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001. list	List of meeting attendees (partial) (1 page)	04/07/93	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Carol Rasco (Meetings, Trips, Events)
OA/Box Number: 4591

FOLDER TITLE:
American Heart Association 4-8-93 2:30 p.m.

rw135

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Both kids issues { ① Excise taxes PTA
② Regulations: No Fed. agency regulates manufacturing, sale, etc. of tobacco products

Leg. sponsors { Synar/ (soon)
Binyamin (already)

Withdrawal/Redaction Marker
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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
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American Heart Association

AMERICAN LUNG ASSOCIATION®
The Christmas Seal People®

AMERICAN CANCER SOCIETY®

Coalition on Smoking OR Health

Waived 4/7/93

April 7, 1993

To: Rosalyn Kelly
Office of Carole Rasco

From: Joy Epstein
Coalition on Smoking OR Health

Re: Participants in Meeting on April 8

Revised

The following are the names, birth dates, and Social Security numbers of the people who will be attending the meeting tomorrow, Thursday, April 8 at 2:30 p.m.:

Alan Davis	P6/b(6)	[redacted]
Scott Ballin		[redacted]
Matthew Myers		[redacted]
Joy Epstein		[redacted]
Robyn Henderson		[redacted]

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 FAX: (202) 452-1417

Call set up April 8 or letter. 30 min.

American Heart Association

AMERICAN LUNG ASSOCIATION®
The Christmas Seal People®

AMERICAN CANCER SOCIETY®

Coalition on Smoking OR Health

faxing clearance info.

March 18, 1993

Carol Rasco
Domestic Policy Advisor
The White House
Washington, D.C. 20500

Dear Ms. Rasco:

On behalf of the American Cancer Society, the American Heart Association, and the American Lung Association, united as the Coalition on Smoking OR Health, we are writing to request a meeting with you to discuss two important issues that could have a significant impact on health in this country. Tobacco use is a major public health problem in this country, killing 434,000 Americans annually. No initiative would have a greater effect on disease prevention and health promotion than a reduction in the use of tobacco products.

First, we would like to discuss a major increase in the tobacco excise tax. This is one action which could both reduce tobacco use and provide a significant source of funding for health care initiatives. If the cigarette excise tax were raised by $2 from its current level of $0.24 per pack, approximately $25 to $35 billion in additional revenue would be generated. A $2 tax increase would also result in approximately 7.6 million fewer smokers. A cigarette tax increase of this magnitude would be a major public health advance.

The second issue is the regulation of tobacco products. The Food and Drug Administration should be given the specific authorities it needs to regulate the manufacture, sale, distribution, labeling, advertising, and promotion of tobacco products. The tobacco industry needs to be held to the same standards as other consumer product industries. The public must be properly informed about tobacco products if they are to take responsibility for preventing health problems. The federal government also must take the lead in ensuring that nonsmokers are protected from environmental tobacco smoke.

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 FAX: (202) 452-1417

We would appreciate an opportunity to meet with you to discuss this important way to improve the health of this nation's citizens. Please contact Joy Epstein at the Coalition office, 202-452-1184, to arrange an appointment.

Sincerely,

Alan C. Davis
Chairman
Coalition on Smoking OR Health
Vice President for Public Issues
American Cancer Society

Scott D. Ballin
Vice President for
Public Affairs
American Heart Association

Fran Du Melle
Deputy Managing Director
American Lung Association

202-234-9000
FAX: 202-332-6480

MATTHEW L. MYERS
Coalition on Smoking OR Health

ASBILL, JUNKIN & MYERS, CHTD.
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ROBYN L. HENDERSON
Legislative Representative
Health Care

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Medical Section of the
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American Heart Association

American Heart Association

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Coalition on Smoking OR Health

SAVING LIVES AND RAISING REVENUE:

The Case for Major Increases In State and Federal Tobacco Taxes

March, 1993

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 FAX: (202) 452-1417

SAVING LIVES AND RAISING REVENUE:

The Case for Major Increases in
State and Federal Tobacco Taxes

Table of Contents

"Saving Lives and Raising Revenue: The Case for Major Increases in Federal and State Tobacco Taxes" outlines rationales for major increases in tobacco taxation at the state and federal levels. It is a working document of the American Cancer Society, American Heart Association and American Lung Association, united as the Coalition on Smoking OR Health. It is intended for general use by state and federal policy makers, the media and health groups. This document will be updated as new information becomes available.

For more information on tobacco taxation and other public policy health issues relating to tobacco use, please contact the Coalition on Smoking OR Health.

The Coalition on Smoking OR Health gratefully acknowledges assistance and advice on tobacco excise tax issues by Jeffrey Harris, M.D., Ph.D., Professor of Economics, Massachusetts Institute of Technology; Eugene Lewit, Ph.D., Director, Research and Grants, Packard Foundation Center for the Future of Children; David Sweanor, J.D., Legal Counsel, Non-Smokers' Rights Association of Canada; Kenneth Warner, Ph.D., Professor and Chairman, Department of Public Health Policy and Administration, School of Public Health, University of Michigan; and Jeffrey Wasserman, Ph.D., Program Manager, SysteMetrics, Inc.

EXECUTIVE SUMMARY

Cigarettes kill 435,000 Americans and cost tens of billions of dollars each year. Ever since the release of the landmark report of the Surgeon General nearly 30 years ago, it has been the policy of our nation that smoking should be discouraged and that particular efforts should be made to discourage children from starting to smoke.

As budget difficulties at all levels of government increase, as the need for revenue to fund such vital needs as health care reform becomes essential, and as more and more Americans die from tobacco use, many of our nation's leading public health officials, economists and elected officials have concluded that the time has come for major increases in state and federal cigarette excise taxes. The case for raising these taxes is persuasive on several fronts:

* **As a health measure.** A significant increase on the tax on tobacco products will reduce tobacco use, particularly by reducing the number of children who will start and serving as a catalyst for many adults to quit. For example, it is estimated that a $2 per pack tax increase, maintained in real terms, would reduce the number of people who smoke by over 7.5 million and would prevent roughly **2 million premature tobacco-caused deaths** over time. That is a saving of a greater number of lives than American losses from all wars combined.

* **As a source of needed revenue.** Cigarette taxes provide a unique opportunity for federal and state governments to save millions of lives and simultaneously raise substantial revenue for priorities such as health care reform. New revenue is needed for health care reform. Conservatively, a $2.00 a pack increase would raise over $20 billion dollars in the first year and close to $100 billion over 5 years.

* **As one of few taxes most Americans support.** While proposals to increase most taxes meet fierce popular resistance, polling data shows that 70 - 80 percent or more of the public supports higher cigarette taxes to help pay for deficit reduction or health care reform.

This document discusses in greater detail how raising tobacco taxes substantially can play a critical role in reducing the death, disease and economic hardships caused by tobacco use. It concludes with the following policy recommendations:

* State and federal governments should enact major increases in cigarette excise taxes.

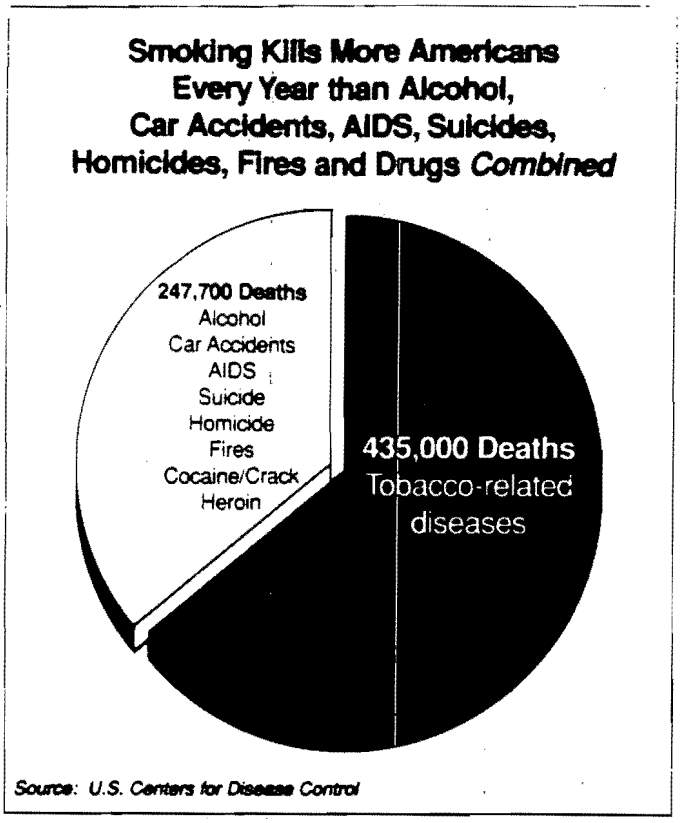
* Federal and state cigarette taxes should be indexed to keep pace with rising product prices.

* All other tobacco products should be taxed in proportion to the rate imposed on cigarettes.

CIGARETTES: AMERICA'S LEADING PREVENTABLE CAUSE OF DEATH

Nearly thirty years after the 1964 Surgeon General's Report sounded the health alarm on smoking, one-fourth of the nation's adult population remains addicted to cigarettes, and smoking remains the leading preventable cause of premature death and crippling disease in the United States. In all, smoking now kills an estimated 435,000 Americans each year -- more than alcohol, heroin, crack, automobile and airplane accidents, homicides, suicides and AIDS combined.

Figure 1



The cigarette is the only legal product that:

* kills more than one out of three long-term users and disables many more, when used as intended

* has been determined to be a major cause of heart disease, lung cancer, mouth and throat cancer, emphysema, chronic bronchitis, chronic obstructive pulmonary disease, low birthweight babies, strokes and a variety of other diseases[1]

* is as addictive as cocaine or heroin

[1] U.S. Department of Health and Human Services. Reducing the Health Consequences of Smoking: 25 Years of Progress. A Report of the Surgeon General. DHHS Publication No. (CDC) 89-8411, 1989.

Environmental tobacco smoke (ETS) -- smoke from other people's cigarettes -- has been identified as the nation's third leading cause of preventable death, causing approximately 35,000 to 40,000 deaths per year from cardiovascular disease among nonsmokers and 3000 lung cancer deaths.[2] A panel of experts appointed by the Environmental Protection Agency has recommended that ETS be labeled a "Group A Carcinogen," a category reserved for only the most serious human carcinogens such as benzene and asbestos.[3]

More than one million teenagers begin smoking each year, a rate of approximately 3000 per day. Ninety percent of young smokers report that they became regular smokers before age 18.[4] Thus reducing smoking by children and teenagers is accepted as a key to reducing the enormous burden of addiction, death and disease smoking imposes on the health and economy of the United States.

Despite public health programs aimed at reducing teenage smoking, and despite the fact that it is illegal (with rare exceptions) to sell cigarettes to children, the smoking initiation rate among children and teenagers remains alarmingly high, and the age of initiation of new smokers has fallen steadily for several decades.[5] This is no accident. It is partly the result of marketing strategies typified by R.J. Reynolds' "Joe Camel" advertising campaign aimed at children and teenagers. Cigarette companies lavish nearly $4 billion on youth-oriented advertising and gimmicks designed to promote and reinforce the image of smoking as youthful, sophisticated and sexy, and to associate smoking with freedom and good health.

In addition to strengthening and enforcing laws to limit youth access to tobacco, the search for an effective strategy to discourage teenage smoking leads to one point upon which health experts and the cigarette industry agree: **major increases in cigarette taxes will dramatically reduce smoking.**

---

[2] Council on Cardiopulmonary and Critical Care, American Heart Association, "Environmental Tobacco Smoke and Cardiovascular Disease," Circulation, August 1992, and U.S. Environmental Protection Agency, Respiratory Health Effects of Passive Smoking, Review Draft, May, 1992.

[3] U.S. Environmental Protection Agency, Respiratory Health Effects of Passive Smoking, Review Draft, May, 1992.

[4] Pierce, Naquin, Gilpin, Giovino, Mills and Marcus, "Smoking Initiation in the United States: A Role for Worksite and College Smoking Bans," Journal of the National Cancer Institute, vol. 83, pp. 1009- 1013 (1991).

[5] CDC, "Differences in Age of Smoking Initiation Between Blacks and Whites, United States," MMWR, Vol. 40, pp. 754-757, November 8, 1991.

HIGHER CIGARETTE TAXES WILL SIGNIFICANTLY REDUCE TOBACCO USE

A fundamental economic concept holds that the demand for a product goes down as its price goes up. This relationship between demand and price is true for cigarettes as well as other products. As a result of numerous studies over the past decade, economists have reached a general consensus on the following points:

* The price elasticity of demand[6] for cigarettes is in the range of -0.3 to -0.5. That means that a 10 percent increase in the price of cigarettes is expected to cause a 3 to 5 percent decline in cigarette consumption. Most economists accept -0.4 as a reasonable mid-range price elasticity of demand estimate for cigarettes.

* Teenagers are **at least** as responsive to changes in price as adults. There is some evidence that teenagers are significantly more responsive to price changes than adults.[7]

* The price elasticity of demand for large price increases is expected to be **at least** as large as for small increases.[8]

* The major response to price increases will be a decrease in the number of people who smoke rather than a decrease in the number of cigarettes smoked by each smoker. This is significant because it means that the primary effect of price increases is to discourage teenagers from starting and encourage current smokers to quit.[9]

Figure 2 illustrates the significant reductions in cigarette consumption that would result from major tax increases. (See page 6)

---

[6] According to the 1992 Surgeon General's report, "Price elasticity of demand measures the degree of responsiveness of demand to changes in price; it is the percent change in the quantity of a good demanded, divided by the percent change in price that caused the demand change." Smoking and Health in the Americas, U.S. Department of Health and Human Services, DHHS Pub. No. (CDC) 92-8419, p. 129.

[7] One study has estimated that the price elasticity of demand for cigarettes among teenagers is in the range of -1.44, more than three times the elasticity figure for adults. Lewit, Coate and Grossman, "The Effects of Government Regulation on Teenage Smoking," Journal of Law and Economics, vol. 24, pp. 545-569, December, 1981.

[8] Consensus statement adopted by the "Tobacco Tax Working Group" convened by the National Cancer Institute, November 11, 1992.

[9] Smoking and Health in the Americas, U.S. Department of Health and Human Services, DHHS Pub. No. (CDC) 92-8419, p. 129-131.

Projected 1993 Consumption of Cigarettes At Alternative Tax Levels

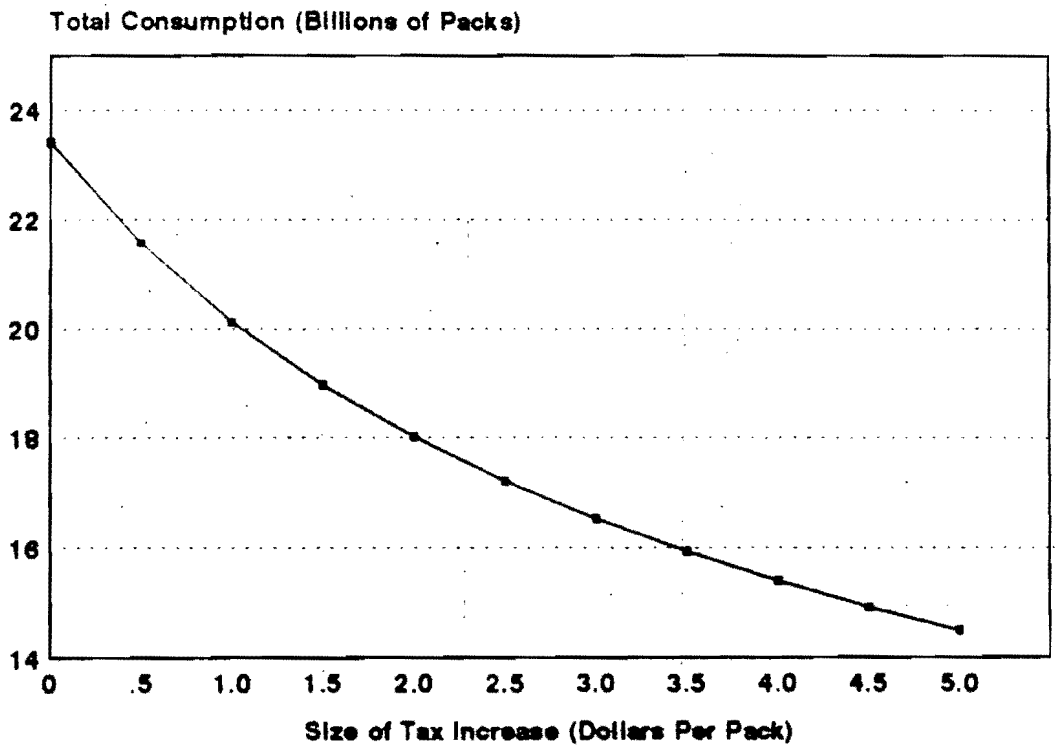


Figure 2

NOTE:
Figure 2 projects total 1993 U.S. cigarette consumption based on the following assumptions: (1) estimated price elasticity of demand for cigarettes of -0.4; (2) estimated average 1993 price per pack of $2.16 in the absence of major tax increases, based on historical trends; (3) estimated 1993 cigarette consumption of 23.418 billion packs in the absence of major tax increases, based on historical trends. For purposes of this illustration, no assumptions were made regarding pricing decisions by manufacturers,wholesalers and retailers in response to tax increases; such decisions could have a significant effect on price and consumption.

BY DISCOURAGING PEOPLE FROM USING TOBACCO, HIGHER CIGARETTE TAXES WILL SAVE MILLIONS OF LIVES

Cigarette taxes have an enormous potential to rapidly and significantly reduce tobacco use by discouraging young people from beginning to smoke and encouraging some current smokers to quit. By reducing the number of people who smoke, over time major cigarette tax increases will save millions of lives. A proposal to raise cigarette taxes is therefore, first and foremost, a public health measure.

The table below provides estimates of the number of people who would not start or would quit using tobacco as a direct result of cigarette tax increases.

BENEFITS OF CIGARETTE TAX INCREASES[10]

Amount of Tax Increase	Number Fewer Tobacco Users
$ .50	2.5 million
$1.00	4.5 million
$2.00	7.6 million
$3.00	9.8 million
$4.00	11.5 million
$5.00	12.8 million

The number of premature deaths that would be averted by major tax increases cannot be predicted with precision, but may be estimated. For example, if one out of four of those discouraged from smoking avoids dying prematurely as a result, then:

* A $1 per pack tax increase, maintained in real terms, would save about **1.1 million lives** over time -- preventing more deaths than have been caused by illicit drugs throughout U.S. history.

* A $2 per pack tax increase, maintained in real terms, would save about **1.9 million lives** over time -- preventing more American deaths than have been caused by all wars in which the U.S. has participated combined.

---

[10] All estimates are based on hypothetical tax increases taking effect in 1993, and are based on the following assumptions: (1) Tax increases are maintained in real terms over time; (2) A price elasticity estimate for smoking participation of -0.26; that is, a 10 percent increase in price is expected to result in approximately a 2.6 percent decrease in the total number of smokers in the population. This estimate is supported by research by Lewit and Coate (1982), as cited in Smoking and Health in the Americas, U.S. Department of Health and Human Services, Office on Smoking and Health, DHHS Publication No. (CDC) 92-8419, p. 131; (3) Projected average price per pack of cigarettes in 1993 of $2.16 in the absence of major tax increases, based on historical trends; (4) A 1993 smoking population of 46 million.

REVENUE POTENTIAL OF HIGHER CIGARETTE TAXES

A major cigarette tax increase will raise tens of billions of dollars to address state and national priorities, such as health care reform.

Federal, state and local governments collected about $11 billion in cigarette excise taxes in 1991.[11] That is a fraction of the revenue that could be generated if cigarette taxes were raised substantially for health reasons.

New revenue generated from substantially increasing cigarette taxes may be used to help meet pressing needs at the state and federal levels, including:

* **Health care reform**
* **Minority and urban health care**
* **Deficit reduction**
* **Health promotion, education and research**
* **Tobacco control**

How much would a substantial tax increase raise?

The Congressional Joint Committee on Taxation conservatively estimates that an increase of one dollar will generate a net gain of revenue of $14.8 billion in the first calendar year (1994), $13.1 billion in 1995, $13.0 billion in 1996, $12.9 billion in 1997 and $12.8 billion in 1998 for a 5 year total of $66.5 billion.

The most conservative estimates of the Joint Committee show that an increase of $2 a pack will generate approximately $90 billion over five years. Other noted economists estimate that a $2 a pack increase is likely to generate more than $100 billion in new revenue over 5 years.

