

**HEARING
MESSAGE
POINTS**

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STATEMENT OF GEOFFREY C. BIBLE
PHILIP MORRIS COMPANIES INC.
BEFORE THE
HOUSE COMMERCE COMMITTEE

January 29, 1998

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**EXECUTIVE SUMMARY
OF
STATEMENT OF GEOFFREY C. BIBLE**

The Proposed Resolution, advanced by state Attorneys General, certain members of the public health community, private litigants and the tobacco industry, if enacted, offers us an opportunity to choose a future of cooperation and progress in which the decades-old policy debate over tobacco policy would be resolved in a comprehensive, meaningful and efficient manner -- and to do so now. It covers virtually every issue that has defined the public debate over tobacco:

- (1) by seeking to prevent underage access to, and dramatically reduce underage use of, tobacco products;
- (2) by providing for comprehensive Food and Drug Administration authority to regulate tobacco products;
- (3) by mandating changes in the corporate culture of tobacco companies;
- (4) by setting minimum national requirements limiting smoking in public places;
- (5) by requiring billions of dollars (\$368.5 billion over 25 years, subject to adjustment) from the tobacco industry to fund programs that Congress deems necessary to implement its policy decisions on tobacco at the federal, state and local levels.
- (6) by preserving the right of every individual to sue the tobacco industry while not relying on the tort system for resolving fundamental policy issues that only Congress should address; and
- (7) by establishing a comprehensive regime of federal regulation and federal and state enforcement of such requirements.

I believe that our nation is at an important crossroads with respect to the future of public policy on tobacco issues. If my perception is correct that most people in this country believe that adults who wish to smoke should continue to be able to do so legally, then the question is how do we go forward and forge a new era of cooperation and progress. Congressional enactment of the Proposed Resolution is intended to answer that question in a comprehensive and sensible way. I urge Congress to enact it as promptly as possible.

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STATEMENT OF GEOFFREY C. BIBLE

PHILIP MORRIS COMPANIES INC.

**BEFORE THE
HOUSE COMMERCE COMMITTEE**

January 29, 1998

I am Geoffrey C. Bible, and for the past three years I have served as Chairman and Chief Executive Officer for Philip Morris Companies Inc. My curriculum vitae is attached. I am proud to represent the largest consumer-products company in the world, with over 150,000 employees -- 70,000 in the United States alone. I appreciate the opportunity to appear before you today to discuss the Proposed Resolution advanced by state Attorneys General, certain members of the public health community, private litigants and the tobacco industry, and the historic opportunity that the proposal presents.

The opportunity that enactment of the Proposed Resolution presents is a future of cooperation and progress in which the decades-old policy debate over tobacco policy would be resolved in a comprehensive, meaningful and efficient manner -- and to do so now. This cooperative spirit is already reflected in the fact that the tobacco industry and its leading adversaries sat down together for the first time and, after much hard work, were able to find common ground on some very contentious issues. But, that was only the first step. The goals of this comprehensive package cannot be achieved without congressional action.

My statement below sets forth the major details of the Proposed Resolution, but, in broad brush terms, it would address the nation's most pressing policy issues on the subject of tobacco, including: prevention of underage tobacco use, public smoking restrictions, marketing restrictions,

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and fundamental changes in the way tobacco companies are regulated and conduct business. And, it would do so sooner rather than later. I also would like to emphasize that, contrary to some imprecise reports, the Proposed Resolution does not provide "immunity" for the tobacco industry.

The alternative is to cling to the past -- a past that embraces what many have seen as the "jackpot" approach of ad hoc, unpredictable and protracted litigation and controversy -- an approach leading only to continued conflict, lack of meaningful progress and instability.

I urge this Committee to seize this opportunity to look towards the future, and to act now to achieve the meaningful reforms presented by the Proposed Resolution by enacting it into law.

SUMMARY OF THE PROPOSED RESOLUTION

The Proposed Resolution covers virtually every issue that has defined the public debate over tobacco. As one of the negotiating state Attorneys General said at a prior hearing:

"[R]egarding teenagers . . . we went into [the negotiations] with great skepticism with these CEOs and their lawyers. There was no reason to believe they would ever come to the table with anything meaningful. But in this area, they have given us, I believe, everything we could think of." (Statement of Arizona Attorney General Grant Woods, Senate Commerce Committee hearing, July 29, 1997.)

