents," said Dan Cohen, President of Dan Cohen Marketing/Communications, a member of the Lung Association's advisory panel.

An analysis of a new Camel Lights print advertisement, which adheres to the proposed tobacco settlement's restrictions, reveals the impact symbols and images have on young people. The advertisement, one in a series of ads in a new Camel campaign, appeared in the July 6, 1997 issue of *Sports Illustrated* and contains the headline "Live Out Loud." Depicted in the ad are several symbols that appeal to young people without the use of traditional images such as human figures or cartoon characters.

"The symbols used in the ad—a motorcycle, the wings of an eagle, a camel and the color black—create powerful visual messages that appeal to adolescents," said Penelope Queen, Director of Band Consultancy, TEAM Strategic International, and a member of the Lung Association panel. "The ad demonstrates how easy it is and will be for the tobacco industry to circumvent the tobacco settlement and create powerful advertising to effectively reach a youth audience."

The proposed tobacco settlement recommends new programs for public education and tobacco-use prevention, including counter-advertising campaigns. The American Lung Association's Tobacco Advertising Advisory Committee will review these proposed programs and make recommendations for steps that must be taken to curb the persuasiveness and influence of tobacco imagery in American culture.

The American Lung Association has been fighting lung disease for more than 90 years. With the generous support of the public and the help of our volunteers, we have seen many advances against lung disease. However, our work is not finished. As we look forward to our second century, we will continue to strive to make breathing easier for everyone. Along with our medical section, the American Thoracic Society, we provide programs of education, community service, advocacy, and research. The American Lung Association's activities are supported by donations to Christmas Seals® and other voluntary contributions. You may obtain additional information via our America Online site, keyword: ALA, or Web site at <http://www.lungusa.org>.

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American Lung Association TOBACCO ADVERTISING/MARKETING GUIDELINES

The American Lung Association created a Tobacco Advertising Advisory Committee to assess the future of tobacco advertising under 1) the recommendations made by the Koop/Kessler Advisory Committee on Tobacco and Public Health and 2) the "Proposed Resolution" reached between the tobacco industry and the state attorneys general.

Based on that assessment, following are guidelines the American Lung Association believes should govern any future tobacco product advertisement and marketing campaigns. In general, these guidelines reflect the Lung Association's endorsement of the Koop/Kessler Committee findings. In some instances, the Lung Association's recommendations are even more specific.

LOOPHOLES IN THE "PROPOSED RESOLUTION"

- The advertising requirements of the "Proposed Resolution" will not appreciably inhibit the tobacco industry's ability to reach and influence the 12-17 year-old segment of the U.S. population.
- The Proposed Resolution's ban on the use of human images and cartoon characters in advertising and promotion is a *mere inconvenience to the tobacco industry*. An analysis of the new Camel Lights advertisement (Attachment A and the Harley Davidson logo marked Exhibit B) shows how easily tobacco manufacturers can develop new ads with enormous appeal to people under the age of 18. Killing off Joe Camel and the Marlborough Man may satisfy many of their critics, but the death of these symbols will not seriously diminish the power of tobacco advertising to reach and influence teens and children.

AMERICAN LUNG ASSOCIATION ADVERTISING/MARKETING GUIDELINES

In addition to the recommendations from the Koop/Kessler Advisory Committee on Tobacco and Public Health (Attachment B), the American Lung Association recommends:

- All tobacco advertising visuals accepted in publications for over-18 audiences should be limited to black-and-white ads showing the product package. No props or scenery of any kind should be allowed. Except for the warning label, no copy should be allowed.
- The Koop/Kessler Advisory Committee recommends a ban on advertising, marketing and promotion of tobacco products directed at persons under age 18. As can be seen in Attachment C, many non-youth oriented magazines reach a significant number of teens. Therefore, all publications that accept tobacco advertising should be required to conduct annual readership studies showing the percentage of readers under age 18. Those with an under-18 readership of more than 15% should be prohibited from running tobacco advertisements or announcements of tobacco marketing or promotional campaigns.
- The Koop/Kessler Advisory Committee makes excellent recommendations for banning direct and indirect payments for tobacco product placement in movies, TV programs and video games. The American Lung Association additionally recommends an end to payments to entertainment/sports figures to smoke "in public" or in the course of their professions (i.e., live music performances)

NEXT STEPS

Both the "Proposed Resolution" and the Koop/Kessler Advisory Committee on Tobacco and Public Health recommend significant new programs for public education and tobacco prevention, including counteradvertising campaigns. The American Lung Association's Tobacco Advertising Advisory Committee next will review and make recommendations to ensure that counteradvertising programs successfully affect the pervasiveness of tobacco imagery and influence in our culture.