Figure 3 shows the amount of revenue independent experts have predicted would be generated. These estimates are based upon the most recent available price information and the best available analysis of the price elasticity of demand for tobacco products. The estimates are higher than those suggested by the Joint Committee on Taxation. For example, Figure 3 estimates that a $2 increase per pack would generate between $30 and $35 billion of new tobacco tax revenue in the first year.

[11] The Tax Burden on Tobacco, The Tobacco Institute, Washington, DC, 1991, vol. 26.

Projected 1993 Cigarette Tax Revenue At Alternative Tax Levels

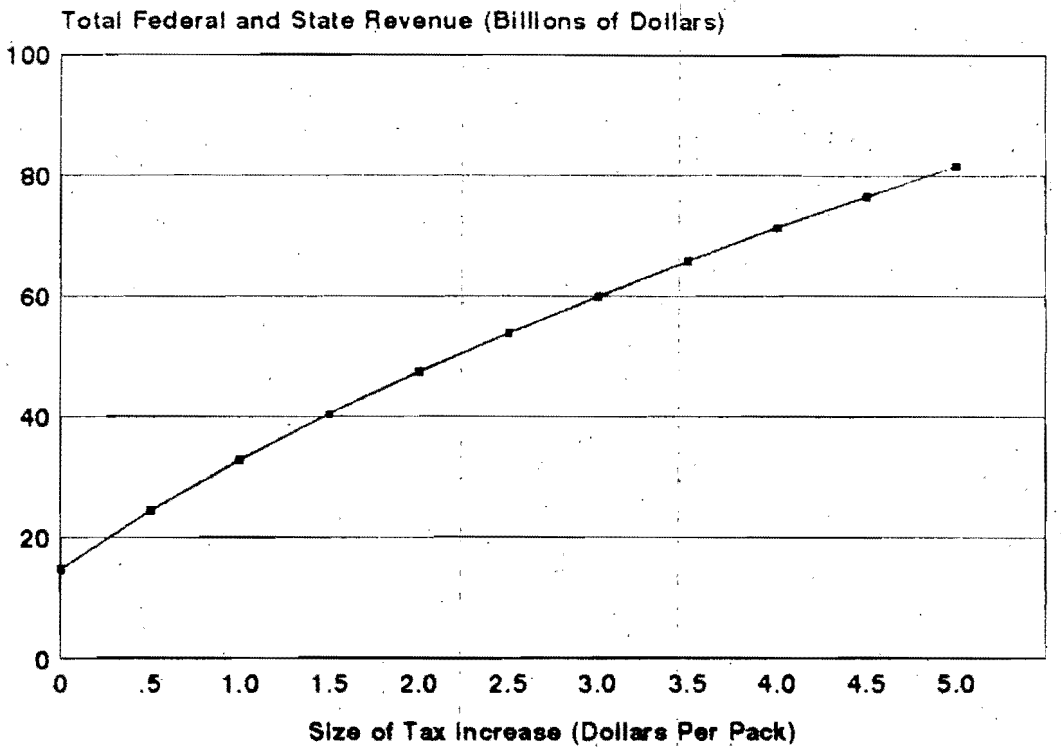


Figure 3

NOTE:
Figure 3 projects combined federal and state revenue in 1993 dollars based on the following assumptions: (1) estimated price elasticity of demand for cigarettes of -0.4; (2) estimated average 1993 price per pack of $2.16 in the absence of major tax increases, based on historical trends; (3) estimated 1993 cigarette consumption of 23.418 billion packs in the absence of major tax increases, based on historical trends. For purposes of this illustration, no assumptions were made regarding pricing decisions by manufacturers, wholesalers and retailers in response to tax increases; such decisions could have a significant effect on price and consumption.

HIGHER TOBACCO TAXES BENEFIT FEDERAL AND STATE GOVERNMENTS

Federal and state governments would gain significant new revenue if tobacco taxes were raised dramatically.

Because today's rates are relatively low, higher tax rates would result in declining smoking rates while still allowing large increases in revenue. State governments may be net winners even if only the federal government increases cigarette taxes significantly, assuming that the states are able to negotiate an equitable revenue sharing formula that returns a portion of federal cigarette tax revenue to the states. Nevertheless, tobacco tax increases at all levels of government would provide the greatest health and economic benefits.

Concerns that higher cigarette taxes will soon lead to declining revenue due to lower smoking rates are not warranted. Higher cigarette taxes will result in higher government revenue even at the highest estimates of the price elasticity of demand for cigarettes. This fact has been proven repeatedly by no greater authority than the tobacco industry itself. It has consistently increased prices by 10-12 percent per year, thereby increasing the cost of cigarettes. As a result, cigarette company profits continue to skyrocket despite reduced consumption.

To ensure that tobacco taxes do not decline in real terms, tobacco taxes must be indexed (i.e. automatically adjusted) to keep pace with rapid increases in the price of cigarettes imposed by the tobacco industry. This is a critical point currently overlooked by state and federal governments alike.

PAYING FOR THE DAMAGE CAUSED BY SMOKING

Tobacco taxes do not pay for the yearly cost of tobacco to the American public. Total tobacco tax revenues (including all federal, state, and local taxes), which total only about $11 billion per year, represent a fraction of the costs tobacco imposes.

Cigarette taxes may be viewed as compensation for the burden of death, disease, health care costs, fires, and lost productivity that smoking imposes on society.

The costs associated with smoking are enormous by any measure. They include:

* An estimated $501 billion in excess lifetime health care costs for current and former smokers. That number grows by approximately $9-10 billion annually due to the additional excess lifetime health care costs of the one million teenagers who take up smoking each year.[12]

* An estimated $65 billion in health care costs and lost productivity in 1985, or $2.17 per pack of cigarettes sold that year.[13] Of that sum, over $23 billion is in health care costs alone.

By focusing on quantifiable costs, these estimates exclude intangible costs such as the pain and suffering of people with tobacco-caused diseases, and of their families and friends. These costs may be as great or greater than the already enormous health care costs. Moreover, this approach assigns no value to the millions of lives higher cigarette taxes would save in the future by discouraging teenagers from beginning to smoke. These factors also should be considered in establishing an adequate cigarette tax.

---

[12] Hodgson, Thomas A., "Cigarette Smoking and Lifetime Medical Expenditures," The Milbank Quarterly, Vol. 70, No. 1, 1992, pp. 81-125. Hodgson's estimates project lifetime health care costs for smokers 25 and older in 1985, based on current smoking trends. Estimates are expressed in 1990 dollars with future costs discounted at 3 percent.

[13] Office of Technology Assessment, U.S. Congress, "Smoking-Related Deaths and Financial Costs," September 1985 (Staff Memorandum).

CIGARETTE TAXES ARE FAIR

Despite overwhelming evidence of the health and economic benefits of higher cigarette taxes, the cigarette industry argues that such taxes are unfair to poor people, the elderly and tobacco farmers. None of these charges withstands scrutiny.

Low income Americans. Proponents of an increase in the tobacco tax are very concerned about both the health and economic well being of low income Americans. Low income Americans are least able to afford the costs of tobacco related disease, are the least likely to have access to health care, and rarely have access to the best smoking cessation services. Nonetheless, for years the tobacco industry has targeted low income Americans, particularly the children of low income Americans, with their advertising and promotional campaigns.

Research shows that a substantial increase in the price of tobacco as the result of an increase in the excise tax will cause many low income children not to start, or to quit before they become addicted.[14] It will also lead many low income smokers to quit altogether. For those who do not start or who quit, there will be an immediate economic gain and a long term health benefit. For those who continue to smoke, the revenue generated by the tax will help to pay for their increased health care needs and possibly to expand health care coverage to many low income Americans not currently covered.

The elderly. Only 11.5 percent of women and 14.6 percent of men over the age of 65 smoke. [15] These are the lowest rates of all age groups. Therefore the elderly will be least affected -- positively or negatively -- by major cigarette tax increases.

Tobacco farmers. The interests of tobacco farmers and the major tobacco manufacturers are not necessarily the same. The tobacco industry argues that higher taxes harm tobacco farmers. The truth is that tobacco farmers now earn only 3 cents of every dollar in cigarette sales, while 73 cents goes to manufacturers, wholesalers and retailers.[16] While the profits of the manufacturers have risen over the last decade as the result of price increases, the price manufacturers pay to farmers has not kept pace. In the case of a $2 per pack increase in the federal cigarette excise tax, tobacco farmers would lose only about $1 due to decreased smoking for every $100 in new revenue raised by higher tobacco taxes. To put it another way, the government would have to forego $100 dollars in revenue for every $1 it "saves" for the tobacco farmer -- an absurdly inefficient subsidy program by any standard.

Tobacco farmers have been hurt more by the decision of the manufacturers to use more imported tobacco than by consumption decreases. More than 36 percent of all tobacco in U.S.-made cigarettes

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[14] Townsend, Joy L., "Cigarette Tax, Economic Welfare and Social Class Patterns of Smoking," Applied Economics, 1987, 19. 355-365.

[15] CDC, "Cigarette Smoking Among Adults, United States, 1990," MMWR, vol 41, pp. 354-362, May 22, 1992.

[16] USDA, "The Cigarette User's Dollar, "Tobacco Situation and Outlook Report, June, 1992.

was imported in 1991, compared to 13 percent in 1969.[17]

The number of farms growing tobacco is already declining on its own. Over the last 28 years close to 200,000 farms have stopped growing tobacco. If a portion of any excise tax increase is allocated to assist farmers who voluntarily wish to stop growing tobacco to make the transition to other crops, the tax could benefit rather than harm those farmers.

For these reasons, the answer to challenges facing U.S. tobacco farmers is **not** to encourage Americans to smoke by keeping taxes low or to promote smoking abroad. A better solution would be to use a small portion of cigarette tax revenues to pay for programs to assist tobacco farmers in substituting alternative crops or finding other employment. Such programs have been used successfully in Canada and New Zealand.

[17] United States Department of Agriculture, Tobacco Situation and Outlook Report, September, 1992, p. 37.

REVERSING THE DECLINE IN U.S. CIGARETTE TAX RATES

It is a bitter irony that, alone among developed countries, the U.S. has allowed cigarette taxes to fall significantly in real terms since the dangers of smoking were first revealed in the 1950s.

The decline in cigarette taxes is even more dramatic when expressed as a percentage of the price of a pack of cigarettes. (See Figure 4.)

In order to restore overall (state and federal) taxes to their 1965 level of 50 percent of pack price, current taxes would, at a minimum, need to be tripled from the 1992 average (federal and state) of approximately 50 cents to about $1.50.

Of course the goal should not be to restore taxes to their level before the health risks of smoking were known, but to raise them substantially for health and economic reasons.

The reason tobacco taxes expressed as a percentage of pack price have fallen so dramatically is that the cigarette industry has raised wholesale prices at three times the rate of inflation in recent years, or about 12 percent per year. (See Figure 5.)

The combination of low tobacco taxes and sharp price increases has resulted in huge profits for the tobacco industry. Philip Morris, for example, enjoyed profits on its domestic cigarette sales of more than 40 percent in 1991.[18] That is more than **eight times** the average profit on other nondurable manufactured products in 1991.[19]

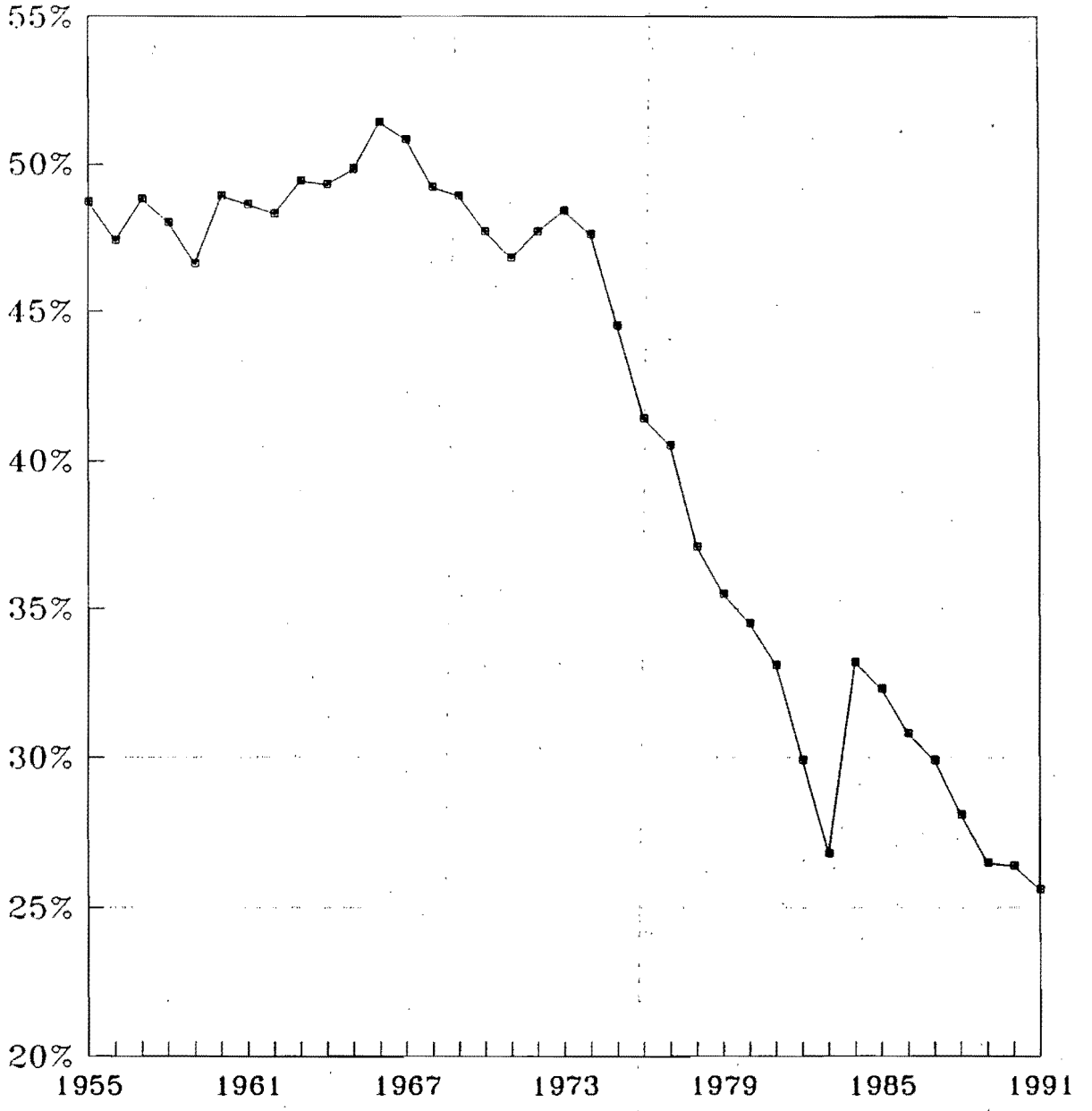
[18] Operating profits divided by operating revenue, Philip Morris Companies Inc. Annual Report, 1991.

[19] Quarterly reports of average profits by nondurable manufacturers ranged from 3 percent to 5 percent in 1991, according to data provided by the Bureau of Labor Statistics, U.S. Department of Labor.

Figure 4

TOBACCO TAXATION IN THE UNITED STATES

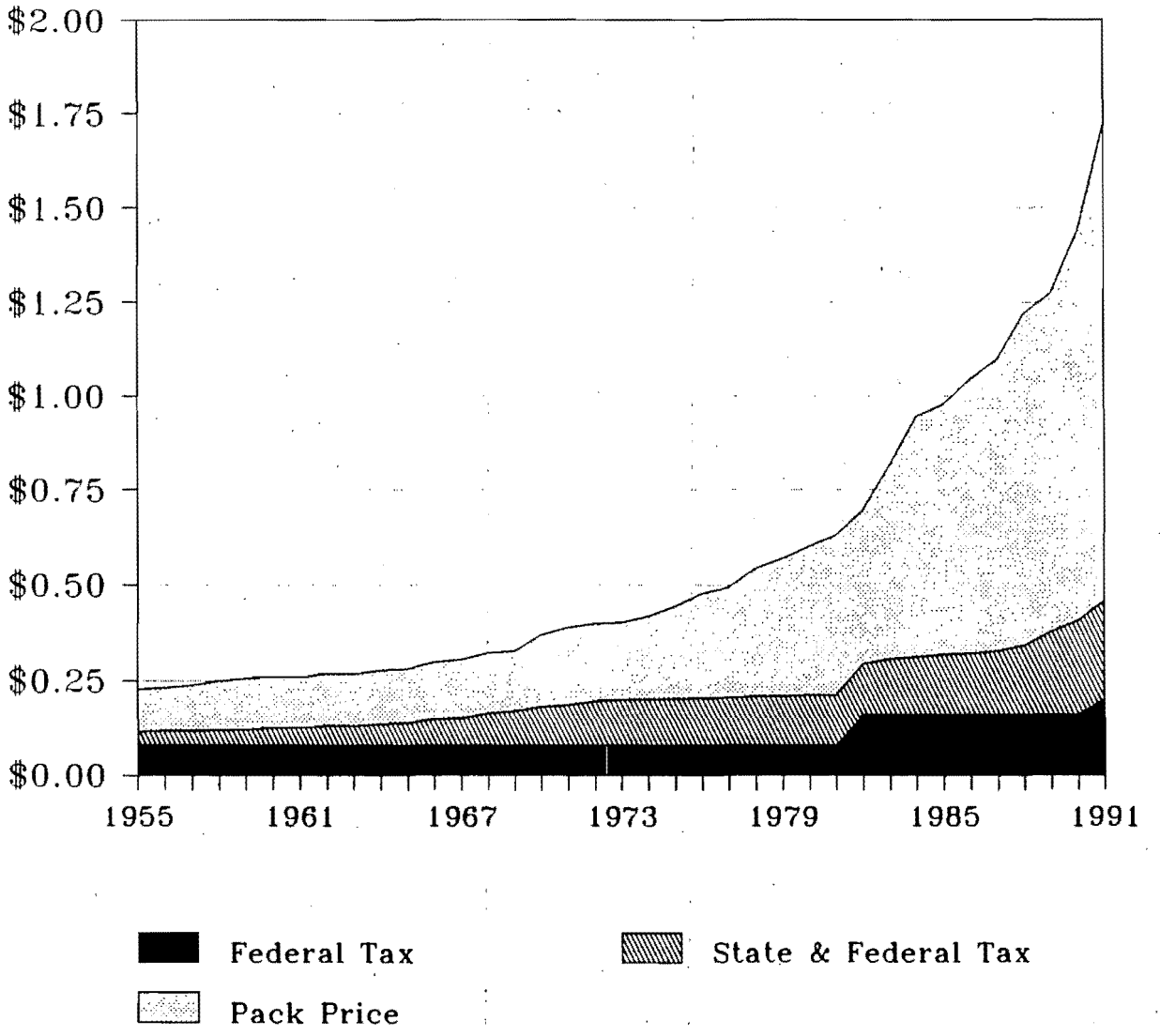
AVERAGE CIGARETTE TAX AS A PERCENTAGE OF RETAIL PRICE



Source: The Tax Burden on Tobacco,
The Tobacco Institute,
Volume 26, 1991, p. 230

Figure 5

U.S. Tobacco Taxes Versus Pack Price 1955–1991



Source: The Tax Burden on Tobacco,
The Tobacco Institute
Volume 26, 1991, p. 230

THE PUBLIC SUPPORTS HIGHER CIGARETTE TAXES

Surveys conducted over the past several years consistently show that higher cigarette taxes are an acceptable method of raising revenue and reducing deficits.

* A March, 1993 USA Today, CNN, Gallup poll found that 83% of the public favors increasing cigarette and other tobacco taxes to help pay for health care reform.[20]

* A March, 1993 Wall Street Journal, NBC news poll found that 70% of those polled favored a $2 increase in the tobacco tax to help pay for health care reform.[21]

* A December, 1992 national poll by Louis Harris and Associates found that 76 percent of voters support higher cigarette and liquor taxes to pay for health care reform.[22]

* An April, 1992 national poll conducted by Peter Hart & Associates showed 76 percent of the public believes that raising cigarette and liquor taxes would be a good (46 percent) or acceptable (30 percent) way to fund a national health insurance plan.[23]

* A 1989 national poll found that 76 percent of the public either favors or strongly favors an increase of the cigarette excise tax as a means of reducing the federal budget deficit.[24]

* A September, 1992 Michigan poll found that more than twice as many voters would vote for a candidate for the state legislature who supported a 25-cent increase in the state's tobacco tax (58 percent) than would vote for a candidate who opposed the tax increase (27 percent).[25]

* A 1992 poll in Massachusetts found 70 percent of the state's public favored a 25-cent increase in the state's cigarette excise tax. Support remained strong (68 percent) even after respondents were told that the increase would give Massachusetts the highest cigarette tax in the nation.[26]

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[20] "Clinton Winning Nation Over," USA Today, March 1, 1993.