The Proposed Resolution, which would be implemented through legislation and a binding contractual Protocol among the participating members of the tobacco industry, mandates a total reformation and restructuring of how tobacco products are manufactured, marketed and distributed in the United States:

- (1) by seeking to prevent underage access to, and dramatically reduce underage use of, tobacco products;
- (2) by providing for comprehensive Food and Drug Administration authority to regulate tobacco products under the Food, Drug, and Cosmetic Act, with certain provisions applicable to tobacco products;
- (3) by mandating changes in the corporate culture of tobacco companies;

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- (4) by setting minimum national requirements limiting smoking in public places (with state and local governments remaining free to set even more stringent requirements);
- (5) by requiring -- in an equitable fashion that will help assure ultimate payment -- billions of dollars from the tobacco industry to fund programs that Congress deems necessary to implement its policy decisions on tobacco at the federal, state and local levels;
- (6) by preserving the right of every individual to sue the tobacco industry while not relying on the tort system for resolving fundamental policy issues that only Congress should address; and
- (7) by establishing a comprehensive regime of federal regulation and federal and state enforcement to implement these requirements.

1. Prevention of Underage Use of Tobacco Products

The Proposed Resolution strikes at the core problem of underage consumption of tobacco products by proposing a drastic voluntary curtailment of advertising and marketing practices by participating companies that have been criticized as appealing to minors; strict controls restricting the sale of tobacco products to adults only; and dramatic reductions in the levels of underage use, with the tobacco industry paying -- without any finding of fault -- substantial economic surcharges if the required reductions are not met. In so doing, the Proposed Resolution would implement the "FDA Rule Plus" -- incorporating all of the restrictions in the FDA's August 1996 tobacco rule, and in many instances, going substantially beyond them.

A. Curtailment of Advertising

With the specific consent of the tobacco companies participating in the Proposed Resolution and a voluntary waiver of their first amendment rights, significant restrictions on tobacco advertising would be mandated. The Proposed Resolution would, among many other things:

1. Prohibit any use of human images and cartoon characters -- such as Joe Camel and the Marlboro Man -- in all tobacco product advertising.

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2. Ban all outdoor tobacco product advertising including advertising in enclosed stadia and advertising inside a retail establishment that is directed outside.
3. Except for advertising in adult-only facilities or adult publications, limit tobacco product advertising to black text on a white background.
4. Ban sponsorships (including concerts and sporting events) in the name, logo or selling message of a tobacco brand.
5. Ban all non-tobacco merchandise (such as caps, jackets and bags) bearing the name, logo or selling message of a tobacco brand.
6. Ban direct or indirect payments for tobacco product placement in movies, television programs and video games.
7. Prohibit direct and indirect payments to "glamorize" tobacco use in media appealing to minors, including live and recorded music performances.
8. Prohibit tobacco product advertising on the Internet unless it is designed to be inaccessible in or from the United States.

B. Access Restrictions

The Proposed Resolution would also serve to sharply restrict minors' access to tobacco products. Without preventing state and local governments from imposing even stricter measures, the Proposed Resolution would incorporate every access restriction embodied in the FDA rule, and would add other significant restrictions as well. The access restrictions would:

1. Set a minimum age of 18 to purchase tobacco products.
2. Establish a requirement of face-to-face transactions for all sales of tobacco products.
3. Require retailers to check photo identification of anyone under 27.
4. Ban all sales of tobacco products through vending machines.
5. Ban self-service displays of tobacco products except in adult-only facilities.

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6. Ban the distribution of tobacco products through the mail except for sales subject to proof of age (with subsequent FDA review to determine whether minors are obtaining tobacco products through the mail).
7. Impose retailer compliance obligations to ensure that all displays, advertising, labeling, and other items conform with all applicable requirements.

These access restrictions would be coupled with an entirely new system of enforcement (which is not in the FDA rule) to ensure that these provisions are meaningful in practice. The Proposed Resolution would mandate minimum federal standards for a retail licensing program: any entity that sells directly to consumers -- whether a manufacturer, wholesaler, importer, distributor or retailer -- would need to obtain and maintain a license. A seller would be subject to stiff penalties and potentially to suspension or loss of its license if it does not comply with the access restrictions. The federal government and state and local authorities would enforce these access and licensing provisions through funding provided by annual tobacco industry payments.