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"Tobacco Settlement and Communities of Color" Press Briefing

Statement of John Garrison,
Managing Director, American Lung Association

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

Statement of Samuel Aguayo, M.D.

**Statement of John Garrison,
Managing Director, American Lung Association**

"Tobacco Settlement and Communities of Color" Press Briefing

July 15, 1997

Washington, DC -- I am John Garrison, Managing Director of the American Lung Association. This morning's press briefing will focus on the global tobacco settlement and communities of color. On June 20, the nation's largest tobacco companies agreed to a Proposed Resolution to settle lawsuits filed by states' Attorneys General seeking to recover Medicaid monies spent on treating tobacco-related diseases. The American Lung Association is opposed to the Proposed Resolution--it is premature and wrong. Proceeding with this settlement could grant legitimacy to an industry whose behavior we find reprehensible. By vindicating the industry, a deal now tells the public that tobacco use is an appropriate and safe behavior.

Make no mistake, the pact is historic. The proposal marks the first time the tobacco industry has agreed to settle smoking-related legal claims. But the benefits of the settlement come at too great a price--the health of our children. The American Lung Association's analysis of the Proposed Resolution shows that its public health provisions are insufficient to keep tobacco out of the hands of children. The settlement weakens the authority of the Food and Drug Administration to regulate tobacco products, providing countless loopholes that allow the tobacco companies to continue to market their lethal product to our children.

The American Lung Association served on the Advisory committee on Tobacco and Public Health chaired by former Surgeon General C. Everett Koop and former FDA Commissioner David Kessler. The Committee produced a blueprint for tobacco control--a document that closes all of the loopholes carefully crafted by the tobacco industry in its own settlement with the states.

This morning our speakers will explore the need for effective tobacco control efforts that provide protections for all of America's children, especially children in our communities of color. We have also included in your packets, statements from the National Coalition of Hispanic Health and Human Services Organizations and the Black Clergy for Substance Abuse Prevention. These important organizations join us in raising concerns about the need for stronger tobacco control efforts in communities of color.

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

"Tobacco Settlement and Communities of Color" Press Briefing

July 15, 1997

Washington, DC -- Good morning, I am Jacqueline McLeod, past president of the American Lung Association. The tobacco settlement is bad deal for all Americans especially for communities of color. For decades the tobacco industry has targeted children. It has targeted the economically disadvantaged and it has targeted communities of color.

The industry also has attempted to purchase legitimacy -- or at least silence -- through its philanthropic efforts in our communities. I do not think the tobacco industry ever succeeded in gaining legitimacy through its dollars. Now we have dozens of ministers from around the country who are part of Black Clergy for Substance Abuse Prevention speaking out against tobacco use in our communities. But, I regret that too many organizations have been too silent for too long because of the lure and power tobacco money. Despite its horrific death toll, tobacco use never really made the top of the priority list for many organizations.

One our greatest concerns is that this settlement will restore legitimacy to the tobacco industry in the eyes of all Americans, especially the children in communities of color. In fact, the tobacco industry's own executives are celebrating it. Listen to what they have to say about the settlement:

Martin Broughton, CEO of B.A.T. Industries PLC (Brown & Williamson) said: "This gives shareholders and employees more certainty and consumers a respite from constant demonization of cigarettes."

Steven Goldstone, CEO of RJR Nabisco Holding Corp said: "Most important, the agreement secures the tobacco industry's rightful place in the mainstream of legitimate U.S. commerce."

Steven Parrish, Phillip Morris Senior Vice President said "We hope that ... legislation will move forward and with it bring a new era of cooperation and tolerance with regard to tobacco issues."

A settlement that brings "respite from demonization," "secures the tobacco industry's rightful place in the mainstream of legitimate U.S. commerce," and provides a "new era of tolerance" is not acceptable to us. We cannot allow an industry that kills 419,000 Americans each year ever to be restored to the mainstream or tolerated in a society that values human life.

For solutions to the tobacco problems, we should look to the recommendations of the Koop/Kessler Commission mentioned by John Garrison. For instance, the commission recommended a plan for placing specific obligations on each tobacco company to reduce prevalence rates. The report recommends that:

Specific and increasingly stringent targets for the reduction of tobacco use by children and adolescents (also known as "performance standards") should be established and become binding on the tobacco industry by brand within the next two years. Failure by the tobacco industry to meet these targets should result in predictable financial penalties sufficiently severe to act as a strong deterrent to continued failure.