[21] "Trade - Offs," Wall Street Journal, March 12, 1993.

[22] Henry J. Kaiser Family Foundation, Harvard University, Louis Harris and Associates, cited in Robert J. Blendon, et. al., "The Implications of the 1992 Presidential Election for Health Care Reform," Journal of the American Medical Association, Vol. 268, pp. 3371-3375.

[23] "Financing National Health Care: A Nationwide Survey of Voters' Opinions," The Mildred and Claude Pepper Foundation, May 15, 1992, p. 29.

[24] "The People, the Press and Politics: Public Opinion About Economic Issues," A Times-Mirror Survey, March, 1989.

[25] "Cigarette Taxes and 1992 State Elections," American Lung Association - Michigan, September 1992.

[26] "A Study of Attitudes Among Voters in Massachusetts," May 20, 1992.

This strong support for higher cigarette taxes has proven resilient in the face of aggressive tobacco industry media campaigns. Californians approved higher cigarette taxes by a 16 point margin in a 1988 referendum, despite a tobacco industry media blitz that outspent health groups by more than 13 to 1. More recently, Massachusetts voters approved a 25-cent increase by a 10 point margin despite an even higher rate of industry spending. In contrast, other revenue-raising options face formidable public opinion barriers. The 1992 Peter Hart & Associates survey showed that cigarette and liquor taxes are more than twice as acceptable to Americans as higher payroll, gasoline, estate or across-the-board income taxes.

PUTTING HIGHER CIGARETTE TAXES TO WORK: EXAMPLES FROM THE U.S. AND ABROAD

The health and economic benefits of higher cigarette taxes are not merely theoretical. They already have been achieved in some developed countries and, to a lesser extent, in some U.S. states. The states and nations that have successfully raised cigarette taxes provide useful models for the United States and proof that higher cigarette taxes work.

California

In 1988, California voters approved Proposition 99, which raised state cigarette taxes from 10 to 35 cents, the second-highest rate in the nation at that time. Health and economic benefits have been substantial:

* Cigarette smoking dropped 17 percent between 1989 and 1991, about twice the U.S. average.[27]

* Regression analysis shows that a 5 and 7 percent decline in consumption during the first year of the tax is due to the tax increase alone. [28]

* Revenue raised by the tobacco tax has been used to fund medical care for the indigent, tobacco control programs and research, parks and wildlife programs and firefighting services.

Canada

Canada provides the clearest example. Combined federal and provincial cigarette taxes there were raised from an average of 46 cents in 1980 to $3.27 in 1991. The sharpest increases came in the late 1980s, as government explicitly adopted a pro-health approach to tobacco taxation. Canada's policy has paid off handsomely:

* Teen smoking has been reduced by approximately two-thirds since 1980, according to the Non-Smokers' Rights Association. This decline in smoking is expected to save hundreds of thousands of lives over time.

* Total cigarette consumption is falling faster than in any major industrialized nation; The rate of decline is more than twice that of the United States. (See Figure 6.)

* Cigarette tax revenue has grown from about $1 billion in 1981 to more than $7 billion in 1991.

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[27] Burns, D. Pierce, J.P., Tobacco Use in California 1980-1991, California Department of Health Services, 1992, p. 31.

[28] Flewelling et al., "First Year Impact of the 1989 California Cigarette Tax Increase on Cigarette Consumption," American Journal of Public Health, June 1992, Vol. 82, No. 6, p. 867-869.

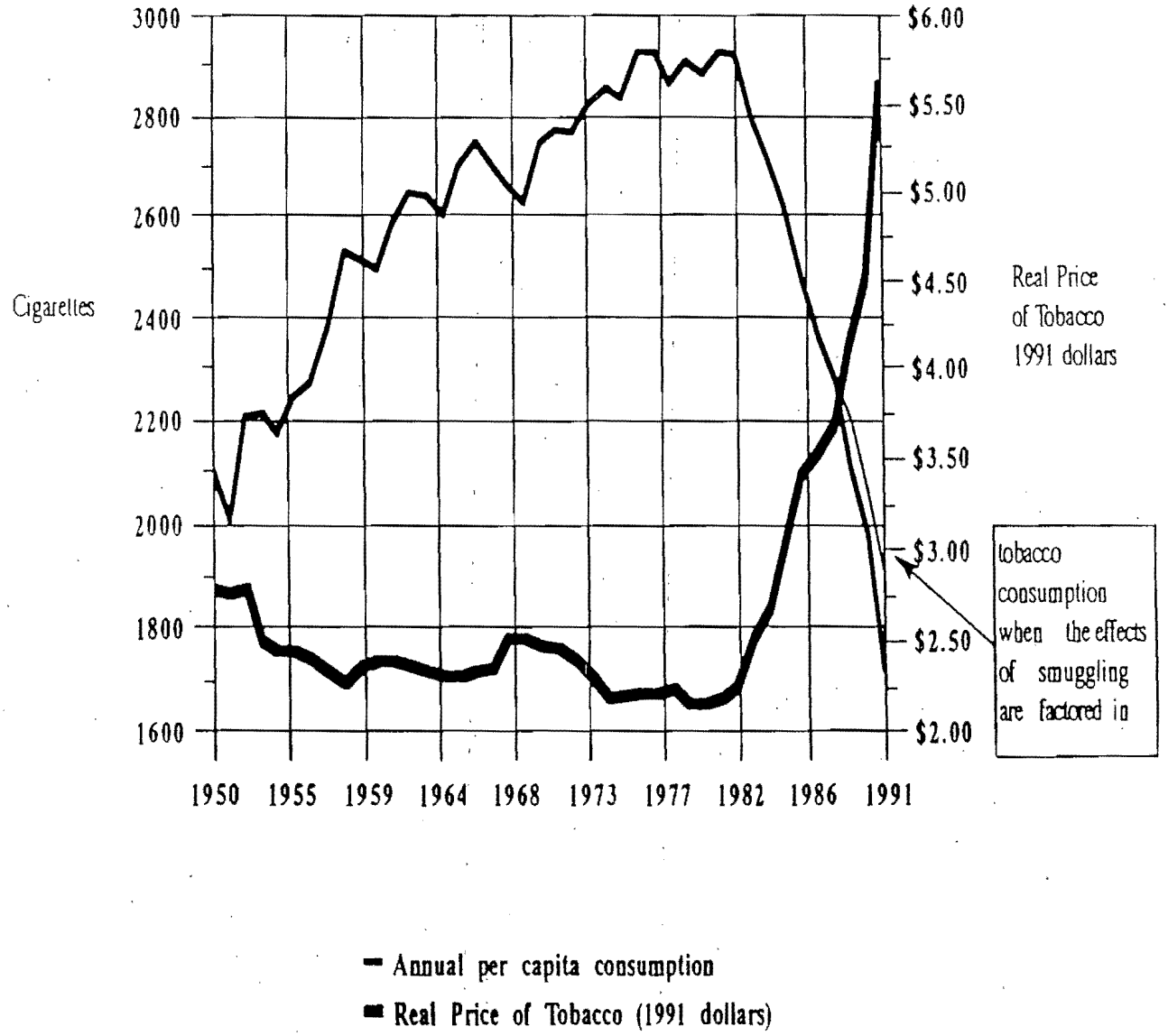
While other factors, such as Canada's ban on cigarette advertising, also contributed to Canada's success, experts agree that the tax increases have been the most important component of Canada's comprehensive tobacco control program.

Other Countries

Other countries, including Australia, New Zealand, the United Kingdom, Ireland and Hong Kong also have raised cigarette taxes substantially on health grounds. In contrast, the steady decline in U.S. cigarette taxes (in real terms) has left the United States with the lowest cigarette tax of the major industrialized nations. (See figure 7.)

Figure 6

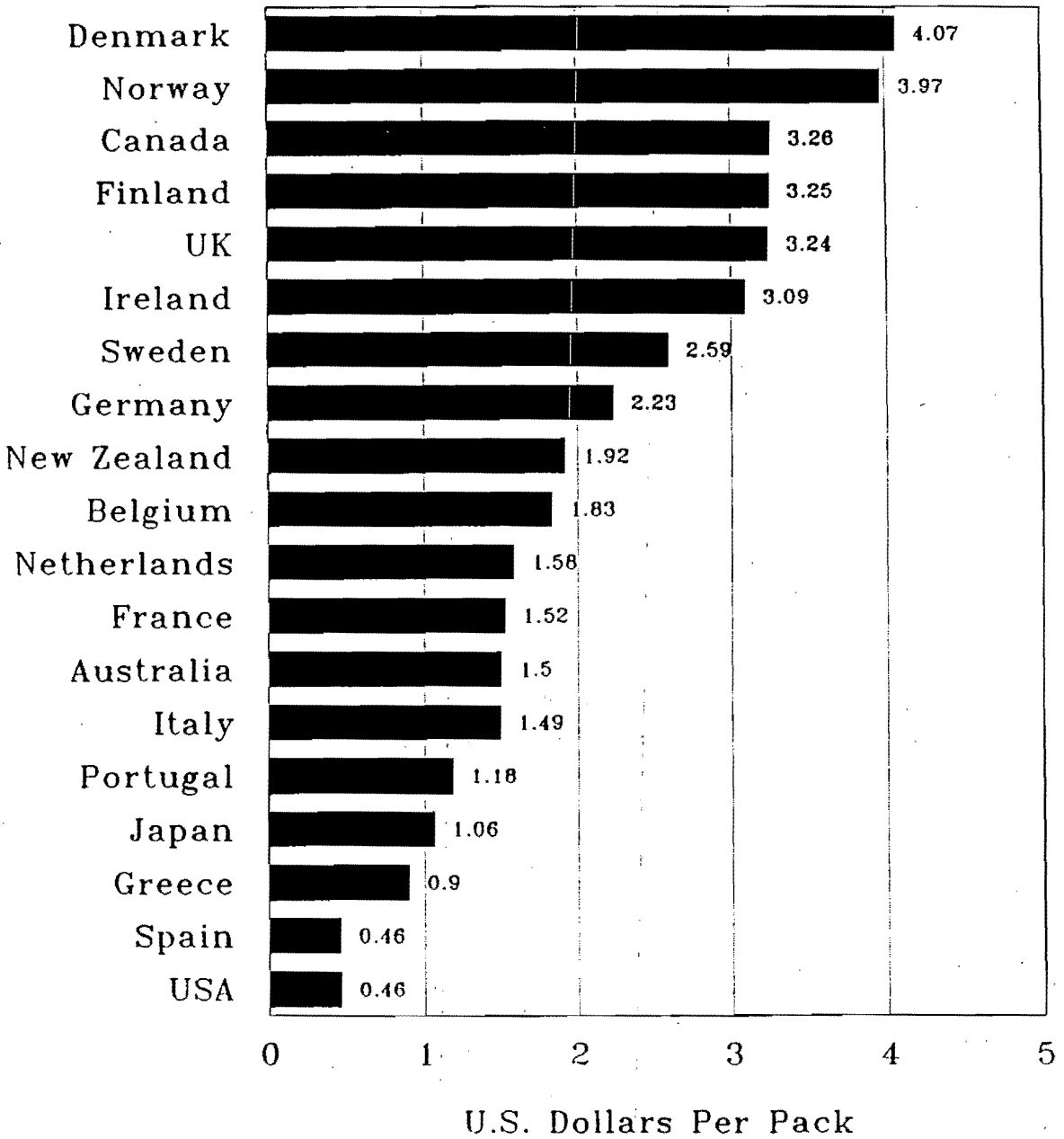
ANNUAL PER CAPITA CONSUMPTION OF CIGARETTES
AND REAL PRICE OF TOBACCO (per 20 cigarettes)
CANADA 1950 - 1991



Note: Cigarettes include fine-cut equivalents. Chart provided courtesy of the Non-Smokers' Rights Association, Ottawa, Canada.

Figure 7

Cigarette Taxes in Developed Nations
Data from 1991 & 1992



Notes:

1. Foreign taxes expressed in U.S. dollars are approximate due to currency fluctuations.
2. Data provided by the Non-Smokers' Rights Association of Canada; analysis by Public Citizens' Health Research Group; chart produced by the Coalition on Smoking OR Health.

POLICY RECOMMENDATIONS

On the basis of the information set forth in this document, the American Cancer Society, American Heart Association and American Lung Association, united as the Coalition on Smoking OR Health, have adopted the following policy positions with respect to the taxation of tobacco products:

1. The time has come for the United States to enact major increases in state and federal cigarette taxes in order to reduce teen smoking, save lives, and offset the costs of smoking by raising significant new revenue.

2. Federal and state cigarette taxes should be indexed to the average wholesale or retail price of cigarettes, or to a comparable measure that will ensure that cigarette taxes will, at a minimum, keep pace with rising prices.

3. All other tobacco products, including snuff, chewing tobacco, rolling tobacco, pipe tobacco and cigars, should be taxed in proportion to the rate imposed on cigarettes.

American Heart Association

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SAVING LIVES AND RAISING REVENUE: THE CASE FOR HIGHER TOBACCO TAXES

Tobacco Facts:

- Cigarettes kill more than 434,000 Americans each year--more than alcohol, heroin, crack, automobile and airplane accidents, murders, suicides and AIDS combined.

- Cigarettes cost the American public more than $65 billion each year in tobacco-related health care costs and lost productivity.

Tobacco Taxes Save Lives and Reduce Tobacco Use:

- A substantial increase in the tax on tobacco products is one of the most effective methods for significantly reducing tobacco use among children and adults.

- For every 10 percent increase in the price of tobacco products, there will be approximately a four percent decrease in tobacco consumption, and possibly an even greater decrease in tobacco use among children.

- A tax increase of approximately $2.00 per pack is likely to reduce tobacco use by about 23 percent and encourage more than 7 million Americans not to smoke, preventing about 2 million premature deaths over time.

Tobacco Taxes Are a Source of Substantial Revenue:

- Federal, state and local governments currently collect about $11 billion dollars in cigarette taxes. Of that sum approximately $4.75 billion is collected by the federal government and approximately $6.0 billion is collected by state and local governments.

- A federal tax increase of $2.00 per pack will generate an additional $25 billion-$35 billion dollars in tobacco tax revenues. An increase of just $1.00 per pack would generate an additional $10 billion-$20 billion in federal tobacco tax revenues.

-Over-

A Tobacco Tax Increase is Needed and is Fair:

- In constant dollars, the federal tax on cigarettes is about one-half what it was in 1955.

- Taxes on tobacco are substantially lower in the United States than in virtually all other industrialized western nations.

- Over the past decade there has been no significant decrease in teen smoking rates in the United States. Higher tobacco taxes in California have led to a drop in cigarette smoking equal to three times the national average. Higher taxes have led to a reduction in teen smoking in Canada of almost two-thirds since 1980.

The Public Supports Higher Tobacco Taxes:

- In November 1992, after the election, Louis Harris & Associates found 76% of voters would support higher liquor and cigarette taxes for a national health insurance program. Other funding sources had much lower levels of support.

- In April, 1992 national poll conducted by Peter Hart & Associates showed 76 percent of the public believes that raising cigarette and liquor taxes would be a good (46 percent) or acceptable (30 percent) way to fund a national health insurance plan.

- A 1989 national poll found that 76 percent of the public either favors or strongly favors an increase of the cigarette excise tax as a means of reducing the federal budget deficit.

- A September, 1992 Michigan poll found that more than twice as many voters would vote for a candidate for the state legislature who supported a 25-cent increase in the state's tobacco tax (58 percent) than would vote for a candidate who opposed the tax increase (27 percent).

American Heart Association

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Organizations Supporting $2 Tobacco Excise Tax Increase

Coalition on Smoking OR Health
- American Cancer Society
- American Heart Association
- American Lung Association

Action on Smoking and Health

American Academy of Family Physicians

American Academy of Otolaryngology

American Academy of Pediatrics

American Association for Respiratory Care

American College of Cardiology

American College of Surgeons

American Medical Association

American Medical Women's Association

American Psychological Association

American Public Health Association

American Society of Clinical Oncology

American Society of Internal Medicine

Americans for Non-Smoker's Rights

Association of State and Territorial Health Officials

Center for Science in the Public Interest

Interreligious Coalition on Smoking OR Health

National Cancer Advisory Board

National PTA

National Coalition of Hispanic Health and Human Services Organization (COSSMHO)

New York Coalition for a Smoke-Free City

Sierra Club

Washington Institute

NUMBER 3310 BusinessWeek MARCH 22, 1993

Editorials

THE TOBACCO TAX IS NO SIN

Extending adequate health care to millions of uninsured and underinsured Americans will cost upwards of $40 billion a year, and President Clinton and Hillary Rodham Clinton clearly favor a big boost in the federal cigarette tax. Startled by reports that the tax could go up by $2 per pack—on top of the current 24¢ a pack—the tobacco industry lost no time in arguing that any such increase would be unfair to the more than 40 million Americans who smoke. The tax would be highly regressive: It would hit with greatest force those people who are least able to afford it, low-income Americans. But the benefits that it might yield, for national health as well as federal finances, will outweigh that burden.

Someone who smokes a pack and a half a day will have to spend about $1,000 a year if the tax is adopted. Unfair? Not if you consider the enormous health costs incurred by smokers. Smoking was involved in 431,000 deaths in the U.S. last year, and the habit costs the nation more than $65 billion annually in health care outlays and lost productivity. Yet last year, federal and state cigarette taxes brought in just $11 billion. Raising cigarette taxes by $2 a pack would generate some $30 billion a year in federal revenues—even after allowing for a fall-off in consumption.

Raising tobacco taxes is also the most effective way to reduce the human cost of smoking. Look at the example of Canada, whose federal and provincial governments more than quadrupled cigarette taxes, to about $3 (U.S.) in the 1980s, pushing the price of a pack to $4.45 today. Since 1982, per capita consumption has plunged 38%, while the percentage of teenagers who smoke is down 60%. Canada's experience suggests that a $2-per-pack increase in the U.S. could cut consumption by 23% within a couple of years and eventually prevent 2 million premature deaths.

While $2 a pack may sound high, per-pack taxes total $3.68 in Denmark, $2.55 in Britain, and $2.11 in Germany. The knowledge of smoking's dangers has reduced consumption in the U.S., but every year the tobacco industry wins new customers—and the health industry some potential candidates for expensive and often fruitless care. Raising the financial disincentive could make Americans healthier and help finance a new, inclusive health-care system at the same time.

THE NATION'S NEWSPAPER
USA TODAY
PUBLISHED BY GANNETT

TUESDAY, MARCH 2, 1993

Today's debate is on **CIGARETTE TAXES** and whether they should be hiked to pay for health-care reform.

Raise tobacco taxes

OUR VIEW **Higher taxes could save lives as well as bring in needed health-care dollars.**

President Clinton says he's considering a big, new tax on tobacco to pay for health-care reform.

And well he should. The idea is overdue. The tax could raise money and save thousands of lives a year.

No plan yet has been proposed, but the White House is said to be considering a tax that would increase cigarette prices by as much as $2 a pack — enough, say some, to raise $35 billion.

That won't cover even the Clinton administration's conservative estimates of the cost of overhauling the health-care system. But it could be a big help.

What fairer way to get money than to tax behavior that adds billions of dollars to the USA's health-care burden?

Fifty million Americans still smoke despite the massive anti-smoking campaign that began in the 1960s.

More than 434,000 Americans die prematurely as a result of smoking every year; another 53,000 are killed by illnesses attributable to "secondhand" smoke, according to a coalition of major health organizations that supports the tax.

Experience at the state level, where taxes range from 2 cents to 51 cents a pack, shows smokers respond to price hikes by cutting back or quitting. In California, for instance, smoking is down 17% five years after a 25-cent tax hike.

A big kick in the current 24-cent-a-pack national tax likely would have an equal or greater impact. While state taxes can be beaten by "buttleggers," who smuggle cigarettes from low-tax states to high-tax ones, national taxes cannot.

Predictably, some members of Congress say that a $2 tax is politically unrealistic.

Even more predictably, lobbyists are arguing that a tobacco tax, like all regressive taxes, places an undue burden on lower- and middle-income Americans.

Maybe it is regressive tax policy. But if so, it's progressive health policy, benefiting the poorest most of all.

And that's good public policy. Full speed ahead.

'Monster Cigarette Tax' of Up to $2 a Pack Is Said to Gain Support

By Dana Priest
Washington Post Staff Writer

President Clinton is reviewing proposals that include raising federal taxes on cigarettes as high as $2 a pack to provide money for health care, proposals that have the support of the departments of Treasury and Health and Human Services, sources said.