The Proposed Resolution also contains powerful economic incentives for the states to do their part to reduce underage tobacco use and to enforce the access restrictions. States would be required to achieve levels of compliance with the access restrictions within their borders of 75% by the fifth year after enactment of the Proposed Resolution, 85% by the seventh year, and 90% by the tenth year and each year thereafter. States that failed to do so would lose a significant portion of the health-care program funds that would otherwise be allocated to them out of the payments to be made by the tobacco industry (which are described below). Funds withheld from states on this basis, in turn, would be reallocated to those states that demonstrated superior "no sales to minors" enforcement records.

C. "Look Back" -- Economic Surcharges on the Tobacco Industry if Underage Use is Not Greatly Reduced

The Proposed Resolution would give the tobacco industry powerful economic incentives to further the goal of dramatically reducing underage tobacco use by imposing surcharges on the industry if required reductions are not achieved. The Proposed Resolution's "look back" provision would establish steep, required reductions in the level of underage tobacco use from estimated levels over the past decade: for underage cigarette use, 30% by year 5 after enactment of the Proposed Resolution, 50% by year 7 and 60% by year 10, with incidence remaining at such reduced levels thereafter.

For any year in which these required reductions are not met, the FDA would be required to impose a mandatory surcharge on the participating members of the industry in question (cigarette or smokeless tobacco) -- whether or not they are in any way responsible for such failure -- based upon an approximation of the present value of the profit the companies would earn over the lives of all underage consumers in excess of the required reduction (subject to a \$2 billion annual cap for the cigarette industry (as adjusted for inflation) and a comparably derived cap for the smokeless tobacco industry). Tobacco product manufacturers could receive a partial refund of this surcharge (up to 75%) only after paying the assessed amount and only if they could thereafter prove to the FDA that they had fully complied with the Proposed Resolution, had taken all reasonably available measures to reduce youth tobacco usage, and had not acted to undermine the achievement of the reduction goals.

2. Regulation of the Tobacco Industry

The Proposed Resolution would usher in a new era as to how tobacco products are made, ~~labeled, and sold in this nation by, among other things, mandating new warning labels, providing~~

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industry-funded cessation programs for people who want to quit, and giving the FDA extensive regulatory powers over the tobacco industry.

A. Warnings and Labeling

The Proposed Resolution would require a new set of rotating warnings to be placed on packages and ads of tobacco products. Their content would follow requirements in other countries, such as Canada. The warnings would be printed in alternating black on white and white on black format. Their location on ads and packages will be more prominent than previous warnings: 25% of the front of cigarette packs (at the top of the pack), and 25% of the principal display panel of smokeless tobacco products. The warning text, and where relevant, constituent yield information, would occupy 20% of press advertisements.

The content of these warnings was dictated by the representatives of the public health community who helped develop the Proposed Resolution. The text of these warnings is as follows:

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

In addition, the Proposed Resolution would expand the health warning concept as applied to advertising. For example, without limiting the FDA's normal rulemaking authority, the Proposed Resolution would require that use of currently employed brand descriptors such as "low tar" and "light" be accompanied by a mandatory disclaimer in advertisements. The FDA also would have

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the corresponding power, but not the obligation, to modify advertising restrictions with respect to tobacco products that it concludes present significantly reduced health risks.

B. Disclosure of Health Research and Information

To ensure access by the FDA to full information about the health effects of tobacco products, the Proposed Resolution would impose a series of comprehensive disclosure obligations on the tobacco industry. First, the industry would be required to disclose to the FDA internal laboratory research relating to health, toxicity, addiction and drug dependence, and the industry would thereafter be under a continuing obligation to disclose to the FDA all such research generated in the future.

Second, all such research (other than legitimate trade secrets), together with industry documents produced (or to be produced) in the pending state Attorney General actions and other litigations, would be made available to the public in a national tobacco document depository. To the extent the industry continues to assert that any such documents are covered by privileges or protections, the Proposed Resolution would provide for a binding, fast-track procedure by which any interested person may challenge such assertion before a specially appointed federal court. Finally, any subpoena authority that FDA has with respect to manufacturers of other devices would also apply to tobacco product manufacturers.

The Proposed Resolution also would institute new and expanded disclosure obligations with respect to non-tobacco ingredients. The tobacco industry would be required to disclose to the FDA the identity and amount of non-tobacco ingredients used in each brand. The industry also could be required to disclose ingredient information to the public to the same degree that current federal law requires for food products (roughly, the identity of ingredients -- other than flavorings and incidental additives -- in descending order of quantity).