In addition to company specific requirements to reduce youth smoking, the tobacco companies must disclose all of the documents they are hiding. We must craft strategies to specifically counter the sales and marketing efforts geared towards each niche market. The tobacco industry has been smart enough to target specific brands to specific customers. While our efforts on tobacco control must be comprehensive, we must tailor our efforts to each community as the Koop and Kessler Commission recommends.

Finally, we cannot forget about the people of the rest of the world. The proposed settlement ignores them. If we are truly going to confront tobacco, our tobacco control policy cannot end at our shores. Children around the world must be protected from the addiction, disease and death tobacco causes.

Statement of Samuel Aguayo, M.D.

"Tobacco Settlement and Communities of Color" Press Briefing

Washington, DC July 15, 1997

Washington, DC -- Good Morning. I am Dr. Samuel Aguayo, Associate Chief of Staff for Education at the Atlanta V.A. Medical Center, and Professor of Medicine at Emory University. I am also an active volunteer for the American Lung Association. As a physician and researcher, I have long been concerned about the growing impact of tobacco use on persons of color. I see patients of varying ethnic origins every day who have been hospitalized due to a smoking-related illness. Like the American Lung Association, I am concerned that compromises outlined in the tobacco settlement fall considerably short of protecting the public health needs of all Americans of all colors.

The tobacco agreement, at first glance, seems to support negotiators' claims that they have solved this nation's tobacco problems. But when the tobacco smoke clears, we still will be faced with the tobacco industry's dismal record of lies, manipulation and bad faith. Advertising and marketing restrictions, that on the surface seem rigid, certainly will not escape the craftiness of the tobacco industry. The industry has never had problems marketing its product in the past. In fact, the industry has just demonstrated how quickly it can reinvent itself by unveiling a brand new series of deceptively slick ads to replace the Joe Camel campaign that so effectively targeted our nation's children.

It should be no surprise that public health protections in the tobacco settlement are minimal. The American Lung Association fears this deal adds up to millions and millions more people suffering from smoking-related disease and death. What's worse will be the disproportionate impact that the settlement will have upon communities of color -- communities already heavily targeted by tobacco industry.

African-Americans, for example, have one of the highest smoking-related mortality rates. More than 47,000 African-Americans die from smoking related diseases each year. Especially troubling is the lung cancer death rate among African-American males, which is nearly 50 percent higher than for whites. Lung cancer accounts for 25 percent of all cancers among black males.

In the Hispanic and Latino communities, smoking rates and the incidence of lung cancer, though previously relatively low, are increasing as more Hispanics begin to smoke. In 1994, smoking prevalence among Hispanics was 19.5 percent. Among Hispanics, men suffer lung cancer mortality rates three times that of women. Among Puerto Rico Americans, 25 percent smoke; among Mexican Americans, the rate is 22.2 percent, and among Cuban Americans the rate is 20.7 percent.

Smoking rates in Native American/Alaskan Native populations are 28 percent for men and 35 percent for women. Some studies suggest smoking rates to be as high as 53.7 % in Alaskan Native men. Smokeless tobacco use remains considerably higher among Native American women, with usage at 9 times the national mean and 38 times that for women in general. We are also concerned about the almost 40 percent of Native American women who endanger their infants' health by smoking during pregnancy.

Although overall smoking rates have remained lower among Asian Americans and Pacific Islanders, research has found that nearly half of the men in some Southeast Asian

communities are smokers. In 1990, chronic obstructive pulmonary disease, which includes emphysema and chronic bronchitis and is almost always caused by smoking, was the fourth leading cause of chronic disease-related deaths in Asian men, and the seventh leading in Asian women.

Statistics such as these will not change under the proposed tobacco settlement. Moreover, the cost of treating tobacco-related diseases is expected to exceed the \$97.2 billion that tobacco use now costs this country each year. Living with a tobacco deal that does not adequately address public health interests should not be a burden imposed upon anyone.

The American Lung Association has been fighting lung disease for 90 years. With the generous support of the public and the help of our volunteers, we have seen many advances against lung disease. However, our work is not finished. As we look forward to our second century, we will continue to strive to make breathing easier for everyone. Along with our medical section, the American Thoracic Society, we provide programs of education, community service, advocacy, and research. The American Lung Association's activities are supported by donations to Christmas Seals® and other voluntary contributions.

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For more information on lung health, programs, and special events, call your local American Lung Association at 1-800-LUNG-USA.

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