The $2 "monster cigarette tax" is favored by some health specialists on the president's health care task force, who have estimated it would raise $35 billion a year that could help finance health coverage for some of the 37 million uninsured Americans.

The current federal tax on a pack of cigarettes is 24 cents and state taxes on a pack, which costs an average of $1.90 nationally, varied last year from 51 cents in Massachusetts to 2.5 cents in Virginia.

Increasing federal taxes on cigarettes, which Clinton said Thursday he is considering, is one of the revenue-raising mechanisms his health care task force is studying. Additional taxes on health care providers, taxing some health benefits and increasing Medicare premiums for wealthy seniors are also being considered.

In an upcoming issue of Health Affairs, an academic journal, two health care specialists who are members of the task force's working group on financing health care, argue that a $2-a-pack tax is a "particularly attractive" way to raise money to pay for health coverage for uninsured Americans.

The idea of taxing cigarettes has wide support in the health community and among members of Clinton's administration and the public. Treasury Secretary Lloyd Bentsen has been a longtime critic of tobacco products, and Health and Human Services Secretary Donna E. Shalala was a committed anti-smoker as chancellor of the University of Wisconsin, where she imposed a smoking ban in nearly all the 900 buildings on the Madison campus.

By boosting cigarette taxes, proponents say, the Clinton administration would send a two-pronged health message: First, that the administration is committed to using its political clout to deal with preventable health risks; second, that it is willing to take on a powerful interest group—the tobacco companies—to raise money for national health care.

The General Assembly in Virginia, a tobacco-producing state, this week gutted a bill to restrict public smoking and strengthened job protections for smokers. The tobacco industry was a major contributor to state legislative races in Virginia and spent more than $70,000 on winning campaigns in the state in 1991.

"This tax is of enormous social value," said Alan Davis, chairman of the Coalition on Smoking OR Health, an anti-smoking umbrella organization for the American Heart Association, the American Lung Association and the American Cancer Society. "The regressivity of the tax would be cyclical. You would send money back into the communities that need it most."

Most objections to a tax on cigarettes, and to excise taxes in general, are based on the argument that the tax is regressive—hitting low-income people harder than high-income people.

> *"Taxing cigarettes is the one way we know for sure stops smoking. There's a direct correlation."*
>
> —Howard Temin, member National Cancer Institute Advisory Board

"We're sure in the end that President Clinton will decide that a regressive tax on the middle class is not the way to fund health care," said a spokeswoman for the Tobacco Institute, a manufacturers' association. "An excise tax falls harder on the people who can least afford to pay. There's no way around that."

To health advocates, however, the tax's regressivity is a positive feature because it hits some consumers where they are likely to respond—in the pocketbook.

"Taxing cigarettes is the one way we know for sure stops smoking. There's a direct correlation," said Howard Temin, a Nobel laureate for his discoveries in molecular biology and a member of the National Cancer Institute Advisory Board. That board last month approved a resolution supporting a tax of at least $2 per pack.

More than 434,000 Americans died in 1988, the latest year for which figures are available, from health problems caused by smoking, according to the Centers for Disease Control. Smoking is the No. 1 cause of preventable deaths in the United States and is responsible for about one-fifth of all deaths.

The federal government estimates that the cost of smoking-related illness and death to the nation is about $65 billion a year. This includes the cost to the government, the private sector and individuals and takes into account not only spending on health care triggered by smoking-related diseases but also hours of work lost by sick individuals.

In 1984, the Canadian government mounted an assault on smoking. It has banned virtually all cigarette advertising and has steadily increased taxes on cigarettes, which were 46 cents a pack in 1980 and now average $3.70.

Tobacco consumption in Canada fell as prices rose, according to the Finance Ministry. Between 1980 and 1991, total domestic sales had fallen by about 37 percent and domestic tobacco sales per capita had fallen by almost 44 percent.

Economists believe cigarettes taxes are a potent deterrent to young smokers, who have less spending money than adults. About 90 percent of all smokers begin to smoke before they turn 18, according to the American Cancer Society.

"It really hits the kids," said Temin.

The CDC warned states yesterday that the federal government will withhold federal health funds from states that fail to enforce bans on tobacco sales to minors. During a recent study conducted in Texas, almost two-thirds of teenagers who tried to buy tobacco were allowed to do so, and another study found almost half succeeded in Missouri. They are among the 47 states that ban tobacco sales to anyone under 18.

Georgia sets the age at 17; New Mexico regulates only smokeless tobacco and Montana has no ban. Federal law gives those three states until September to make 18 the legal age to buy tobacco or they will lose part of their annual federal grants to fight substance abuse.

Staff writer Peter Baker contributed to this story from Richmond.

Twofer Taxes

WASH POST 3/1/93

TAXING TOBACCO more heavily—as President Clinton suggested the other day—is a thoroughly good idea. It's a twofer. The tax not only would raise substantial amounts of money for a government that desperately needs it but would exercise greater pressure on people to cut down their smoking. It's not as though smoking has not been repeatedly identified by health authorities as a major cause of deaths in the country and the most easily preventable major cause.

While he's at it, Mr. Clinton should also consider higher taxes on alcohol. The same logic applies there. It's another twofer. It's like his proposal for an energy tax, which would not only raise money but encourage conservation. Enlightened policy favors, wherever possible, taxes that can serve more than one public purpose.

Before the tobacco and alcohol lobbies begin shrieking about unfairness to their abused customers, you might want to consider the history of those taxes. Like most American excises, they have been severely eroded by inflation over the years. The federal tax on cigarettes was set at 8 cents a pack in 1951. Adjusting it for inflation, that was the equivalent of 44 cents today. But the actual tax now is only 24 cents. Merely putting it back where it was in real terms four decades ago would raise more than $3 billion a year. Raising it further to $2 a pack, as some people in the administration suggest, would raise many more billions—and discourage smoking much more powerfully.

The shrinkage of the excise taxes over the past generation is, incidentally, a reason why a heavier share of the federal tax load now falls on personal income taxes. You can see the same thing in the levies on alcohol. In 1951 the tax on distilled liquor was $10.50 per gallon of alcohol. In today's dollars, that's $57.35. But today's tax is only $13.50 per gallon—in real terms, less than one-fourth the rate in the early 1950s, when people's incomes were half the present level. The taxes on the alcohol content of beer and wine are a bit less. The Congressional Budget Office calculates that a uniform tax of $16.50 per gallon on alcohol for all beverages—still less than a third of the rate four decades ago—would raise an impressive $4.7 billion a year.

Taken together, tobacco and alcohol taxes can provide a significant contribution to closing the budget deficit. But they can do more. They can help carry some of the costs of caring for the illnesses that accompany tobacco and alcohol. As the country approaches health care reform, it's reasonable to require these two products to bear at least some small part of the financial liabilities they create. And to the extent that higher prices might also mean marginally less smoking and drinking, that couldn't be bad for the country's health.

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THE CASE FOR CLEAN INDOOR AIR

A growing body of statistical and clinical evidence has determined that the involuntary inhalation of environmental tobacco smoke (ETS) is a causative factor in death and disease among nonsmokers. Several recent developments underline the urgency of addressing this issue.

The U.S. Environmental Protection Agency has issued a risk assessment that classifies ETS as a Group A carcinogen, i.e. a known human cancer-causing agent. Other Group A carcinogens include asbestos and benzene.

The American Heart Association's Council on Cardiopulmonary and Critical Care has released a study identifying ETS as a major preventable cause of cardiovascular diseases and death.

The National Institute for Occupational Safety and Health (NIOSH) has recommended that smoking be eliminated in the workplace, and if it cannot, that any smoking area be a physically separate area, separately ventilated.

Following is a summary of evidence presented by the U.S. Surgeon General, the National Academy of Sciences, the National Cancer Institute, EPA and the American Heart Association:

Health Hazards of Involuntary Smoking

In adults:

- Environmental tobacco smoke is responsible for more than 3,000 lung cancer deaths per year in U.S. nonsmokers, and more than 35,000 cardiovascular deaths per year.
- In a long-term study of 2,100 adult subjects, researchers found that a chronic exposure to tobacco smoke in the work environment is harmful to the nonsmoker and significantly reduces small-airways function.
- Women married to men who smoke more than 20 cigarettes a day have twice the risk of developing lung cancer as do women married to nonsmokers. Some studies suggest the risk is dose-related.
- Women married to current or former smokers have a 14.9% greater chance of dying from ischemic heart disease than

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do women married to men who have never smoked.

In children:

- ETS exposure increases the risk of lower respiratory tract infections such as bronchitis and pneumonia. EPA estimates that between 150,000 and 300,000 of these cases annually in infants and young children up to 18 months of age are attributable to exposure to ETS. Of these, between 7,500 and 15,000 will result in hospitalization.

- ETS exposure increases the prevalence of fluid in the middle ear, a sign of chronic middle ear disease.

- ETS exposure increases the frequency of episodes and severity of symptoms in asthmatic children. The EPA risk assessment estimates that 200,000 to 1,000,000 asthmatic children have their condition worsened by exposure to environmental tobacco smoke.

There are more than 4,000 chemicals, including at least 40 carcinogens in ETS. Substances in ETS include "tar," nicotine, ammonia, benzene, carbon monoxide, and carbon dioxide. Environmental tobacco smoke can remain in the air, particularly indoors, for several hours after the actual act of smoking has ended.

A 1992 Gallup Poll commissioned by the American Lung Association found that among **current smokers**, 89% believe ETS is harmful to infants and young children, 86% believe that it is harmful to pregnant women, and 76% believe that it is harmful to older healthy adults. The survey also found that there is increasing public support for total bans or restrictions on smoking in workplaces, restaurants, hotels, buses and trains.

Given the above evidence, it is imperative that measures be taken immediately to protect nonsmokers from the hazards of environmental tobacco smoke. The American Cancer Society, American Heart Association and American Lung Association, united as the Coalition on Smoking OR Health, recommend that smoking be prohibited in all public places, most importantly schools, child day care centers and workplaces.

PUBLIC POLICY BRIEF

Environmental Tobacco Smoke

On January 7, 1993, the U.S. Environmental Protection Agency (EPA) released a long-awaited report assessing current scientific evidence on the health risks of exposure to environmental tobacco smoke (ETS).

Based on the total weight of evidence in the scientific literature, the EPA report concludes that exposure to ETS, also known as secondhand smoke, is more dangerous to the respiratory health of nonsmoking adults and children than previously believed.

Major Conclusions

In adults -- After evaluating 30 epidemiological studies on lung cancer in individuals who have never smoked, the EPA determined that --

- ETS is now classified as a Group A (known human carcinogen) responsible for approximately 3,000 lung cancer deaths each year in U.S. nonsmokers. Other Group A carcinogens include asbestos, benzene and radon.

- 20 percent of all lung cancers caused by factors other than smoking are attributable to exposure to ETS. That translates into a risk of abut 1 in 1,000.

- Higher exposures cause higher risks. People whose spouses smoke in the home, for example, face an additional risk of about 2 in 1,000.

In children -- After evaluating more than 100 studies on respiratory health in children, the EPA concluded that --

- ETS exposure increases the risk of lower respiratory tract infections such as bronchitis and pneumonia, annually causing an estimated 150,000 to 300,000 cases of these illnesses in children up to 18 months. Of these, 7,500 to 15,000 result in hospitalization.

- ETS exposure increases the prevalence of fluid in the middle ear, a sign of chronic middle ear disease.

Exposure to environmental tobacco smoke increases the risk of lower respiratory tract infections in young children.

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- ETS irritates the upper respiratory tract and is associated with a significant reduction in lung function.

- ETS exposure increases the frequency and severity of symptoms in 200,000 to 1,000,000 children with asthma.

- ETS exposure is a risk factor for new cases of asthma in children who have not previously displayed symptoms of that disease.

In addition to the EPA findings, the U.S. Department of Health and Human Services reports that children whose mothers smoked during and after pregnancy are three times more likely than children of nonsmoking mothers to die of Sudden Infant Death Syndrome (SIDS). If the mother smoked after the child's birth, but not during pregnancy, the SIDS rate is still double that of a child reared in a nonsmoking environment.

Public Policy Implications

The EPA's risk assessment of ETS is expected to arm state and local officials, businesses and employees with the scientific basis for instituting no-smoking policies.

At the federal level -- On the heels of the EPA report, the Department of Health and Human Services (HHS) launched a major new information initiative, "Secondhand Smoke: We're All at Risk." The goal of this campaign, produced by the Office on Smoking and Health within the Centers for Disease Control and Prevention, is to increase public awareness of the specific hazards of ETS and to stimulate action to reduce exposure.

In January 1991, then-HHS Secretary Sullivan, M.D., asked President Bush to issue an Executive Order prohibiting smoking in most federal buildings. Under current rules, federal agencies are permitted to set their own individual smoking policies. Smoking is already prohibited in buildings occupied by the EPA and HHS and in VA medical facilities. Although Sullivan pressed Bush to sign the Executive Order up until his final days in the White House, Bush left office without signing the document.

The Labor Department's Occupational Safety and Health Administration (OSHA) is expected to utilize the EPA's findings during its ongoing process rulemaking on indoor air quality.

At the state and local levels -- As of January 1993, 45 states and the District of Columbia had laws restricting smoking in public places. The laws vary greatly in scope and enforcement.

The American Lung Association, working as part of the Coalition on Smoking OR Health (ALA, American Cancer Society and American Heart Association) has developed model legislation to help states with nonexistent or weak tobacco-control laws enact comprehensive clean indoor air measures to protect nonsmokers, especially children, from ETS.

Legislative Activity -- 102nd Congress

During the 102nd Congress, Sen. Frank Lautenberg (D-NJ) and Rep. Dick Durbin (D-IL) introduced the Preventing Our Kids from Inhaling Deadly Smoke (PRO-KIDS) Act that would require no-smoking policies in facilities that receive federal funds for programs serving children under the age of 5. Included would be health and educational services such as Head Start and the Women's, Infants and Children feeding program. Smoking would be permitted only in areas not normally used to serve the children and in areas that are separately ventilated from the childrebn's areas.

The Senate included PRO-KIDS in its fiscal 1993 appropriation bill for the Departments of Labor, Health and Human Services and Education. It was dropped by a House-Senate appropriations conference committee.

Legislative Activity -- 103rd Congress

The American Lung Association will continue to seek enactment and enforcement of legislation and regulations to reduce the exposure of nonsmoking adults and children to ETS, with an emphasis on facilities and activities that expose the greatest number of people to ETS for the longest periods of time, such as workplaces, schools, day care centers and health care facilities. Possible mechanisms include --

- comprehensive clean indoor air legislation;
- legislation prohibiting smoking or requiring no-smoking policies in selected federally funded programs or facilities; and
- regulatory action by appropriate federal agencies, provided it does not restrict the ability of state and local governments to enact more comprehensive protections, if needed.

For More Information, Contact...

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ALA Deputy Managing Director
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(202) 785-3355; FAX: (202) 452-1805

Hildy Dillon
Manager, ALA Smoking OR Health Programs
(212) 315-8712

Recommended Reading...

Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders. U.S. Environmental Protection Agency, December 1992. Publication Number: EPA/600/6-90-006F. Available from the EPA's Indoor Air Quality Information Clearinghouse, P.O. Box 37133, Washington, D.C. 20013-7133; 1 (800) 438-4318.

Reducing the Health Risks of Secondhand Smoke: What you can do at home, work and in public places. American Lung Association, January 1993. Available from the ALA National Office, 1740 Broadway, New York, NY 10019-4374; (212) 315-8700.

"Secondhand Smoke: We're All at Risk" campaign materials. Available from the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1(800) CDC-1311.

Framework for Public Policy Activities of the Coalition on Smoking OR Health 1993. Available from the Coalition at 1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036; (202) 452-1184; FAX: (202) 452-1417.

State Legislated Actions on Tobacco Issues, 1992. Available from the Coaliton on Smoking OR Health (address above).

S. 261. A bill to protect children from exposure to environmental tobacco smoke in the provision of children's services, and for other purposes; to the Committee on Labor and Human Resources.

S. 262. A bill to require the Administrator of the Environmental Protection Agency to promulgate guidelines for instituting a nonsmoking policy in buildings owned or leased by Federal agencies, and for other purposes; to the Committee on Environmental and Public Works.

SECONDHAND SMOKE

• Mr. LAUTENBERG. Mr. President, I rise today to introduce two bills to protect Americans against environmental tobacco smoke or secondhand smoke. I am introducing these bills for one simple irrefutable reason; secondhand smoke kills.

An EPA report released on January 7, 1993, undeniably confirmed what public health officials have reported for several years, smoking kills those who smoke and those who breathe secondhand smoke. This scientifically peer reviewed report concluded that secondhand smoke was indeed a group A carcinogen, a group that includes toxins such as asbestos, benzene, and arsenic. The evidence is clear that secondhand smoke is taking an enormous toll on the health of Americans, particularly our children. According to the EPA report, 3,000 lung cancer deaths per year among nonsmokers result from exposure to secondhand smoke. Secondhand smoke also causes more than 200,000 lower respiratory tract infections in young children annually, including bronchitis and pneumonia, resulting in 7,500 to 15,000 hospitalizations. Furthermore, secondhand smoke exacerbates asthmatic symptoms in children and is associated with 8,000 to 26,000 new asthma cases in children. In a separate study, the American Heart Association concluded that exposure to secondhand smoke increases the risk of lung cancer, heart disease, and emphysema. They reported that approximately 50 percent of all children are exposed to secondhand smoke.

Now that the evidence is in, it is time for the Congress to take action and protect Americans from this deadly substance. In 1990, the Congress passed the Clean Air Act to regulate 189 hazardous air pollutants which were estimated to cause 1,500 deaths per year. Now we must act to regulate an air pollutant which causes at least 3,000 deaths per year.

The first step we must take is to protect our children, because they are most threatened by secondhand smoke. That is why I am introducing the Preventing Our Kids from Inhaling Deadly Smoke [PRO-KIDS] Act of 1993. PRO-KIDS will protect children from secondhand smoke while they are participating in federally funded children's programs such as Head Start, WIC, Chapter 1, health care, and day care programs. It will require participants in federally funded programs to establish a nonsmoking policy if they provide health services to children under the age of 18 or provide other social services primarily to children under the age of 18, including elementary and secondary education.

The legislation I am introducing today to address this threat would require nonsmoking policies that would limit indoor smoking in facilities associated with these federally funded programs to those areas which are not normally used to serve children and which are ventilated separately from these areas. Evidence accumulated by the EPA and other organizations shows that separate ventilation is necessary to prevent secondhand smoke from recirculating through the ventilation system right into the rooms used by the children. In cases where unusual extenuating circumstances prevent total compliance, programs could apply for a partial waiver from this provision if they protect children from exposure to secondhand smoke to the extent possible. This legislation also allows the adoption of the nonsmoking policy to be done through collective bargaining if such an agreement exists.

The second piece of legislation that I am introducing today is called PRotecting Our FEderal workers and visitors from Deadly Smoke or PROFEDS. This legislation takes an important first step to protect adults from unwanted exposure to secondhand smoke. This legislation expands the nonsmoking policy, that already is in place at the U.S. Department of Health and Human Services and the Environmental Protection Agency, to all buildings owned of leased by agencies of the executive, legislative, and judicial branches of the Federal Government. This would include the White House offices and the Congress, but not cover Federal buildings which serve primarily as living quarters. This bill also includes a provision that would also allow unions to adopt this requirement through collective bargaining.

This legislation also provides an expanded role for the Environmental Protection Agency [EPA] with regard to environmental tobacco smoke. Under this legislation, the EPA will establish guidelines for compliance under this act.

This bill also directs the EPA to provide technical assistance to entities which must comply with this act. Under the bill the EPA will conduct an outreach campaign to inform the public about the dangers of environmental tobacco smoke. It also establishes an Environmental Tobacco Smoke Advisory Office within the Office of Radiation and Indoor Air at EPA. With a telephone inquiry hotline, this office will answer inquiries about how to protect people from environmental tobacco smoke.

Now that the studies are completed, it is time to take action to protect people from the dangers of secondhand smoke. The Department of Health and Human Services initially banned smoking in all of its buildings because our top health officials understand the danger of environmental tobacco smoke. We've banned smoking on all domestic airplane flights. Children are the most vulnerable members of our society. They depend upon us to protect them and safeguard their health. They are the future of this country. Isn't it time to give our children, especially those who depend on the Federal Government for valuable services like health care and preschool training, the same protection we already afford to airplane travelers and some Federal workers?