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C. Cessation Programs

The Proposed Resolution -- in line with a recommendation of the state Attorneys General -- would provide funding for people who want to quit using cigarettes or smokeless tobacco. The Proposed Resolution would authorize the FDA to accredit cessation programs and techniques that it determines to be effective. Those cessation programs and techniques would then be made available to members of the public, to be paid for by funds provided under the Proposed Resolution by the tobacco industry.

D. Regulation of Tobacco Products

If enacted, the Proposed Resolution would impose a new regulatory regime to govern the manufacturing, content and development of tobacco products in this country. This regime would give FDA the authority to review the ingredients used in tobacco products and to impose standards for reducing the level of certain constituents, including nicotine.

First, the Proposed Resolution would require the tobacco industry to follow "good manufacturing practice" standards comparable to those applicable to other FDA-regulated industries, but tailored specifically to tobacco products. Those standards include requirements regarding quality control systems, FDA inspections (including inspections of facilities and records), and record-keeping and reporting.

Second, the Proposed Resolution would greatly expand federal regulatory authority over the non-tobacco ingredients used in tobacco products. In addition to requiring full disclosure of these ingredients to the FDA, the Proposed Resolution would require manufacturers to submit within 5 years a safety assessment for ingredients currently used, and to submit for the FDA's evaluation any new ingredients. The FDA would have authority to disapprove an ingredient's safety. In connection with this process, manufacturers would be required to have procedures for the selection,

testing, purchase, storage, and use of ingredients; keep records regarding the foregoing; and allow FDA access to such records, with appropriate protections for proprietary information.

Third, the Proposed Resolution would grant the FDA substantial authority over product development by imposing a regulatory regime that would, among other things, permit the agency to set standards for the modification of certain constituents, including nicotine.

Finally, the Resolution would grant FDA authority to encourage the development of "reduced-risk" tobacco products.

3. Changes in Corporate Culture

The Proposed Resolution would require participating members of the tobacco industry to take steps to ensure that they comply with the spirit, as well as the letter, of the Proposed Resolution.

Participating manufacturers would be required to create, and to update each year, plans to ensure compliance; to identify ways to reduce underage use of tobacco products; and to provide internal incentives for reducing underage use and for developing products with "reduced risk."

Participating manufacturers would also implement programs, standards and procedures for employees and agents that are designed to ensure compliance with the requirements of the Proposed Resolution. These programs would be required to assign to specific high-level personnel the overall responsibility for overseeing compliance; forbid delegation of substantial discretionary authority to individuals who have shown a propensity to disregard corporate policies; establish training or equivalent means of educating employees and agents; and institute appropriate disciplinary measures and steps to respond to violations and prevent similar ones from recurring.

Participating manufacturers would further be required to take affirmative steps to inculcate the spirit of the new regime. They would have to promulgate corporate principles that express and explain the company's commitment to compliance, reduction of underage tobacco use, and the

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development of "reduced-risk" tobacco products. They would be required to work with retail organizations on compliance, including retailer compliance checks and financial incentives for compliance. And they would be obliged to disband industry associations that have been criticized by public health authorities, and could only form new ones subject to strict oversight of their activities.

Companies would be subject to fines and penalties (including "Scarlet Letter" advertising) for breaching any of their obligations. To assist with enforcement, companies would be obliged to direct their employees to report known or alleged violations to the company compliance officer, who in turn would be required to provide reports to the FDA. Finally, "whistleblowers" in the tobacco industry would be provided with the maximum protection available under current federal statutes.

4. Nationwide Standards To Minimize Involuntary Exposure To Environmental Tobacco Smoke

If signed into law, the Proposed Resolution would mandate the first federal minimum standards governing smoking in public places or at work (with states and localities retaining power to impose stricter requirements). The Resolution would:

- Restrict indoor smoking in "public facilities" to ventilated areas with systems that exhaust the air directly to the outside, maintain the smoking area at "negative pressure" compared with adjoining areas and do not recirculate the air inside the public facility.
- Ensure that no employee can be required to enter a designated smoking area while smoking is occurring.
- Exempt restaurants (other than fast food restaurants) and bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.

The Occupational Safety and Health Administration would have authority to enforce these restrictions.

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5. Payments by the Tobacco Industry

The Proposed Resolution would require the participating companies to pay hundreds of billions of dollars that Congress may decide to allocate to federal, state and local governments for health care needs and research; to provide payments that yield public benefits and thereby resolve punitive damages claims that otherwise might be asserted in litigation based on past conduct; to fund federal and state enforcement efforts; and to pay for the expenses related to the administration of the Proposed Resolution.

Although the ultimate allocation of these huge, unprecedented sums is up to Congress, those who created the Proposed Resolution firmly believe that one particular priority for these expenditures would be to fund a variety of public and private non-profit efforts to discourage minors from beginning to use tobacco products and to assist current tobacco consumers who want to quit. Those programs would include research, public education campaigns, individual cessation programs and impact grants to communities and individuals affected by the Proposed Resolution.

Upon the Resolution's enactment, the participating companies would be required to make an aggregate, up-front \$10 billion payment. Thereafter, they would make specified annual payments tied to volume of domestic sales; these payments would be increased to reflect inflation and are to continue for as long as the companies continue to sell tobacco products in this nation. (If the industry's specified annual payment is to be reduced in a given year as a result of a decline in volume, but the industry's profit for that year is larger than its base year profits (as adjusted for inflation), the reduction in the annual payment due to the decline in volume would be offset to the extent of 25% of the increase in profit.)

At current levels of sales and prior to any adjustment for inflation, the Proposed Resolution would require total payments of \$368.5 billion over the first 25 years and \$743.5 billion over the

first 50 years (subject to credits described below in connection with potential civil tort liability). These payments would be separate and apart from any surcharges required under the "look back" provision discussed above. These payments would be the joint responsibility of the participating companies, and would receive priority in any bankruptcy or reorganization proceeding.

The payments would be allocated among the programs and entities referred to above, as determined by Congress and the President. The Proposed Resolution contemplates that the companies would then pass the annual payments through to consumers through price increases in order to promote the maximum reduction in underage use.

6. Preservation of Every Individual's Right to Sue

The Proposed Resolution attempts to strike a balance among preserving individuals' right to sue, allocating available funds most fairly and efficiently to the best uses and affording some measure of predictability and stability to companies who participate in the new tobacco regime.

First, the Proposed Resolution would settle the government and parens patriae actions, and bar similar nonfederal actions from being maintained in the future. It also would settle the currently pending class actions, to the extent they are not reduced to final judgment prior to enactment of the Act. Addiction claims would be likewise settled.

Second, the Proposed Resolution would preserve access to the tort system by individuals. Existing legal doctrine regarding the type of tort claims that can be brought, as reflected in the Supreme Court's Cipollone decision, also would be preserved. Claims could not be maintained, however, on a class or other aggregated basis, and could be maintained only against tobacco manufacturing companies (and not their retailers, distributors, affiliated companies or growers). In addition, claimants could seek punitive damages only with respect to claims predicated upon conduct taking place after enactment of the Proposed Resolution, since, as noted above, part of the aggregate industry payments are in settlement of punitive damages claims. Finally, all third-party

payor (and similar) claims, except those pending as of June 9, 1997, could be maintained only on a subrogated basis.

Judgments and settlements arising from tort actions would be paid as follows: The Proposed Resolution would set an annual aggregate cap equal to 33% of the industry's annual payment (including any modifications for volume adjustments or increases for inflation). Any excess judgments or settlements above the cap in a year would roll over until the next year. Moreover, while judgments and settlements would run against the defendant, they would give rise to an 80-cent-on-the-dollar credit against the industry's annual payment. Finally, to ensure that the available funds are not allocated disproportionately, any individual judgments in excess of \$1 million would be paid at the rate of \$1 million per year unless every other judgment and settlement could first be satisfied within the annual aggregate cap. In all circumstances, however, the companies would remain fully responsible for costs of defense.

7. Enforcement

Finally, the Proposed Resolution would provide for a comprehensive system of enforcement. Violations of the Proposed Resolution's requirements would carry civil and criminal penalties based upon the penalty provisions of the Food, Drug, and Cosmetic Act and, where applicable, the provisions of the United States Criminal Code. Special enhanced civil penalties would attach to violations of the obligations to disclose research about health effects and information about the toxicity of non-tobacco ingredients -- up to ten times the penalties applicable to similar violations by pharmaceutical companies.