As a Department of Health and Human Services report notes, "25 years ago, smoking in the workplace and public places was considered a virtual birthright. Today, acceptance of smoking in public places has largely disappeared, replaced by an increasing recognition of the right to breathe air free from the harmful effects of tobacco smoke." We've come a long way, baby. But we still have a way to go. We should prohibit smoking in federally funded institutions which serve children under the age of 18 immediately, so that our children can breath healthy air. We must also expand the smoking ban that already exists at the Department of Health and Human Services and the Environmental Protection Agency to all agencies in the Federal Government.

This legislation has been endorsed by the American Heart Association, the American Lung Association, the American Cancer Society, the Association for Respiratory Care, the Association of Maternal and Child Health Programs, the Asthma and Allergy Foundation of America, and the National Coalition for Cancer Research.

I ask unanimous consent to have a press release from former EPA Administrator Reilly and a New York Times article entitled "U.S. Ties Secondhand Smoke to Cancer" included in the RECORD following this statement. I also ask unanimous consent that these bills be printed in full in the RECORD following this statement.

I urge my colleagues to support and cosponsor this legislation.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

S. 261

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Preventing Our Kids From Inhaling Deadly Smoke (PRO-KIDS) Act of 1993".

SEC. 2. FINDINGS.

Congress finds that—

(1) environmental tobacco smoke comes from secondhand smoke exhaled by smokers and sidestream smoke emitted from the burning of cigarettes, cigars, and pipes;

(2) since citizens of the United States spend up to 90 percent of a day indoors, there is a significant potential for exposure to environmental tobacco smoke from indoor air;

(3) exposure to environmental tobacco smoke occurs in schools, public buildings, and other indoor facilities;

H.R. 710

The PRO-KIDS Act (PReventing Our Kids from Inhaling Deadly Smoke)

Introduced by Reps. Dick Durbin, James Hansen, and Romano Mazzoli

The PReventing Our Kids from Inhaling Deadly Smoke (PRO-KIDS) Act of 1993 provides protection from environmental tobacco smoke ("secondhand smoke") to children while they are participating in federally-funded children's programs, and to federal employees and visitors in all federal buildings.

On January 7, 1993, after an exhaustive multi-year study, the Environmental Protection Agency formally classified secondhand smoke as a Group A carcinogen. This classification is reserved for substances which are known to cause cancer in humans, including asbestos, benzene, and arsenic. EPA found that secondhand smoke is responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers.

In addition, EPA concluded that exposure to secondhand smoke is the source of a variety of illnesses in children. Exposure to secondhand smoke:

* Causes 150,000 to 300,000 lower respiratory tract infections such as bronchitis and pneumonia in young children each year;

* Causes additional episodes of asthma and increased severity of asthma symptoms in children who already have asthma; and

* May be a risk factor for 8,000 to 26,000 new cases of asthma annually in children who would not otherwise become asthmatic.

H.R. 710 requires federally-funded children's programs to establish a nonsmoking policy prohibiting smoking indoors, except in areas of their facilities which are not normally used to serve the children and which are ventilated separately from the children's areas. This provision applies to all federally-funded health programs serving children, and all other federally-funded programs that primarily serve children, including schools, Head Start, WIC, and day care programs.

The bill also prohibits smoking in all building space owned or leased by the executive, judicial, or legislative branches of the federal government, except in areas that are ventilated separately from the rest of the building. This provision protects visitors as well as federal employees.

The bill does not require that separately ventilated smoking areas be established. Smoking could be banned entirely by the children's program or federal agency, and a totally smokefree policy is the most economical way to protect nonsmokers. If smoking is permitted, it must be allowed only in separately ventilated areas, because otherwise the smoke will circulate directly or through the ventilation system into the rooms used by nonsmokers.

Provisions of H.R. 710

The PRO-KIDS Act (PReventing Our Kids from Inhaling Deadly Smoke)

Introduced by Reps. Dick Durbin, James Hansen, and Romano Mazzoli

SMOKING IN THE FEDERAL WORKPLACE

1. EPA shall develop, within 180 days, guidelines for instituting and enforcing a nonsmoking policy at each federal agency, which will prohibit smoking except in separately ventilated areas.

2. As soon as is practicable, the head of each Executive agency shall adopt a nonsmoking policy that meets the requirements of the EPA guidelines. The Director of the Administrative Office of the U.S. Courts shall adopt a nonsmoking policy for Judicial Branch buildings. The House Building Commission, the Senate Rules Committee, and the Architect of the Capitol shall adopt nonsmoking policies for Legislative Branch buildings.

3. The Administrator of the General Services Administration shall certify that each Executive agency's policy meets the requirements of the EPA guidelines.

4. Agency heads may publicly petition for a waiver, which may be granted if (1) unusual extenuating circumstances prevent enforcement and the agency establishes and enforces an alternative policy protecting individuals to the maximum extent possible, or (2) the agency establishes an alternative policy that provides protection equal to that of the EPA guidelines.

5. Agencies subject to collective bargaining agreements shall engage in collective bargaining to ensure implementation, and may exempt work areas for up to 1 year that are covered by a previous agreement permitting smoking.

SMOKING IN FEDERALLY-FUNDED CHILDREN'S PROGRAMS

6. Any entity using federal funds to provide health services to children under age 18 or to provide other services primarily to children under age 18 shall establish and make a good-faith effort to enforce a nonsmoking policy that prohibits smoking except in separately ventilated areas, beginning with the first fiscal year after enactment.

7. Entities may petition the agency funding them for a waiver, which may be granted if the conditions in #4 are met. Entities subject to collective bargaining agreements that permit smoking may request a waiver of up to 1 year.

8. Entities that fail to establish or make a good-faith effort to enforce the nonsmoking requirement are subject to civil penalties of up to $1,000 per violation per day, which would be assessed by the head of the agency that provided the federal funds, with an opportunity for a hearing. The agency head could reduce or waive the penalty and take into account mitigating factors and the violator's willingness to abide by the law in the future.

TECHNICAL ASSISTANCE AND OUTREACH ACTIVITIES

9. EPA and HHS shall provide technical assistance to agency heads and other persons who request it, including information on smoking cessation programs for employees and information to assist in compliance with this Act.

10. EPA shall establish an Environmental Tobacco Smoke Advisory Office and an outreach program to inform the public of the dangers of secondhand smoke, operate a telephone hotline, and provide information to those requesting it.

Organizations Endorsing
H.R. 710, the PRO-KIDS Act
Introduced by Reps. Dick Durbin, James Hansen, and Romano Mazzoli

American Cancer Society
American Heart Association
American Lung Association
(united as the Coalition on Smoking OR Health)

Association of Maternal and Child Health Programs
National Education Association

American Association for Respiratory Care
American College of Chest Physicians
American College of Occupational and Environmental Medicine
American Medical Association
American Nurses Association
Americans for Nonsmokers Rights
ASH (Action on Smoking and Health)
Association of State and Territorial Health Officials
Asthma and Allergy Foundation of America
National Coalition for Cancer Research

Cosponsors of H.R. 710

THE PRO-KIDS BILL (PREVENTING OUR KIDS FROM INHALING DEADLY SMOKE)

Introduced by Reps. Dick Durbin, James Hansen, and Romano Mazzoli

As of March 26, 1993

Gary Ackerman (D-NY)
Michael Andrews (D-TX)
Thomas Barrett (D-WI)
Anthony Beilenson (D-CA)
George Brown, Jr. (D-CA)
Ronald Coleman (D-TX)
Barbara-Rose Collins (D-MI)
Cardiss Collins (D-IL)
John Conyers, Jr. (D-MI)
Richard Durbin (D-IL) (sponsor)
Lane Evans (D-IL)
Harris Fawell (R-IL)
Barney Frank (D-MA)
Martin Frost (D-TX)
Luis Gutierrez (D-IL)
James Hansen (R-UT)
Maurice Hinchey (D-NY)
Bob Inglis (R-SC)
Andrew Jacobs, Jr. (D-IN)
Tim Johnson (D-SD)
Marcy Kaptur (D-OH)
Mike Kreidler (D-WA)
John LaFalce (D-NY)
John Lewis (D-GA)
William Lipinski (D-IL)
Carolyn Maloney (D-NY)
Romano Mazzoli (D-KT)
Alfred McCandless (R-CA)
Bill McCollum (R-FL)
Jim McDermott (D-WA)
Cynthia McKinney (D-GA)
Martin Meehan (D-MA)
George Miller (D-CA)
James Moran (D-VA)
Constance Morella (R-MD)
Eleanor Holmes Norton (D-DC)
James Oberstar (D-MN)
Nancy Pelosi (D-CA)
John Porter (R-IL)
Carlos Romero-Barcelo (D-PR)
Lynn Schenk (D-CA)
Patricia Schroeder (D-CO)
Karen Shepherd (D-UT)
Jim Slattery (D-KS)
Fortney Pete Stark (D-CA)
Ted Strickland (D-OH)
Gerry Studds (D-MA)
Mike Synar (D-OK)
Jolene Unsoeld (D-WA)
Lynn Woolsey (D-CA)
Sidney Yates (D-IL)

FACT SHEET ON H. R. 881

"BAN ON SMOKING IN FEDERAL BUILDINGS ACT"

* H.R. 881 would prohibit smoking in any indoor portion of a Federal building and in any other space owned or leased for use by a Federal agency. This prohibition would extend to the Executive, Legislative and Judicial branches of the Federal government.

* **Under H.R. 881, any person in a Federal building who wishes to smoke, must go outside.** The prohibition would take effect 180 days after enactment into law.

* On March 11, 1993 the Committee on Public Works and Transportation, Subcommittee on Public Buildings and Grounds held a hearing on H.R. 881. Another hearing is scheduled for April 15, 1993.

* According to the General Services Administration, the current regulation governing smoking in the Public Building Service's facilities does not adequately protect non-smokers from secondhand smoke which is recirculated throughout buildings through the ventilation system. The cost of altering existing space to provide separately ventilated areas would be significant -- about $30 to $50 per square foot. In terms of the total square footage owned by the Federal government, total cost could be as high as $275 million.

* A number of states and municipalities have already banned all smoking in their public buildings, including California, Idaho, Maryland, Michigan, Ohio and Utah. Private companies as well as public entities are increasingly finding it feasible to implement a workplace smoking ban.

* The Building Owners and Managers Association (BOMA), whose membership owns or manages over five billion square feet of commercial office space in the United States, supports a smoking ban in either public or private workplaces. BOMA has testified that existing buildings are not separately ventilated and retrofitting of ventilation systems is very costly, if not impossible in some cases.

For more information on H.R. 881, please contact Paul Marcone, Office of Congressman James A. Traficant, Jr., at 202/225-5261.

American Heart Association

AMERICAN LUNG ASSOCIATION®
The Christmas Seal People®

AMERICAN CANCER SOCIETY®

Coalition on Smoking OR Health

TESTIMONY OF ALFRED MUNZER, M.D.

ON BEHALF OF

THE COALITION ON SMOKING OR HEALTH

to the

House Committee on Public Works and Transportation

Subcommittee on Public Buildings and Grounds

U.S. House of Representatives

RE: H.R. 881, LEGISLATION TO BAN SMOKING IN FEDERALLY OWNED AND LEASED OFFICE BUILDINGS

March 11, 1993

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 FAX: (202) 452-1417

Mr. Chairman, and members of the subcommittee on Public Buildings and Grounds, I am Dr. Alfred Munzer, President-elect of the American Lung Association (ALA). I am also Director of Critical Care and Pulmonary Medicine at Washington Adventist Hospital in Takoma Park, MD, where I specialize in the treatment of diseases of the lung.

The ALA is the nation's oldest voluntary health organization and is dedicated to the prevention and control of lung disease. This organization, and its medical section, the American Thoracic Society, has long recognized the contribution of indoor and outdoor air pollution to the development and exacerbation of lung disease. The ALA has devoted the past 26 years to the implementation of programs aimed at improving air quality in our homes and in our communities.

Today I am testifying of behalf of the American Lung Association, the American Cancer Society, and the American Heart Association, united as the Coalition on Smoking OR Health. Formed in 1982, the coalition has worked to heighten public awareness about the impact of tobacco consumption upon public health. It believes strong measures should be imposed to discourage tobacco use in all segments of the population, including youth, women, and minorities.

As a pulmonary physician, I all too often see first had the devastation cased by tobacco use. I see the men and women who come to me with end-stage lung cancer or emphysema, seeking a medical miracle to cure their disease. I see the children who cough and wheeze as their asthma is made worse by exposure to smoke exhaled by smokers and that comes from the burning end of a cigarette, pipe, or cigar. Smoke of this nature is commonly called involuntary, passive, or secondhand smoke. However, more recently, it increasingly referred to as "ETS", or environmental tobacco smoke.

I cannot express to you how critical it is for us to respond to the ETS issue. Conclusions drawn from the Environmental Protection Agency's (EPA) risk assessment on ETS reenforces the sense of urgency in this regard. If we do not take immediate action, or ignore its impact on public health, ETS can easily be the cause of approximately 3,000 lung cancer deaths in nonsmokers in the coming year. I am certain this is not the future trend our society desires to establish.

Today, I do not intend to argue whether smokers should have a right to smoke it public, nor am I here to urge the subcommittee to revoke this privilege. However, I have elected to appear before you due to ongoing concern regarding the health effects of ETS for nonsmokers and particularly children, and the need to impose stringent measures, both in

government and the private sector, to adequately address this growing public health concern.

I want to begin by reflecting on the evidence which has supported and recently led to the EPA findings on ETS, and move into a examination of the methodology which supports this agency's assertion that ETS is a carcinogen. I will speak briefly to the claims raised by tobacco advocates regarding the validity of the EPA findings, and lastly, focus on public interest in and support for significant action to limit or eliminate exposure to ETS is public areas.

ETS has been the topic of discussion for more than 20 years. Its health effects were first reviewed in 1972 in the U.S. Surgeon General's report on smoking and health. That report was devoted, in part, to public exposure to air pollution caused by tobacco smoke. It concluded that "an atmosphere contaminated with tobacco smoke can contribute to the discomfort of many individuals."

In 1982, the U.S. Surgeon General <u>again</u> examined the issue of passive smoking, but this time in the context of smoking and the development of cancer. At that time there were only 3 epidemiologic studies linking passive smoking and lung cancer. Even with this limited amount of evidence, the Surgeon General concluded that the evidence in these studies

is the cause for serious concern regarding the possible serious public health problem associated with passive smoke and lung cancer.

By 1986, federal interest in the health effects of ETS had grown to the extent that the U.S. Surgeon General released a report devoted entirely to the issue of passive smoking. By that time, the number of epidemiologic studies had increased to 13, 11 of which showed a positive correlation between passive smoking and lung cancer in healthy nonsmokers. Based upon these findings, the Surgeon General concluded that exposure to secondhand smoke is a cause of lung cancer in healthy nonsmokers. He also concluded that children whose parents smoked had an increased frequency of respiratory symptoms and infections, compared to children whose parents were nonsmokers.

Several private organizations -- the National Academy of Science and the International Agency for Cancer Research -- published reports which drew conclusions similar to those of the EPA. The International Agency for Cancer Research, for example, released a report on cancer which concluded that "knowledge of the nature of sidestream and mainstream smoke, of materials absorbed during passive smoking, and of the quantitative relationships between dose and effect that are commonly observed from exposure to carcinogens leads to the

conclusion that passive smoking gives rise to some risk of cancer."

Shortly after the release of these studies, the EPA began to examine the health effects of passive smoking on children and adults. The agency issued an initial analysis of the risks of exposure to ETS in May, 1990. Entitled, "Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children," the risk assessment focused on the potential correlation between ETS and lung cancer in nonsmoking adults and respiratory disease and pulmonary effects in children.

On January 7, 1993, the EPA released its final report assessing current scientific evidence on the risks of exposure to ETS. Based on the total weight of evidence in the scientific literature, the EPA designated ETS as a Group A carcinogen, a rating used only for extremely hazardous substances known to cause cancer in humans. It ranked ETS in a class of carcinogens which includes asbestos, benzene, and radon.

After evaluating 30 epidemiological studies on lung cancer in nonsmoking adults, the EPA determined that ETS is responsible for approximately 3,000 lung cancer deaths each year. The agency also added that ETS accounts for the development of 20

percent of all lung cancers caused by factors other than smoking. For the average adult, ETS increases their risk of cancer to approximately 2 per 1,000. From these conclusions, it is clear that ETS is far more hazardous to the health of nonsmoking adults.

After evaluating more than 100 studies on respiratory health in children, the EPA concluded that ETS exposure increases their risk of lower respiratory infections, like bronchitis and pneumonia. ETS is known to cause an estimated 150,000 to 300,000 cases of respiratory illnesses in children up to 18 months each year. Of these cases, 7,500 to 15,000 result in hospitalization.

ETS exposure is also associated with additional attacks and increased severity of symptoms in children with asthma. The EPA estimates that 200,000 to 1 million asthmatic children have their condition worsened by ETS, and that ETS is a risk factor for new cases of asthma in children without a history of symptoms.

Also of concern are the risks for children whose mothers smoked during and after pregnancy. The U.S. Department of Health and Human Services has reported that, under these circumstances, children are three times more likely to die of Sudden Infant Death Syndrome (SIDS) than children of

nonsmoking mothers. The risks of SIDS double for children whose mothers smoked after birth and not during pregnancy than for children reared in nonsmoking environments.

The evidence presented represents very sound science and more than adequately supports the conclusions by the EPA regarding exposure to ETS. Uniquely, each of the studies and reports used to reach this conclusion were developed and edited by different processes. In contrast to assertions made of opponents of the EPA's findings, such as those offered by the tobacco industry, it is this diverse methodology which only strengthens the validity of the conclusion of this research combined.

Without spending too much time on the tobacco industry's criticisms of the risk assessment, let me first remind the subcommittee that after 60,000 studies linking smoking with disease and death, this industry still fails to acknowledge that it produces a lethal product. This is an industry which has criticized each Surgeon General's report since 1964. Among the industry criticisms is the failure of the EPA to include studies which show no relationship between ETS and lung cancer. Among the studies cited by the industry as examples are several funded by the National Cancer Institute:

- Brownson, PhD., et.al. Passive Smoking and Lung

Cancer in Nonsmoking Women. Am J Public Health 82:1525-1530, 1992.

This study was published in November 1992, too late for inclusion in the risk assessment unless it was further delayed. The industry contends that the risk assessment would change if the study were included. However, the author's of the study conclude: "Ours and other recent studies suggest a small but consistent increase risk of lung cancer from passive smoking. Comprehensive actions to limit smoking in public places and worksites are well-advised."

♦ Stockwell, Sc.D., et.al. Environmental Tobacco Smoke and Lung Cancer in Nonsmoking Women. J Natl Cancer Inst 84:1417-1422, 1992.

This study was not included in the final risk assessment and again the industry claims it is a negative study therefore left out purposefully. However, the author's conclude:

"These findings suggest that long-term exposure to environmental tobacco smoke increases the risk of lung cancer in women who have never smoked."

The real issue here is statistical significance and how it is used. In defining the true meaning of statistical

significance, I'd like to defer to the description used by a well-noted environmental epidemiologist, Dr. Douglas Dockery, and Associate Professor at the Harvard School of Public Health. Dr. Dockery suggests:

> " A naive critique would say that those studies which are not 'statistically significant' do not show an effect. However, statistical significance is not a measure of association or environmental tobacco smoke with lung cancer, but rather a measure of the stability of the association. It measures the statistical power of the study. In a crude sense it is a measure of study size, and studies that do not achieve statistical significance are simply too small. This does not mean that they do not provide important information on risks. It is not appropriate to discard studies which do not achieve statistical significance, but rather they should be included giving them a weight which reflects the stability, that is the uncertainty, of their effect estimate. This is exactly what the meta-analysis of these studies provides."

Mr. Chairman, we at the Coalition on Smoking OR Health believe the EPA's findings are clear, objective, and complete in regard to ETS. The evidence used to show the relative risks associated with exposure to ETS, and its linkage to the development of lung cancer, are more compelling than similar

correlations drawn for other environmental carcinogens. I hope the evidence I have presented to the subcommittee today will enable you to step beyond the criticisms offered regarding the validity of the EPA risk assessment, and encourage to you move forward in your efforts to address the real issue on the table -- adequately responding to the public health issue associated with exposure to ETS, particularly in those places where people spend a lot of time.

Let me commend the subcommittee for the effort and commitment it has made to this issue, thus far. The introduction and careful review of legislation to ban smoking in federal buildings is a very important step in this process. The Coalition on Smoking OR Health supports the bill -- H.R. 881 -- on which this hearing is being held today, and similar proposals offered by other Members of Congress, from whom you will hear later.

In examining the proposal to ban smoking in federal buildings, let me remind you that the federal government has taken little initiative to protect federal workers from exposure to secondhand smoke. Any action taken to date remains inconsistent with each federal agency responsible for its own policy. The General Services Administration (GSA) is reconsidering its regulations, but GSA space accounts for

only 10 percent of federal building space.

I urge this subcommittee to take into consideration growing interest in smoke-free public places, which has gained momentum since the release of the EPA risk assessment. Based on a public opinion survey conducted by the American Lung Association, it is clear that more and more Americans believe ETS is harmful, and that they prefer smoke-free public places, as opposed to those environments in which smoke is permitted.

In this survey, the Lung Association found that 8 in 10 smokers know that ETS is bad for the people around them. We also found that nonsmokers are more likely than smokers to strongly agree about the harmful effects of ETS exposure. The survey found increasing support for total bans on smoking in public places such as restaurants, workplaces, hotels, buses, and trains. And though current smokers are more likely than others to believe that smoking in public places should be restricted, very few smokers surveyed favored no restrictions.

Clearly, as the awareness of the health hazards of ETS increases, more Americans are striving to live, work, and breathe in smoke-free environments. Very few of us make it through each day without exposure to ETS. Those who are

confined to indoor environments -- like employees and staffers in the House of Representatives -- are no exception. It is unfortunate that the House Building Commission's recent decision to merely restrict smoking to certain areas does not provide the adequate protection needed.

I believe the 1986 report of the Surgeon General has the best recommendation for us to consider. In its conclusion, the report clearly states, "Simple separation of smokers and nonsmokers within the same air space may reduce, but does not eliminate, exposure of nonsmokers to ETS." Therefore, it is the responsibility of employers and employees to "ensure that the act of smoking does not expose the nonsmoker to tobacco smoke" and for smokers to "assure that their behavior does not jeopardize the health of other workers." In addition, the Surgeon General stated that nonsmokers have the "responsibility to provide a supportive environment for smokers who are attempting to stop."

The House of Representatives owes its employees and the people of this country who frequent the Capitol grounds to provide a healthy and safe environment. By going smoke-free, the House will contribute to the notion that nonsmoking is a social norm.

On behalf of the American Lung Association, and other members

of the Coalition on Smoking OR Health, I would like to thank you for the opportunity to testify before the subcommittee on the impact of ETS exposure upon public health. Again, we urge you to step beyond the criticism offered regarding the validity of the EPA data and take into account the points we have raised today, which demonstrate a need for government action. Please know you have our organization's support and encouragement as you continue to review this very pressing issue.

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Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders

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1. SUMMARY AND CONCLUSIONS

1.1. MAJOR CONCLUSIONS

Based on the weight of the available scientific evidence, the U.S. Environmental Protection Agency (EPA) has concluded that the widespread exposure to environmental tobacco smoke (ETS) in the United States presents a serious and substantial public health impact.

In adults:

- ETS is a human lung carcinogen, responsible for approximately 3,000 lung cancer deaths annually in U.S. nonsmokers.

In children:

- ETS exposure is causally associated with an increased risk of lower respiratory tract infections (LRIs) such as bronchitis and pneumonia. This report estimates that 150,000 to 300,000 cases annually in infants and young children up to 18 months of age are attributable to ETS.

- ETS exposure is causally associated with increased prevalence of fluid in the middle ear, symptoms of upper respiratory tract irritation, and a small but significant reduction in lung function.

- ETS exposure is causally associated with additional episodes and increased severity of symptoms in children with asthma. This report estimates that 200,000 to 1,000,000 asthmatic children have their condition worsened by exposure to ETS.

- ETS exposure is a risk factor for new cases of asthma in children who have not previously displayed symptoms.

1.2. BACKGROUND

Tobacco smoking has long been recognized (e.g., U.S. Department of Health, Education, and Welfare [U.S. DHEW], 1964) as a major cause of mortality and morbidity, responsible for an estimated 434,000 deaths per year in the United States (Centers for Disease Control [CDC], 1991a). Tobacco use is known to cause cancer at various sites, in particular the lung (U.S. Department of Health and Human Services [U.S. DHHS], 1982; International Agency for Research on Cancer [IARC], 1986). Smoking can also cause respiratory diseases (U.S. DHHS, 1984, 1989) and is a major risk factor for heart disease (U.S. DHHS, 1983). In recent years, there has been concern that nonsmokers may also be at risk for some of these health effects as a result of their exposure ("passive smoking") to the tobacco smoke that occurs in various environments occupied by smokers. Although this ETS is dilute compared with the mainstream smoke (MS) inhaled by active smokers, it is chemically similar, containing many of the same carcinogenic and toxic agents.

In 1986, the National Research Council (NRC) and the Surgeon General of the U.S. Public Health Service independently assessed the health effects of exposure to ETS (NRC, 1986; U.S. DHHS, 1986). Both of the 1986 reports conclude that ETS can cause lung cancer in adult nonsmokers and that children of parents who smoke have increased frequency of respiratory symptoms and acute lower respiratory tract infections, as well as evidence of reduced lung function.

More recent epidemiologic studies of the potential associations between ETS and lung cancer in nonsmoking adults and between ETS and noncancer respiratory effects more than double the size of the database available for analysis from that of the 1986 reports. This EPA report critically reviews the current database on the respiratory health effects of passive smoking; these data are utilized to develop a hazard identification for ETS and to make quantitative estimates of the public health impacts of ETS for lung cancer and various other respiratory diseases.

The weight-of-evidence analysis for the lung cancer hazard identification is developed in accordance with U.S. EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 1986a) and established principles for evaluating epidemiologic studies. The analysis considers animal bioassays and genotoxicity studies, as well as biological measurements of human uptake of tobacco smoke components and epidemiologic data on active and passive smoking. The availability of abundant and consistent human data, especially human data at actual environmental levels of exposure to the specific agent (mixture) of concern, allows a hazard identification to be made with a high degree of certainty. The conclusive evidence of the dose-related lung carcinogenicity of

MS in active smokers (Chapter 4), coupled with information on the chemical similarities of MS and ETS and evidence of ETS uptake in nonsmokers (Chapter 3), is sufficient by itself to establish ETS as a known human lung carcinogen, or "Group A" carcinogen under U.S. EPA's carcinogen classification system. In addition, this document concludes that the overall results of 30 epidemiologic studies on lung cancer and passive smoking (Chapter 5), using spousal smoking as a surrogate of ETS exposure for female never-smokers, similarly justify a Group A classification.

The weight-of-evidence analyses for the noncancer respiratory effects are based primarily on a review of epidemiologic studies (Chapter 7). Most of the endpoints examined are respiratory disorders in children, where parental smoking is used as a surrogate of ETS exposure. For the noncancer respiratory effects in nonsmoking adults, most studies used spousal smoking as an exposure surrogate. A causal association was concluded to exist for a number of respiratory disorders where there was sufficient consistent evidence for a biologically plausible association with ETS that could not be explained by bias, confounding, or chance. The fact that the database consists of human evidence from actual environmental exposure levels gives a high degree of confidence in this conclusion. Where there was suggestive but inconclusive evidence of causality, as was the case for asthma induction in children, ETS was concluded to be a risk factor for that endpoint. Where data were inconsistent or inadequate for evaluation of an association, as for acute upper respiratory tract infections and acute middle ear infections in children, no conclusions were drawn.

This report also has attempted to provide estimates of the extent of the public health impact, where appropriate, in terms of numbers of ETS-attributable cases in nonsmoking subpopulations. Unlike for qualitative hazard identification assessments, where information from many sources adds to the confidence in a weight-of-evidence conclusion, for quantitative risk assessments, the usefulness of studies usually depends on how closely the study population resembles nonsmoking segments of the general population. For lung cancer estimates among U.S. nonsmokers, the substantial epidemiology database of ETS and lung cancer among U.S. female never-smokers was considered to provide the most appropriate information. From these U.S. epidemiology studies, a pooled relative risk estimate was calculated and used in the derivation of the population risk estimates. The large number of studies available, the generally consistent results, and the condition of actual environmental levels of exposure increase the confidence in these estimates. Even under these circumstances, however, uncertainties remain, such as in the use of questionnaires and current biomarker measurements to estimate past exposure, assumptions of exposure-response linearity, and extrapolation to male never-smokers and to ex-smokers. Still, given the strength of the evidence for the lung carcinogenicity of tobacco smoke and the extensive human database from actual environmental exposure levels, fewer assumptions are necessary than

is usual in EPA quantitative risk assessments, and confidence in these estimates is rated medium to high.

Population estimates of ETS health impacts are also made for certain noncancer respiratory endpoints in children, specifically lower respiratory tract infections (i.e., pneumonia, bronchitis, and bronchiolitis) and episodes and severity of attacks of asthma. Estimates of ETS-attributable cases of LRI in infants and young children are thought to have a high degree of confidence because of the consistent study findings and the appropriateness of parental smoking as a surrogate measure of exposure in very young children. Estimates of the number of asthmatic children whose condition is aggravated by exposure to ETS are less certain than those for LRIs because of different measures of outcome in various studies and because of increased extraparental exposure to ETS in older children. Estimates of the number of new cases of asthma in previously asymptomatic children also have less confidence because at this time the weight of evidence for asthma induction, while suggestive of a causal association, is not conclusive.

Most of the ETS population impact estimates are presented in terms of ranges, which are thought to reflect reasonable assumptions about the estimates of parameters and variables required for the extrapolation models. The validity of the ranges is also dependent on the appropriateness of the extrapolation models themselves.

While this report focuses only on the respiratory health effects of passive smoking, there also may be other health effects of concern. Recent analyses of more than a dozen epidemiology and toxicology studies (e.g., Steenland, 1992; National Institute for Occupational Safety and Health [NIOSH], 1991) suggest that ETS exposure may be a risk factor for cardiovascular disease. In addition, a few studies in the literature link ETS exposure to cancers of other sites; at this time, that database appears inadequate for any conclusion. This report does not develop an analysis of either the nonrespiratory cancer or the heart disease data and takes no position on whether ETS is a risk factor for these diseases. If it is, the total public health impact from ETS will be greater than that discussed here.

1.3. PRIMARY FINDINGS

A. Lung Cancer in Nonsmoking Adults

1. Passive smoking is causally associated with lung cancer in adults, and ETS, by the total weight of evidence, belongs in the category of compounds classified by EPA as Group A (known human) carcinogens.
2. Approximately 3,000 lung cancer deaths per year among nonsmokers (never-smokers and former smokers) of both sexes are estimated to be attributable to ETS in the United States. While there are statistical and modeling uncertainties

in this estimate, and the true number may be higher or lower, the assumptions used in this analysis would tend to underestimate the actual population risk. The overall confidence in this estimate is medium to high.

B. Noncancer Respiratory Diseases and Disorders

1. Exposure of children to ETS from parental smoking is causally associated with:
   a. increased prevalence of respiratory symptoms of irritation (cough, sputum, and wheeze),
   b. increased prevalence of middle ear effusion (a sign of middle ear disease), and
   c. a small but statistically significant reduction in lung function as tested by objective measures of lung capacity.
2. ETS exposure of young children and particularly infants from parental (and especially mother's) smoking is causally associated with an increased risk of LRIs (pneumonia, bronchitis, and bronchiolitis). This report estimates that exposure to ETS contributes 150,000 to 300,000 LRIs annually in infants and children less than 18 months of age, resulting in 7,500 to 15,000 hospitalizations. The confidence in the estimates of LRIs is high. Increased risks for LRIs continue, but are lower in magnitude, for children until about age 3; however, no estimates are derived for children over 18 months.
3. a. Exposure to ETS is causally associated with additional episodes and increased severity of asthma in children who already have the disease. This report estimates that ETS exposure exacerbates symptoms in approximately 20% of this country's 2 million to 5 million asthmatic children and is a major aggravating factor in approximately 10%.
   b. In addition, the epidemiologic evidence is suggestive but not conclusive that ETS exposure increases the number of new cases of asthma in children who have not previously exhibited symptoms. Based on this evidence and the known ETS effects on both the immune system and lungs (e.g., atopy and airway hyperresponsiveness), this report concludes that ETS is a risk factor for the induction of asthma in previously asymptomatic children. Data suggest that relatively high levels of exposure are required to induce new cases of asthma in children. This report calculates that previously asymptomatic children exposed to ETS from mothers who smoke at least 10 cigarettes per day will exhibit an estimated 8,000 to 26,000 new cases of

asthma annually. The confidence in this range is medium and is dependent on the conclusion that ETS is a risk factor for asthma induction.

4. Passive smoking has subtle but significant effects on the respiratory health of nonsmoking adults, including coughing, phlegm production, chest discomfort, and reduced lung function.

This report also has reviewed data on the relationship of maternal smoking and sudden infant death syndrome (SIDS), which is thought to involve some unknown respiratory pathogenesis. The report concludes that while there is strong evidence that infants whose mothers smoke are at an increased risk of dying from SIDS, available studies do not allow us to differentiate whether and to what extent this increase is related to in utero versus postnatal exposure to tobacco smoke products. Consequently, this report is unable to assert whether or not ETS exposure by itself is a risk factor for SIDS independent of smoking during pregnancy.

Regarding an association of parental smoking with either upper respiratory tract infections (colds and sore throats) or acute middle ear infections in children, this report finds the evidence inconclusive.

1.3.1. ETS and Lung Cancer

1.3.1.1. *Hazard Identification*

The Surgeon General (U.S. DHHS, 1989) estimated that smoking was responsible for more than one of every six deaths in the United States and that it accounted for about 90% of the lung cancer deaths in males and about 80% in females in 1985. Smokers, however, are not the only ones exposed to tobacco smoke. The sidestream smoke (SS) emitted from a smoldering cigarette between puffs (the main component of ETS) has been documented to contain virtually all of the same carcinogenic compounds (known and suspected human and animal carcinogens) that have been identified in the mainstream smoke (MS) inhaled by smokers (Chapter 3). Exposure concentrations of these carcinogens to passive smokers are variable but much lower than for active smokers. An excess cancer risk from passive smoking, however, is biologically plausible.

Based on the firmly established causal association of lung cancer with active smoking with a dose-response relationship down to low doses (Chapter 4), passive smoking is considered likely to affect the lung similarly. The widespread presence of ETS in both home and workplace and its absorption by nonsmokers in the general population have been well documented by air sampling and by body measurement of biomarkers such as nicotine and cotinine (Chapter 3). This raises the question of whether any direct evidence exists for the relationship between ETS exposure and lung cancer in the general population and what its implications may be for public health. This

report addresses that question by reviewing and analyzing the evidence from 30 epidemiologic studies of effects from normally occurring environmental levels of ETS (Chapter 5). Because there is widespread exposure and it is difficult to construct a truly unexposed subgroup of the general population, these studies attempt to compare individuals with higher ETS exposure to those with lower exposures. Typically, female never-smokers who are married to a smoker are compared with female never-smokers who are married to a nonsmoker. Some studies also consider ETS exposure of other subjects (i.e., male never-smokers and long-term former smokers of either sex) and from other sources (e.g., workplace and home exposure during childhood), but these studies are fewer and represent fewer cases, and they are generally excluded from the analysis presented here. Use of the female never-smoker studies provides the largest, most homogeneous database for analysis to determine whether an ETS effect on lung cancer is present. This report assumes that the results for female never-smokers are generalizable to all nonsmokers.

Given that ETS exposures are at actual environmental levels and that the comparison groups are both exposed to appreciable background (i.e., nonspousal) ETS, any excess risk for lung cancer from exposure to spousal smoke would be expected to be small. Furthermore, the risk of lung cancer is relatively low in nonsmokers, and most studies have a small sample size, resulting in a very low statistical power (probability of detecting a real effect if it exists). Besides small sample size and low incremental exposures, other problems inherent in several of the studies may also limit their ability to detect a possible effect. Therefore, this report examines the data in several different ways. After downward adjustment of the relative risks for smoker misclassification bias, the studies are individually assessed for strength of association, both for the overall data and for the highest exposure group when exposure-level data are available, and for exposure-response trend. Then the study results are pooled by country using statistical techniques for combining data, including both positive and nonpositive results, to increase the ability to determine whether or not there is an association between ETS and lung cancer. Finally, in addition to the previous statistical analyses that weight the studies only by size, regardless of design and conduct, the studies are qualitatively evaluated for potential confounding, bias, and likely utility to provide information about any lung carcinogenicity of ETS. Based on these qualitative considerations, the studies are categorized into one of four tiers and then statistically analyzed successively by tier.

Results from all of the analyses described above strongly support a causal association between lung cancer ETS exposure. The overall proportion (9/30) of individual studies found to show an association between lung cancer and spousal ETS exposure at all levels combined is unlikely to occur by chance ($p < 10^{-4}$). When the analysis focuses on higher levels of spousal exposure, every one of the 17 studies with exposure-level data shows increased risk in the highest

exposure group; 9 of these are significant at the $p < 0.05$ level, despite most having low power, another result highly unlikely to occur by chance ($p < 10^{-7}$). Similarly, the proportion (10/14; $p < 10^{-9}$) showing a statistically significant exposure-response trend is highly supportive of a causal association.

Combined results by country showed statistically significant associations for Greece (2 studies), Hong Kong (4 studies), Japan (5 studies), and the United States (11 studies), and in that order of strength of relative risk. Pooled results of the four Western European studies (three countries) actually showed a slightly stronger association than that of the United States, but it was not statistically significant, probably due to the smaller sample size. The combined results of the Chinese studies do not show an association between ETS and lung cancer; however, two of the four Chinese studies were designed mainly to determine the lung cancer effects of high levels of other indoor air pollutants indigenous to those areas, which would obscure a smaller ETS effect. These two Chinese studies do, however, provide very strong evidence on the lung carcinogenicity of these other indoor air pollutants, which contain many of the same components as ETS. When results are combined only for the other two Chinese studies, they demonstrate a statistically significant association for ETS and lung cancer.

The heterogeneity of observed relative risk estimates among countries could result from several factors. For example, the observed differences may reflect true differences in lung cancer rates for never-smokers, in ETS exposure levels from nonspousal sources, or in related lifestyle characteristics in different countries. For the time period in which ETS exposure was of interest for these studies, spousal smoking is considered to be a better surrogate for ETS exposure in more "traditional" societies, such as Japan and Greece, than in the United States. In the United States, other sources of ETS exposure (e.g., work and public places) are generally higher, which obscures the effects of spousal smoking and may explain the lower relative risks observed in the United States. Nevertheless, despite observed differences between countries, all showed evidence of increased risk.

Based on these analyses and following the U.S. EPA's *Guidelines for Carcinogen Risk Assessment* (U.S. EPA, 1986a), EPA concludes that environmental tobacco smoke is a Group A (known human) carcinogen. This conclusion is based on a total weight of evidence, principally:

- Biological plausibility. ETS is taken up by the lungs, and components are distributed throughout the body. The presence of the same carcinogens in ETS and MS, along with the established causal relationship between lung cancer and active smoking with the dose-response relationships exhibited down to low doses, establishes the plausibility that ETS is also a lung carcinogen.

- Supporting evidence from animal bioassays and genotoxicity experiments. The carcinogenicity of tobacco smoke has been demonstrated in lifetime inhalation studies in the hamster, intrapulmonary implantations in the rat, and skin painting in the mouse. There are no lifetime animal inhalation studies of ETS; however, the carcinogenicity of SS condensates has been shown in intrapulmonary implantations and skin painting experiments. Positive results of genotoxicity testing for both MS and ETS provide corroborative evidence for their carcinogenic potential.
- Consistency of response. All 4 of the cohort studies and 20 of the 26 case-control studies observed a higher risk of lung cancer among the female never-smokers classified as ever exposed to any level of spousal ETS. Furthermore, every one of the 17 studies with response categorized by exposure level demonstrated increased risk for the highest exposure group. When assessment was restricted to the 19 studies judged to be of higher utility based on study design, execution, and analysis (Appendix A), 17 observed higher risks, and 6 of these increases were statistically significant, despite most having low statistical power. Evaluation of the total study evidence from several perspectives leads to the conclusion that the observed association between ETS exposure and increased lung cancer occurrence is not attributable to chance.
- Broad-based evidence. These 30 studies provide data from 8 different countries, employ a wide variety of study designs and protocols, and are conducted by many different research teams. Results from all countries, with the possible exception of two areas of China where high levels of other indoor air lung carcinogens were present, show small to modest increases in lung cancer associated with spousal ETS exposure. No alternative explanatory variables for the observed association between ETS and lung cancer have been indicated that would be broadly applicable across studies.
- Upward trend in exposure-response. Both the largest of the cohort studies--the Japanese study of Hirayama with 200 lung cancer cases--and the largest of the case-control studies--the U.S. study by Fontham and associates (1991) with 420 lung cancer cases and two sets of controls--demonstrate a strong exposure-related statistical association between passive smoking and lung cancer. This upward trend is well supported by the preponderance of epidemiology studies. Of the 14 studies that provide sufficient data for a trend test by exposure level, 10 were statistically significant despite most having low statistical power.
- Detectable association at environmental exposure levels. Within the population of married women who are lifelong nonsmokers, the excess lung cancer risk from

exposure to their smoking husbands' ETS is large enough to be observed, even for all levels of their spousal exposure combined. Carcinogenic responses are usually detectable only in high-exposure circumstances, such as occupational settings, or in experimental animals receiving very high doses. In addition, effects are harder to observe when there is substantial background exposure in the comparison groups, as is the case here.