In addition, terms of the Proposed Resolution would be embodied in state consent decrees, giving the states concurrent enforcement powers. State enforcement could not impose obligations or requirements beyond those imposed by the Proposed Resolution (except where the Proposed

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Resolution specifically does not preempt additional state law obligations) and would be limited to the penalties specified in the Proposed Resolution and by prohibition on duplicative penalties.

WHAT THE PROPOSAL DOES AND DOES NOT DO

While we had hoped that the Proposed Resolution would speak for itself, the debate thus far has evidenced some fundamental misunderstandings and misperceptions about its details and potential impact. I hope to shed some light on some of these today so that this proposal can be judged on its true merits and potential.

The Proposed Resolution Would Take Strong and Immediate Steps to Combat Underage Tobacco Use.

As described above, the Proposed Resolution contains many elements designed to take strong and immediate steps to combat underage tobacco use. Philip Morris is committed to this program.

Indeed, Philip Morris' efforts to stem the underage use of its products predate its acceptance of the Proposed Resolution. For example, in 1995, we launched "Action Against Access," a voluntary program designed to address the issue of youth access to cigarettes. Our goal was a retail environment where it would only be possible to purchase cigarettes when proof of age could be verified in person, in order to prevent minors from buying cigarettes. AAA elements, which Philip Morris undertook on its own, included:

- A ban on sampling to consumers.
- A ban on mail distribution of cigarettes to consumers.
- Promotion of retailer compliance education.
- Steps to prevent unauthorized use of our trademarks.
- Support of state legislation providing for more vigorous enforcement of minors' laws.
- Inclusion on all packs of the notice: "Underage Sale Prohibited."
- Suspension of merchandising benefits to retailers for whom valid conviction notices for sales to minors are received.

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But Philip Morris recognized that it could not effectively address youth smoking on its own. In 1996, in conjunction with the United States Tobacco Company, we therefore presented a further blueprint for federal legislation. That program included, among other things:

- A ban on vending machines.
- A ban on outdoor tobacco advertising within 1000 feet of any elementary or secondary school.
- A ban on brand name advertising on promotional items, such as caps and t-shirts.
- A ban on mass transit advertising.

There are many more elements to the Philip Morris/United States Tobacco proposal. For your further information, I have attached to my statement copies of advertisements that we ran on the AAA program and Philip Morris/United States Tobacco proposal.

Now, of course, we and UST can not bring about such bans on our own. For example, there are third parties, such as retailers, who must be involved. That is why the Proposed Resolution builds on these efforts in ways that no tobacco company could do unilaterally and that even Congress can not accomplish constitutionally.

How would the proposal address underage tobacco use? As discussed above, the Proposed Resolution would implement **every single measure in the FDA's tobacco rule** – a rule that FDA said it presumed would reduce underage tobacco use by 50% over seven years. (*See Preamble of FDA Rule*, 61 Fed. Reg. 44396, 44573) And, one about which Dr. Kessler said the following only a little over a year ago:

"I stand by the rules we've put in place. Right now, I don't see any other regulation as being necessary." (Barron's, Dec. 30, 1996)

On top of this, the Proposed Resolution's marketing restrictions for participating companies would go even further than the FDA rule, with a total ban on outdoor advertising and the use of human images or cartoon characters. To avoid the constitutional problems, which commentators

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such as constitutional expert Laurence Tribe have recognized, these restrictions would need to be accomplished by a binding, contractual Protocol.

Finally, the proposal would adopt many other features to combat youth tobacco use, which I already mentioned, including unprecedented surcharges on tobacco companies -- without any showing of fault -- if youth smoking targets are not met, licensing of every tobacco retailer in the United States, and a \$500 million annual advertising campaign recommended by the state Attorneys General to discourage tobacco use. Together, I am hopeful that these steps will lead to meaningful reductions in youth tobacco use -- and do so sooner rather than later.

The Proposed Resolution Would Not Grant the Industry "Immunity."

One of the main criticisms -- and mischaracterizations -- I have heard about the Proposed Resolution is that it grants "immunity" to the tobacco industry. I urge this Committee to evaluate this proposal on the facts and its merits alone.