- Effects remain after adjustment for potential upward bias. Current and ex-smokers may be misreported as never-smokers, thus inflating the apparent cancer risk for ETS exposure. The evidence remains statistically significant and conclusive, however, after adjustments for smoker misclassification. For the United States, the summary estimate of relative risk from nine case-control plus two cohort studies is 1.19 (90% confidence interval [C.I.] = 1.04, 1.35; $p < 0.05$) after adjustment for smoker misclassification. For Greece, 2.00 (1.42, 2.83), Hong Kong, 1.61 (1.25, 2.06), and Japan, 1.44 (1.13, 1.85), the estimated relative risks are higher than those of the United States and more highly significant after adjusting for the potential bias.
- Strong associations for highest exposure groups. Examining the groups with the highest exposure levels increases the ability to detect an effect, if it exists. Nine of the sixteen studies worldwide for which there are sufficient exposure-level data are statistically significant for the highest exposure group, despite most having low statistical power. The overall pooled estimate of 1.81 for the highest exposure groups is highly statistically significant (90% C.I. = 1.60, 2.05; $p < 10^{-6}$). For the United States, the overall pooled estimate of 1.38 (seven studies, corrected for smoker misclassification bias) is also highly statistically significant (90% C.I. = 1.13, 1.70; $p = 0.005$).
- Confounding cannot explain the association. The broad-based evidence for an association found by independent investigators across several countries, as well as the positive exposure-response trends observed in most of the studies that analyzed for them, make any single confounder highly unlikely as an explanation for the results. In addition, this report examined potential confounding factors (history of lung disease, home heat sources, diet, occupation) and concluded that none of these factors could account for the observed association between lung cancer and ETS.

1.3.1.2. *Estimation of Population Risk*

The individual risk of lung cancer from exposure to ETS does not have to be very large to translate into a significant health hazard to the U.S. population because of the large number of smokers and the widespread presence of ETS. Current smokers comprise approximately 26% of the U.S. adult population and consume more than one-half trillion cigarettes annually (1.5 packs per day, on average), causing nearly universal exposure to at least some ETS. As a biomarker of tobacco smoke uptake, cotinine, a metabolite of the tobacco-specific compound nicotine, is detectable in the blood, saliva, and urine of persons recently exposed to tobacco smoke. Cotinine has typically been detected in 50% to 75% of reported nonsmokers tested (50% equates to 63 million U.S. nonsmokers age 18 or older).

The best estimate of approximately 3,000 lung cancer deaths per year in U.S. nonsmokers age 35 and over attributable to ETS (Chapter 6) is based on data pooled from all 11 U.S. epidemiologic studies of never-smoking women married to smoking spouses. Use of U.S. studies should increase the confidence in these estimates. Some mathematical modeling is required to adjust for expected bias from misclassification of smoking status and to account for ETS exposure from sources other than spousal smoking. The overall relative risk estimate of 1.19 for the United States, already adjusted for smoker misclassification bias, becomes 1.59 after adjusting for background ETS sources (1.34 for nonspousal exposures only). Assumptions are also needed to relate responses in female never-smokers to those in male never-smokers and ex-smokers of both sexes, and to estimate the proportion of the nonsmoking population exposed to various levels of ETS. Overall, however, the assumptions necessary for estimating risk add far less uncertainty than other EPA quantitative assessments. This is because the extrapolation for ETS is based on a large database of human studies, all at levels actually expected to be encountered by much of the U.S. population.

The components of the 3,000 lung cancer deaths figure include approximately 1,500 female never-smokers, 500 male never-smokers, and 1,000 former smokers of both sexes. More females are estimated to be affected because there are more female than male nonsmokers. These component estimates have varying degrees of confidence; the estimate of 1,500 deaths for female never-smokers has the highest confidence because of the extensive database. The estimate of 500 for male never-smokers is less certain because it is based on the female never-smoker response and is thought to be low because males are generally subject to higher background ETS exposures than females. Adjustment for this higher background exposure would lead to higher risk estimates. The estimate of 1,000 lung cancer deaths for former smokers of both sexes is

considered to have the lowest confidence, and the assumptions used are thought to make this estimate low as well.

Workplace ETS levels are generally comparable with home ETS levels, and studies using body cotinine measures as biomarkers demonstrate that nonspousal exposures to ETS are often greater than exposure from spousal smoking. Thus, this report presents an alternative breakdown of the estimated 3,000 ETS-attributable lung cancer deaths between spousal and nonspousal exposures. By extension of the results from spousal smoking studies, coupled with biological measurements of exposure, more lung cancer deaths are estimated to be attributable to ETS from combined nonspousal exposures--2,200 of both sexes--than from spousal exposure--800 of both sexes. This spouse-versus-other-sources partitioning depends on current exposure estimates that may or may not be applicable to the exposure period of interest. Thus, this breakdown contains this element of uncertainty in addition to those discussed above with respect to the previous breakdown.

An alternative analysis, based on the large Fontham et al. (1991) study, which is the only study that provides biomarker estimates of both relative risk and ETS exposure, yields population risk point estimates of 2,700 and 3,600. These population risk estimates are highly consistent with the estimate of 3,000 based on the combined U.S. studies.

While there is statistical variance around all of the parameters used in the quantitative assessment, the two largest areas of uncertainty are probably associated with the relative risk estimate for spousal ETS exposure and the parameter estimate for the background ETS exposure adjustment. A sensitivity analysis that independently varies these two estimates yields population risk estimates as low as 400 and as high as 7,000. These extremes, however, are considered unlikely; the more probable range is narrower, and the generally conservative assumptions employed suggest that the actual population risk number may be greater than 3,000. Overall, considering the multitude, consistency, and quality of all these studies, the weight-of-evidence conclusion that ETS is a known human lung carcinogen, and the limited amount of extrapolation necessary, the confidence in the estimate of approximately 3,000 lung cancer deaths is medium to high.

1.3.2. ETS and Noncancer Respiratory Disorders

Exposure to ETS from parental smoking has been previously linked with increased respiratory disorders in children, particularly in infants. Several studies have confirmed the exposure and uptake of ETS in children by assaying saliva, serum, or urine for cotinine. These cotinine concentrations were highly correlated with smoking (especially by the mother) in the child's presence. Nine to twelve million American children under 5 years of age, or one-half to

two-thirds of all children in this age group, may be exposed to cigarette smoke in the home (American Academy of Pediatrics, 1986; Overpeck and Moss, 1991).

With regard to the noncancer respiratory effects of passive smoking, this report focuses on epidemiologic evidence appearing since the two major reports of 1986 (NRC and U.S. DHHS) that bears on the potential association of parental smoking with detrimental respiratory effects in their children. These effects include symptoms of respiratory irritation (cough, sputum production, or wheeze); acute diseases of the lower respiratory tract (pneumonia, bronchitis, and bronchiolitis); acute middle ear infections and indications of chronic middle ear infections (predominantly middle ear effusion); reduced lung function (from forced expiratory volume and flow-rate measurements); incidence and prevalence of asthma and exacerbation of symptoms in asthmatics; and acute upper respiratory tract infections (colds and sore throats). The more than 50 recently published studies reviewed here essentially corroborate the previous conclusions of the 1986 reports of the NRC and Surgeon General regarding respiratory symptoms, respiratory illnesses, and pulmonary function, and they strengthen support for those conclusions by the additional weight of evidence (Chapter 7). For example, new data on middle ear effusion strengthen previous evidence to warrant the stronger conclusion in this report of a causal association with parental smoking. Furthermore, recent studies establish associations between parental smoking and increased incidence of childhood asthma. Additional research also supports the hypotheses that in utero exposure to mother's smoke and postnatal exposure to ETS alter lung function and structure, increase bronchial responsiveness, and enhance the process of allergic sensitization, changes that are known to predispose children to early respiratory illness. Early respiratory illness can lead to long-term pulmonary effects (reduced lung function and increased risk of chronic obstructive lung disease).

This report also summarizes the evidence for an association between parental smoking and SIDS, which was not addressed in the 1986 reports of the NRC or Surgeon General. SIDS is the most common cause of death in infants ages 1 month to 1 year. The cause (or causes) of SIDS is unknown; however, it is widely believed that some form of respiratory pathogenesis is generally involved. The current evidence strongly suggests that infants whose mothers smoke are at an increased risk of dying of SIDS, independent of other known risk factors for SIDS, including low birthweight and low gestational age, which are specifically associated with active smoking during pregnancy. However, available studies do not allow this report to conclude whether that increased risk is related to in utero versus postnatal exposure to tobacco smoke products, or to both.

The 1986 reports of the NRC and Surgeon General conclude that both the prevalence of respiratory symptoms of irritation and the incidence of lower respiratory tract infections are higher in children of smoking parents. In the 18 studies of respiratory symptoms subsequent to

the 2 reports, increased symptoms (cough, phlegm production, and wheezing) were observed in a range of ages from birth to midteens, particularly in infants and preschool children. In addition to the studies on symptoms of respiratory irritation, 10 new studies have addressed the topic of parental smoking and acute lower respiratory tract illness in children, and 9 have reported statistically significant associations. The cumulative evidence is conclusive that parental smoking, especially the mother's, causes an increased incidence of respiratory illnesses from birth up to the first 18 months to 3 years of life, particularly for bronchitis, bronchiolitis, and pneumonia. Overall, the evidence confirms and strengthens the previous conclusions of the NRC and Surgeon General.

Recent studies also solidify the evidence for the conclusion of a causal association between parental smoking and increased middle ear effusion in young children. Middle ear effusion is the most common reason for hospitalization of young children for an operation.

At the time of the Surgeon General's report on passive smoking (U.S. DHHS, 1986), data were sufficient to conclude only that maternal smoking may influence the severity of asthma in children. The recent studies reviewed here strengthen and confirm these exacerbation effects. The new evidence is also conclusive that ETS exposure increases the number of episodes of asthma in children who already have the disease. In addition, the evidence is suggestive that ETS exposure increases the number of new cases of asthma in children who have not previously exhibited symptoms, although the results are statistically significant only with children whose mothers smoke 10 or more cigarettes per day. While the evidence for new cases of asthma itself is not conclusive of a causal association, the consistently strong association of ETS both with increased frequency and severity of the asthmatic symptoms and with the established ETS effects on the immune system and airway hyperresponsiveness lead to the conclusion that ETS is a risk factor for induction of asthma in previously asymptomatic children.

Regarding the effects of passive smoking on lung function in children, the 1986 NRC and Surgeon General reports both conclude that children of parents who smoke have small decreases in tests of pulmonary output function of both the larger and smaller air passages when compared with the children of nonsmokers. As noted in the NRC report, if ETS exposure is the cause of the observed decrease in lung function, the effect could be due to the direct action of agents in ETS or an indirect consequence of increased occurrence of acute respiratory illness related to ETS.

Results from eight studies on ETS and lung function in children that have appeared since those reports add some additional confirmatory evidence suggesting a causal rather than an indirect relationship. For the population as a whole, the reductions are small relative to the interindividual variability of each lung function parameter. However, groups of particularly susceptible or heavily exposed children have shown larger decrements. The studies reviewed

suggest that a continuum of exposures to tobacco products starting in fetal life may contribute to the decrements in lung function found in older children. Exposure to tobacco smoke products inhaled by the mother during pregnancy may contribute significantly to these changes, but there is strong evidence indicating that postnatal exposure to ETS is an important part of the causal pathway.

With respect to lung function effects in adults exposed to ETS, the 1986 NRC and Surgeon General reports found the data at that time inconclusive, due to high interindividual variability and the existence of a large number of other risk factors, but compatible with subtle deficits in lung function. Recent studies confirm the association of passive smoking with small reductions in lung function. Furthermore, new evidence also has emerged suggesting a subtle association between exposure to ETS and increased respiratory symptoms in adults.

Some evidence suggests that the incidence of acute upper respiratory tract illnesses and acute middle ear infections may be more common in children exposed to ETS. However, several studies failed to find any effect. In addition, the possible role of confounding factors, the lack of studies showing clear dose-response relationships, and the absence of a plausible biological mechanism preclude more definitive conclusions.

In reviewing the available evidence indicating an association (or lack thereof) between ETS exposure and the different noncancer respiratory disorders analyzed in this report, the possible role of several potential confounding factors was considered. These include other indoor air pollutants; socioeconomic status; effect of parental symptoms; and characteristics of the exposed child, such as low birthweight or active smoking. No single or combined confounding factors can explain the observed respiratory effects of passive smoking in children.

For diseases for which ETS has been either causally associated (LRIs) or indicated as a risk factor (asthma cases in previously asymptomatic children), estimates of population-attributable risk can be calculated. A population risk assessment (Chapter 8) provides a probable range of estimates that 8,000 to 26,000 cases of childhood asthma per year are attributable to ETS exposure from mothers who smoke 10 or more cigarettes per day. The confidence in this range of estimates is medium and is dependent on the suggestive evidence of the database. While the data show an effect only for children of these heavily smoking mothers, additional cases due to lesser ETS exposure also are a possibility. If the effect of this lesser exposure is considered, the range of estimates of new cases presented above increases to 13,000 to 60,000. Furthermore, this report estimates that the additional public health impact of ETS on asthmatic children includes more than 200,000 children whose symptoms are significantly aggravated and as many as 1,000,000 children who are affected to some degree.

This report estimates that ETS exposure contributes 150,000 to 300,000 cases annually of lower respiratory tract illness in infants and children younger than 18 months of age and that 7,500 to 15,000 of these will require hospitalization. The strong evidence linking ETS exposure to increased incidence of bronchitis, bronchiolitis, and pneumonia in young children gives these estimates a high degree of confidence. There is also evidence suggesting a smaller ETS effect on children between the ages of 18 months and 3 years, but no additional estimates have been computed for this age group. Whether or not these illnesses result in death has not been addressed here.

In the United States, more than 5,000 infants die of SIDS annually. It is the major cause of death in infants between the ages of 1 month and 1 year, and the linkage with maternal smoking is well established. The Surgeon General and the World Health Organization estimate that more than 700 U.S. infant deaths per year from SIDS are attributable to maternal smoking (CDC, 1991a, 1992b). However, this report concludes that at present there is not enough direct evidence supporting the contribution of ETS exposure to declare it a risk factor or to estimate its population impact on SIDS.

TOBACCO PRODUCTS: AMERICA'S LEAST REGULATED, ADDICTIVE DRUG

IT'S TIME TO LEVEL THE REGULATORY PLAYING FIELD

Coalition on Smoking OR Health

AMERICAN CANCER SOCIETY®

American Heart Association

AMERICAN LUNG ASSOCIATION

American Heart Association

AMERICAN LUNG ASSOCIATION®
The Christmas Seal People®

AMERICAN CANCER SOCIETY®

Coalition on Smoking OR Health

WHO'S MINDING THE TOBACCO STORE?

IT'S TIME TO LEVEL THE REGULATORY PLAYING FIELD

John Slade, M.D.
Scott Ballin, J.D.

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"We accept an interest in people's health
as a basic responsibility, paramount to
every other consideration in our business."

Tobacco Industry Advertisement to the American Public
The New York Times, January 1954

I. INTRODUCTION

As the Food and Drug Administration continues to use its authorities to protect the health and welfare of the American public from misbranded, adulterated, dangerous products, there still remains one product that in spite of the fact that it kills over 430,000 Americans each year remains, as columnist Ellen Goodman noted, the "Missing Entree in the Regulatory Menu." That product is tobacco. Its absence from specific regulatory controls is not an accident but rather a tribute to the tobacco industry's long time strangle hold over the Congress and the Executive branch. What other product can boast that it is a major cause of cancer, heart disease, emphysema, stroke, premature births and other ailments and still be allowed on the market? What other addictive drug (nicotine) can be sold on the market with virtually no federal advertising, promotion and distribution constraints except for so-called industry "voluntary efforts," which have not protected the public, for nearly 30 years? And what other product can make unsubstantiated implied health claims about itself (i.e. low tar, low nicotine and weight control), contain dozens of untested and undisclosed chemical additives, as well as undisclosed harmful constituents, and still remain on the market?

It is now almost 30 years since the first Surgeon General's Report was released implicating cigarettes as a cause of cancer -- almost 30 years since Surgeon General Luther Terry, M.D. first indicated that any voluntary efforts by the tobacco industry did not "obviate the desirability of enacting specific regulatory authority to express those minimum standards that protection of the public interest requires."

In 1964, when the first Surgeon General's Report on cigarette smoking and cancer was first released, numerous bills were introduced in Congress that would have resulted in specific authorities being vested in the Federal Trade Commission and the Food and Drug Administration designed to ensure the proper regulation of this dangerous consumer product. Unfortunately the tobacco industry was quick to develop legislative and public relations strategies that were designed to ensure that no such laws were enacted. As a former Vice President of the Tobacco Institute, Frederick R. Panzer, was to later acknowledge in a 1972

the Toxic Substances Act and the Federal Hazardous Substances Act. Because the Congress has failed to deal with the tobacco issue, millions of people have needlessly died or been disabled from cardiovascular disease, cancer, emphysema, stroke and a host of other diseases. With health care costs continuing to skyrocket, with preventive health measures finally being viewed as critical to health care reform, many national health organizations as well as many members of Congress believe it is time for a change.

FDA Commissioner David Kessler has on many occasions expressed his strong belief about the role he sees for the FDA in carrying out its statutory responsibilities, especially for high risk products which have the greatest impact on health. As he said in a speech published in the November 1991 edition of the Food Drug Cosmetic Law Journal:

> I have set a range of goals to make the agency more credible, more efficient and better equipped to serve the country in the future. But if you ask what is the essence of my program I would answer quite simply that it is to enforce the law.

Setting aside the historical, political, or economic circumstances surrounding the tobacco issue, it is obvious that this product should have and would have been removed from the marketplace a long time ago. Instead, today we find ourselves at the other extreme -- faced with the manufacturing, distribution, sale, labeling and advertising of a widely used, addictive product that is subject to minimal and ineffective regulation. What follows is a three pronged proposal to correct this national travesty.

- **The Executive Branch at both federal and state levels should use every available means to make the regulation of tobacco products a central feature of health policy and practice.**

- **The FDA and the analogous existing authorities within states should regulate tobacco products which make health claims (implied or direct) or which seek to alter the structure or function of the body and therefore fall squarely under the definitional requirements for "drugs."**

- **The Food, Drug and Cosmetic Act (FDC Act) should be amended through legislation to specifically and unequivocally bring tobacco in line with the ways and means other products (particularly those presenting health risks to the public) are regulated.**

> the article, through his representations in connection with its sale can determine the use to which the article is to be put. (Senate Report 74-361, 74th Congress 1st Session, 1935p. 4. See also, U.S. v. Article---Sudden Change, 409 F.2d 734, 739., 1969.)

It is, thus, legally arguable that low tar and low nicotine cigarettes clearly fit within the parameters of what both the Congress and the courts and state laws intended when they defined drugs. Tobacco companies manufacture, advertise, promote, and sell low tar and low nicotine with the obvious intention of playing on the public's perception that use of these products will mitigate and prevent the onset of disease associated with smoking.

Court Rulings Find Tobacco Products to be "Drugs" Under the FDC Act

The expanded definition of "drugs" was applied against cigarettes in two FDA related court cases in the 1950s. The courts found that conventional cigarettes could be "drugs" under certain circumstances. In the court's view, the question of whether or not the FDA could assert jurisdiction over tobacco hinged on whether or not the products were being sold as articles intended to either mitigate or prevent disease or intended to affect the function or structure of the body and thus were not sold just for "smoking pleasure only."

As the court noted in U.S. v. 46 Cartons Fairfax Cigarettes:

> If claimant's labeling was such that it created in the mind of the public the idea that these cigarettes could be used for the mitigation or prevention of the various named diseases, claimant cannot now be heard to say that it is selling only cigarettes and not drugs.... The ultimate impression upon the mind of the reader arises from the sum total of not only what is said, but also all that is reasonably implied. If claimant wishes to reap the reward of such claims let it bear the responsibility as Congress has seen fit to impose on it. (Emphasis added.)