The immunity issue is a red herring. There simply is nothing in the proposal that confers "immunity" on the industry. Let me explain why:

- **Every individual who believes he or she has a tobacco-related personal injury claim would still be able to seek full compensation from the industry in court.** These individuals would be aided by a national document depository and an expedited system for resolving disputes over claims of privilege and trade secrets.
- **The industry would be fully subject to punitive damages for anything it may do in the future;** and, with respect to past conduct, the industry would pay more than \$60 billion in settlement of any claims of punitive damages.

In addition, the Proposed Resolution would not provide "immunity" for any possible criminal prosecution.

It also bears noting that there are sound public policy reasons for the Proposed Resolution's civil liability provisions, which I described earlier. Colorado State Attorney General Norton articulated the following rationale:

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"In litigation, a few lucky winners will get the full reward. They will get to buy expensive cars and mansions, while everyone else gets no financial benefit. Through the settlement, the public as a whole will receive cessation programs, health care improvements, anti-smoking campaigns — exactly the benefits sought by the public health community. I certainly think most people would prefer the latter approach, the one embodied in the settlement." (Senate Judiciary Committee hearing, July 16, 1997.)

Moreover, the courts have become increasingly aware that class actions are inappropriate devices to resolve thousands of individual smoker claims.

Another important consideration is the financial uncertainty and unpredictability that the status quo brings to the industry and to potential plaintiffs who may not have rushed to the front of the litigation line. It would do the public no good for current tobacco manufacturers to agree to increased government regulation, severe and unprecedented advertising restrictions, and huge payments, only to be driven out of existence, for example, by a few plaintiffs who are the first "winners" in a litigation lottery. A state-by-state settlement approach also raises the same risks of a windfall to a few states, nothing to others. It brings virtually none of the other nonfinancial benefits of the Proposed Resolution and potential financial dislocation for the industry. The Proposed Resolution would bring some order to the chaos of unmanageable class actions and other aggregated-type claims -- but it still would permit every individual to have his or her day in court against the industry. Those lawsuits -- which under the Proposed Resolution could result in recoveries of \$5 billion a year -- would hardly constitute "immunity" for the industry.

The Proposed Resolution Would Respond to the Public Health Community's Request for New Warnings.

As discussed above, the Proposed Resolution would respond to the public health community's request for a single, consistent public health message on the issues of causation and addiction and include for the first time a warning on environmental tobacco smoke.

We have also agreed to refrain from further public debate on scientific questions relating to causation and addiction, and we will do so. At the same time, we have been asked to state our

views on these questions in this and other fora. So that there will be no doubt on our beliefs, we will state them here for all to see:

Causation

We recognize that there is a substantial body of evidence which supports the judgment that cigarette smoking plays a causal role in the development of lung cancer and other diseases in smokers. We previously have acknowledged that the strong statistical association between smoking and certain diseases, such as lung cancer and emphysema, establishes that smoking is a risk factor for and, in fact, may be a cause of those diseases. For example, of all the risk factors for lung cancer that have been identified, none is more strongly associated with the disease, or carries a greater risk, than cigarette smoking; a far greater number of smokers than non-smokers develop lung cancer.

Despite the differences that may exist between our views and those of the public health community, in order to ensure that there will be a single, consistent public health message on this issue, we will refrain from debating the issue other than as necessary to defend ourselves and our opinions in the courts and other fora in which we are required to do so. For that reason, we are also prepared to defer to the judgment of public health authorities as to what health warning messages will best serve the public interest, as reflected in the proposed new health warnings.

"Addiction"

We recognize that nicotine, as found in cigarette smoke, has mild pharmacological effects, and that, under some definitions, cigarette smoking is "addictive." The word "addiction" has been and is currently used differently by different people in different contexts, and the definition of the term has undergone significant changes over the past several decades. In 1964, for example, the Advisory Committee to the Surgeon General of the United States concluded that smoking, although "habit forming," did not fit within its definition of "addiction." However, in 1988, the Surgeon

General redefined the term, and concluded that smoking is "addictive." We have not embraced those definitions of "addiction" which do not include historically accepted and objective criteria, such as intoxication and physical withdrawal, as important markers.

Again, however, while we acknowledge that our views are at odds with those of the public health community, in the final analysis there is little point to a continuing public debate about the definition of a word used both colloquially and technically to describe many different kinds of behavior. And while we continue to believe that people can quit smoking if they resolve to do so, we recognize that it can be difficult to do so. Accordingly, to ensure that there is a single, consistent public health message on the issue of addiction, we will refrain from debating the issue other than as necessary to defend ourselves and our opinions in the courts and other forums in which we are required to do so, and, again, we will also defer to the judgment of the public health authorities as to what health warning messages concerning addiction will best serve the public interest, as reflected in the proposed new health warnings.

Environmental Tobacco Smoke

The warnings relating to environmental tobacco smoke (ETS) in the Proposed Resolution accurately reflect the views of the Environmental Protection Agency, the Surgeon General and certain health authorities. While we believe that the evidence with respect to ETS is not persuasive, nevertheless, we are again prepared to defer to the judgment of public health authorities as to what ETS health warning messages will best serve the public interest, as reflected in the proposed new health warnings.

The Proposed Resolution Would Give the FDA Broad Authority Over All Aspects of Tobacco Manufacturing Without Usurping Congress' Role In Deciding Whether Tobacco Products Stay on the Market.

As detailed above, the Proposed Resolution would adopt for participating companies every restriction on youth access and marketing in the FDA rule. It also would subject the industry to

detailed FDA regulation of how the industry makes and sells its products. Some of these regulatory provisions, however, have been improperly characterized as requiring the FDA to jump through unreasonable “hoops.” Some critics instead call for what they have dubbed a “no limitations” approach to FDA regulation. But what are those supposed “hoops,” and what would a “no limitations” approach mean?

The Proposed Resolution contemplates that the Congress would continue to be the final arbiter of fundamental policy decisions, such as whether tobacco products remain legal, which is why it does not provide the FDA with carte blanche authority to ban tobacco products tomorrow through regulatory fiat. Like any other statute, the Proposed Resolution, if enacted, would include congressionally defined and rational criteria for the FDA to follow should it decide to pursue steps short of an outright ban, such as the reduction or elimination of nicotine, other constituents and ingredients. These criteria recognize the unique issues relating to tobacco.

A “no limitations” approach, by contrast, would give FDA unfettered discretion – using the “safety and efficiency standards” applicable to medical devices -- to regulate tobacco products without resolving the inherent tensions these products present. For example, nothing in existing law would permit FDA to take in consideration an adult’s ability to choose to consume a risky product. Even Dr. Kessler recognized that this is akin to fitting a square peg into a round hole. As he put it when he launched his initiative:

“The blunt instruments we have at F.D.A. to deal with the issue after making a finding [that nicotine is a drug] are not necessarily the best to find a reasonable final policy. (The New York Times, June 29, 1994)

And even Secretary Shalala, who has argued for “affirming FDA’s role in regulating tobacco, as it does other drugs and medical devices” (Press Briefing, Sept. 17, 1997), recently confirmed in her congressional testimony that the FDA would thereby have the power to totally ban the use of tobacco entirely. (Senate Labor Committee hearing, Sept. 25, 1997)

By contrast, those who worked long and hard over the regulatory provisions in the Proposed Resolution -- including some of our most severe critics -- have accepted the fact that the American people do not want to give an unelected FDA Commissioner the authority to ban tobacco products entirely. Even Dr. Kessler once recognized this fact and repeatedly reiterated it in public. Such powers should be reserved for an elected Congress -- and that is what the Proposed Resolution provides.

The Proposed Resolution Would Be a Bitter Economic Pill for the Industry.

I also have heard comments that the Proposed Resolution is not enough of a "bitter pill" for the industry, and that we can afford to pay more than the massive amount it provides. Our company conservatively estimates that the retail price of a pack of cigarettes would increase at least \$1.50 in nominal terms over the next ten years as a result of the Resolution. We also believe that it is possible that volume could decline by as much as 43% in the next decade.

With respect to the pass-through of the payments to consumers through increased prices, the proposal does not specify that the up-front payment or any surcharges imposed under the "look-back" provisions must be passed through. The annual payments, however, would be subject to a mandatory pass-through in furtherance of the policy announcement by the President, the state Attorneys General, the public health community and some Members of Congress that higher retail prices are needed to reduce underage consumption.

CONCLUSION

I believe that our nation is at an important crossroads with respect to the future of public policy on tobacco issues. If my perception is correct that most people in this country believe that adults who wish to smoke should continue to be able to do so legally, then the question is how do we go forward and forge a new era of cooperation and progress. Congressional enactment of the

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Proposed Resolution is intended to answer that question in a comprehensive and sensible way. I urge Congress to enact it as promptly as possible.

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