This was the first time that cigarettes were found to be subject to the FDA's jurisdiction because they were not sold "merely for smoking pleasure" but had other intended purposes. Because those cigarettes could not meet the statutory and regulatory requirements of the FDC Act, they were removed from the marketplace.

The idea of classifying cigarettes as drugs has been reaffirmed by the FDA in testimony before Congress on numerous occasions and again more recently by the courts. In 1977, for example, in attempting to further clarify FDA's jurisdiction, Action on Smoking and Health (ASH) and others filed a petition with FDA seeking to classify all cigarettes as drugs under Section 201 (g)(C) as articles "intended to affect the structure or any function of the body of

The Coalition's petition concludes that there is a clear indication that the tobacco industry has marketed these products with the clear intention that by using low tar and low nicotine products a smoker can "mitigate" or "prevent" diseases associated with the smoking habit. A series of advertisements run by Vantage brand cigarettes such as the one below in Time magazine on January 8, 1973, blatantly indicated this intended purpose:

> For years, a lot of people have been telling the smoking public not to smoke cigarettes, especially cigarettes with high "tar" and nicotine.... Since the cigarette critics are concerned about high "tar" and nicotine, we would like to offer a constructive proposal. Perhaps, instead of telling us not to smoke cigarettes, they can tell us what to smoke. For instance, perhaps they ought to recommend that the American public smoke Vantage cigarettes.... Vantage gives the smoker flavor like a full-flavor cigarette. But it's the only cigarette that gives him so much flavor with so little "tar" and nicotine....

The message contained in that Vantage advertisement is one that is repeated over and over again in today's marketing of low yield cigarettes. In one recent edition of Life magazine, three such advertisements appeared.

The Coalition's petition has remained pending at the FDA since 1988. Since that petition was filed, over one and a half million Americans have died from cigarette smoking.

Also in 1988, the Coalition on Smoking OR Health and the American Medical Association filed separate petitions seeking to classify a newly developed R. J. Reynolds' cigarette-like device named Premier as a drug under the FDC Act. The arguments asking FDA to assert jurisdiction were based on a premise similar to the low tar and low nicotine petition: that R. J. Reynolds called its new product "cleaner," one which "reduces the controversial compounds" and sold it as "safer," that is, designed to mitigate and prevent disease and to affect functions or structures of the body. Because R. J. Reynolds withdrew the product from the marketplace, no action from the FDA was forthcoming. Petitions on other similar products were filed in 1991 and 1992.

Defining when FDA can -- or cannot -- assert jurisdiction over cigarette or cigarette-like products was further clarified in February 1987. A manufacturer wanted to market a non-tobacco "cigarette-like device consisting of a plug impregnated with nicotine solution inserted with a small tube -- corresponding in appearance to a conventional cigarette." FDA had no difficulty in classifying the product as a "drug." After reviewing promotional material as well as registration material filed with the Securities and Exchange Commission (SEC), the FDA reached the following conclusion:

> It is our position that Favor is a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure or one or more functions of the body.

III. THE NEED TO AMEND THE FOOD, DRUG AND COSMETIC ACT TO REGULATE THE MANUFACTURE, DISTRIBUTION, SALE, ADVERTISING AND PROMOTION OF TOBACCO PRODUCTS

Because tobacco products are dangerous and addictive, it is only rational that, at a minimum, tobacco products be regulated in a manner similar to how other dangerous but legal consumer products are regulated. Past attempts to bring tobacco under the jurisdiction of one or more of the federal health and safety agencies have failed. In recent years, however, new efforts to regulate tobacco have enjoyed increasing support inside and outside of Congress.

The Congress and the public are becoming increasingly aware that, unlike other consumer products, and because of the clout of the tobacco industry, no federal regulatory agency has exerted or been able to exert any health or safety jurisdiction over tobacco products except in the narrow exceptions outlined above.

The tobacco industry would rather this fact be ignored. One of the tobacco industry's public relations ploys has been to try to convince legislators and the public that they are already burdensomely over-regulated and that there is no need to apply standards similar to those that are applied to foods, drugs and cosmetics to tobacco. The reality of the matter is that tobacco products are so dangerous that subjecting them to present FDA laws governing other products would likely result in their total ban. Thus the industry has had to ensure that no health and safety regulations are applied to their products. The discovery documents released in the Cipollone case indicate that they have done this with exceptional skill.

Somewhere between the extremes of the present absence of significant health and safety regulation and a complete ban of the product is a middle ground that will both allow the product to remain on the market and at the same time subject it to necessary regulations governing its manufacture, distribution, sale, labeling, advertising and promotion. Achieving this will require amending the Federal Food, Drug and Cosmetic Act to specifically and unequivocally give the FDA authority over tobacco products. Under such an approach, the tobacco industry would be required to adhere to requirements with which manufacturers of other products have had to comply. For example, does it make sense for the FDA to have full regulatory control over nicotine patches and gum which are designed to help people quit their addictive smoking habits and not be able to have comparable regulatory control over the products causing addiction and death? Clearly, the double standard must end. The health of the public should be put above the political clout of the tobacco industry. Tobacco products should thus be subjected to regulation governing:

- toxicologic testing and disclosure of chemical additives in tobacco products,
- disclosure and warnings related to constituents in both mainstream and sidestream smoke (there are some 4,000 distinct chemicals in tobacco smoke),

cigarette smoking causes disease. In 1954 the Tobacco Industry ran an advertisement in The New York Times that stated:

> "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business." (Emphasis added.)
>
> "We believe the products we make are not injurious to health."
>
> "We always have and always will cooperate closely with those whose task it is to safeguard the public health." (Emphasis added.)

In 1964 Bowman Gray, Chairman of the Board of R. J. Reynolds told a House Committee, "If it is proven that cigarettes are harmful we want to do something regardless of what somebody else tells us to do.. And we would do our level best. This is just being human." Thirty years later, after 50,000 studies have proven that cigarette smoking is a major cause of cancer, cardiovascular disease, emphysema and stroke, the tobacco industry still denies that any relationship between use of their products and disease has been proven and is still engaged in a "holding strategy" designed to head off any serious or significant attempts at having its products properly regulated.

Congress was presented with the opportunity in 1964 to pass significant legislation that could have resulted in the saving of millions of American lives, but failed. The recent decision by the U.S. Supreme Court in Cipollone, while reaffirming the right of individuals to sue tobacco companies under many causes of action, also reminded us of the glaring loophole that exists in our federal health and safety laws when it comes to tobacco. By attempting to reserve for itself the role of solo regulator of tobacco products and then failing to carry out its responsibilities, Congress has done a tremendous disservice to the health of all Americans. Unless Congress (as well as the FDA) has the courage to undo what it did in 1964 under pressures from the industry, tobacco products will, tragically, remain the leading cause of preventable death and disability in the United States.

IV. OPPORTUNITIES FOR STATE REGULATION OF TOBACCO PRODUCTS.

Under our federal system of government, the protection of the public health is largely a responsibility of state and, by extension, local government. Although there has been little regulation of tobacco products at the state level, states have a variety of powers to protect their citizens. Existing consumer protection laws can be used for this purpose, and the U.S. Supreme Court's decision in Cipollone (June 1992) opens up additional opportunities for protecting the public at the state and local levels.

States pursuing actions under these laws might seek remedies which have symmetry with the losses suffered because of tobacco products. These might include:

- funding a public information campaign,[1]
- payments to Medicaid for the costs of care for tobacco-caused illness, and
- undoing the fraud by paying for quit-smoking treatment.

Under many laws, individuals can pursue private actions as well. In such actions, the person(s) bringing the complaint must make a showing of injury or damage. As with state action, though, the private party need not show reliance on the deceptive practice. Penalties are only available for injury or damage caused by deceptive practices.

New Opportunities to Regulate Tobacco Products. The U.S. Supreme Court's decision in Cipollone severely limits the degree to which federal law preempts state regulation of tobacco products. While the tobacco industry had claimed an expansive protection, immunizing itself from virtually all state action, the Court held that the only thing states could not do was regulate cigarette advertising in a couple of narrow, specific ways.

Section 5 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C.A. S 1334, as amended) includes the following preemption provision:

> (a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

Edward O. Correia, a professor of law at Northeastern University School of Law, has explored the opportunities available to states in the wake of the Cipollone decision in his

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[1] American Brands, the maker of MISTY cigarettes calls its direct mail operation a "Smokers Information Center." Since each tobacco company maintains extensive mailing lists of its customers and potential customers, information on harms from smoking and advice on how to quit could easily be sent to these individuals directly as part of public information campaigns.

- FDA should use its existing authorities to regulate all "low yield" tobacco products as drugs under Sec. 201 of the Federal Food, Drug and Cosmetic Act.

- Congress should enact specific statutory authorities which without question give the Food and Drug Administration the authority and the resources to regulate the manufacture, distribution, sale, labeling, advertising and promotion of tobacco products.

State

- The nation's governors should make the regulation of tobacco products a priority in health policy initiatives.

- States should use their existing drug authorities to regulate "low yield" tobacco products as drugs.

- States should consider enacting specific statutory provisions which would regulate the manufacture, distribution, sale, labeling, advertising and promotion of tobacco products as a class of drug. These new requirements should include full disclosures of ingredients and of information known to the manufacturers about the toxicity of the products as well as requirements that the manufacturers assist customers who want to quit.

- States should ban billboards which advertise tobacco products.

- States should use existing consumer protection authorities to regulate the manufacture, distribution, sale, labeling, advertising and promotion of tobacco products.

25 YEARS OF FAILED SELF-REGULATION AND CORPORATE IRRESPONSIBILITY

"We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business.

"We believe the products we make are not injurious to health."

Tobacco Industry Research Committee
paid advertisement that appeared in the
New York Times on
January 4, **1954**

* * * * * *

"Cigarette Makers Adopt an Industry Code for Ads"

"The nation's major cigarette companies have agreed on a cigarette advertising code that would be enforced by an independent administrator.... Provisions of the code would bar ads directed mainly at persons under 21 years of age...."

New York Times,
April 28, **1964**

* * * * * *

"Advertising is basic to the successful distribution and sale of any consumer item on a national basis.

"On April 27, (1964) the cigarette companies announced the Cigarette Advertising Code. This code prescribes certain standards for cigarette advertising. The standards relate primarily to two areas: advertising which has an appeal to young people.... Under the code, all cigarette advertising must be submitted to the administrator before it is used. The administrator is fully empowered to determine whether advertising complies with the standards of the code. If it doesn't he will veto its use. Any company who violates the administrators ruling may be required to pay up to $100,000.

"This advertising code represents a sincere effort by the industry to respond to criticism of the industry's advertising which has been voiced in some quarters. It is an earnest effort at industry self regulation. I hope that the industry will be given a reasonable opportunity to implement this code."

Statement of Bowman Gray, on behalf of the
tobacco industry,
before the House Committee on Interstate and
Foreign Commerce,
June 25, **1964**

* * * * * *

"It's conduct (tobacco industry's) has been both responsive and responsible to an extent unparalleled in American industry.... In 1964 it established an advertising and promotion code to limit its message from reaching youth audiences. Although the code has been technically terminated, its principles are still adhered to."

Statement of Horace Kornegay
President, Tobacco Institute
before the Senate Committee on Commerce
February 1, 1972

* * * * * *

"After three decades of investigation and millions of dollars invested ... the smoking and health controversy remains unresolved. The net result of all of this effort has been that no causal link between smoking and disease has been established. This is a scientific fact readily available to anyone willing to make an objective unemotional study of the existing evidence."

Statement of Edward A. Horrigan, Jr.
on behalf of the Tobacco Institute
before the House Energy and Commerce Committee
March 12, 1982

* * * * * *

"Smoking is an adult practice to be considered only by those mature enough to make an informed decision. In 1964 we adopted a cigarette advertising code prohibiting advertising, marketing and sampling directed at young people.

"In short our industry has acted responsibly in the past and we see no reason anyone should feel that we will not continue to do so in the future."

Statement of Edward A. Horrigan, Jr.
on behalf of the Tobacco Institute
before the House Energy and Commerce Committee
March 16, 1982

* * * * * *

"As you know the cigarette industry has long taken the position that cigarette smoking is only for those adults who choose to smoke. The voluntary advertising and sampling restrictions ... have been designed to implement that policy decision."

"In addition, such advertising may not suggest that smoking is essential to social prominence, distinction, success or sexual attraction."

"The major U.S. cigarette manufacturers also have adopted, and have aggressively implemented a Code of Cigarette Sampling Practices."

"In addition the Institute as well as individual cigarette manufacturers have sponsored a variety of advertisements encouraging parents to intercede with their children to prevent them from smoking."

"The gist of the advertisements perhaps can be illustrated by the headline, 'Do cigarette companies want kids to smoke?' No. As a matter of policy. No. As a matter of practice. No. As a matter of Fact No!"

"Working with the National Association of State Boards of Education, or NASBE, we have undertaken an ambitious program to assist parents in persuading their children not to become involved in activities appropriately reserved for adults, including cigarette smoking. That program has been vigorously promoted by extensive advertising in major media."

"We are proud of the industry's record with respect to cigarette advertising generally and youth smoking in particular. We would submit that the industry's record is one of unparalleled restraint and responsibility."

Statement of Horace R. Kornegay Chairman,
Tobacco Institute
Before the House Energy and Commerce Committee,
August 1, 1986

* * * * * *

"The Tobacco Institute is today announcing a series of new initiatives. These broad based, new programs are designed to discourage youth ... to reduce youth access to products and to address concerns that have been expressed recently about cigarette advertising and promotion. In announcing these initiatives, I feel it's important to first point out that they expand and reaffirm this industry's long standing commitment and a history of positive actions against youth smoking."

Statement of Brennan M. Dawson
Vice President, Tobacco Institute
December 11, 1990

* * * * * *

American Heart Association

AMERICAN LUNG ASSOCIATION® The Christmas Seal People®

AMERICAN CANCER SOCIETY®

Coalition on Smoking OR Health

February 19, 1993

The Honorable
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative :

You have previously received from the Coalition on Smoking OR Health copies of our 1993 legislative/regulatory agenda as well as a copy of an extensive article that appeared in the Greensboro News & Record concerning the misinformation campaigns conducted by the tobacco industry to mislead the public and Congress about the need to regulate this dangerous product. We hope you have taken the time to seriously review those articles.

Enclosed you will find another article on the same subject that appeared on the front page of the Wall Street Journal on Thursday, February 11, 1993. Again the findings are revealing and of great concern to the health community.

As a member of the House Energy and Commerce Committee only you can undo the tragic mistake that was made back in 1964 when the tobacco industry convinced legislators that they were truly seeking the answers and the solutions to the tobacco and health problem. As the Wall Street Journal article notes, the deception really began in 1954 when the industry ran a full page advertisement in the New York Times in which they assured the public that they accepted "an interest in people's health as a basic responsibility, paramount to every other consideration in our business."

It is no longer appropriate to talk about health care reform and turn a blind eye to the one product that accounts for 430,000 deaths each year and is conspicuously absent from any regulatory controls. It is time to regulate the

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manufacture, distribution, sale, labeling and advertising of this product in a manner consistent with the way other legal products in our society are regulated. It is time for the Food and Drug Administration to be given the clear statutory authority it needs to ensure that the health of the American public is protected to the maximum extent possible without banning the product. It is time to end this thirty year charade that has taken the lives of millions and millions of Americans. We hope that you will put health above the economic interests of the tobacco industry and do what is both fair and equitable.

Sincerely,

Alan Davis
Vice President for Public Affairs
American Cancer Society

Scott D. Ballin
Vice President for Public Affairs
American Heart Association

Fran Du Melle
Deputy Managing Director
American Lung Association

cc: local American Heart Association, American Lung Association and American Cancer Society Affiliates

Smoke and Mirrors

How Cigarette Makers Keep Health Question 'Open' Year After Year

Council for Tobacco Research Is Billed as Independent But Guided by Lawyers

An Industry Insurance Policy

By Alix M. Freedman
And Laurie P. Cohen
Staff Reporters of The Wall Street Journal

This is the story of the longest-running misinformation campaign in U.S. business history, and how it may ultimately backfire on its corporate sponsors.

The tale opens in 1954. Cigarette smoking, like tail fins and the new music called rock-and-roll, was fun and glamorous. But a warning had just been sounded that smoking might not be good for you. A scientist at Memorial Sloan-Kettering Cancer Center had painted tobacco tars on the backs of mice and produced tumors. The tobacco industry met this sudden threat head-on.

In full-page newspaper ads headlined "A Frank Statement to Cigarette Smokers," tobacco companies announced that a new research group, funded by the industry but independent, would examine "all phases of tobacco use and health." Its solemn pledge: "We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business."

The tobacco industry's main vehicle for damage control was up and running.

Sowing Doubt

For almost four decades, the Council for Tobacco Research in New York City has been the hub of a massive effort to cast doubt on the links between smoking and disease. Sponsored by U.S. tobacco companies and long run behind the scenes by tobacco-industry lawyers, the ostensibly independent council has spent millions of dollars advancing sympathetic science. At the same time, it has sometimes disregarded, or even cut off, studies of its own that implicated smoking as a health hazard.

"When CTR researchers found out that cigarettes were bad and it was better not to smoke, we didn't publicize that" in press releases, says Dorothea Cohen, who for 24 years until her retirement in 1989 wrote summaries of grantee research for the Council's annual report. "The CTR is just a lobbying thing. We were lobbying for cigarettes."

Many companies under attack for their products have underwritten research to buttress safety claims. What sets the tobacco industry apart are the scope, aggressiveness and persistence of its undertaking. For decades rival tobacco companies have acted in concert to combat the growing body of evidence linking their products to cancer, heart disease and emphysema.

Cheap Insurance

The U.S. Centers for Disease Control today links 434,000 deaths a year to smoking. The surgeon general has declared smoking "the single largest preventable cause of death and disability," citing "overwhelming" evidence from no less than 50,000 studies. Yet the wisp of uncertainty supplied by the Council has always been enough to protect the $50 billion industry in Congress and especially in court, and tobacco companies have never paid a dime in product liability claims.

Addison Yeaman, a former Brown & Williamson Co. lawyer and ex-chairman of the Council, says the passage of time hasn't altered his faith in this view expressed at a Council meeting in 1975: The "CTR is [the] best and cheapest insurance the tobacco industry can buy, and without it, the industry would have to invent CTR or would be dead."

Michael Pertschuk, a former chairman of the Federal Trade Commission, finds the industry's defense extraordinary: "There never has been a health hazard so perfectly proven as smoking, and it is a measure of the Council's success that it is able to create the illusion of controversy in what is so elegantly a closed scientific case."

A Legal Peril

But now the device the industry has so long used to deflect attack has become its biggest vulnerability. That is because the Supreme Court last year said smokers can sue accusing the industry of deliberately hiding or distorting smoking's dangers. And the U.S. attorney's office in Brooklyn, N.Y., is conducting a criminal investigation into whether the industry used the Council to defraud the public.

Whether anything will come of the criminal inquiry – and whether plaintiffs can convince juries that the industry did in fact misrepresent health hazards – are very much open questions; just last month, one jury rejected allegations of a conspiracy. But if plaintiffs should begin to succeed, perhaps by gaining access to now-secret Council documents, they could turn on its head what up to now has been an almost totally winning industry strategy.

The Council for Tobacco Research declined to respond to questions about its activities, as did all of the Big Six tobacco companies – Philip Morris Cos., RJR Nabisco Holdings Corp., American Brands Inc., B.A.T Industries PLC (parent of Brown & Williamson), Loews Corp. (parent of Lorillard) and Brooke Group Ltd. (parent of Liggett Group).

At the outset, many in the industry

Continued From First Page

thought the late-1953 crisis posed by the Sloan-Kettering mouse research was entirely manageable. With the Council, "the industry was told that in the best of worlds, we'd do a great service to mankind," says James Bowling, a former Philip Morris director. "Our product either would be exonerated or, if involved [in causing cancer], they'd identify the ingredients and we'd take them out. We thought this is marvelous."

So apparently did some scientists. The Council snagged a noted figure, Clarence Cook Little, as its scientific director. Thanks to his renown as a former University of Michigan president and director of a prestigious laboratory, the Council was able to attract an illustrious scientific advisory board, which culled through proposals from a who's who of American scientists who sought its research grants. Over the years, it has doled out more than $200 million.

But the Council's role was never just research. It was largely a creature of Hill & Knowlton, the public-relations firm, which cigarette merchants retained when the mouse research came out. Hill & Knowlton installed the Council in the Empire State Building in New York one floor beneath its own offices, with one of the PR firm's staffers as the supposedly independent research council's executive director. Hill & Knowlton also began publishing a newsletter that reported such news items as "Lung Cancer Found In Non-Smoking Nuns," and it helped authors generate books with titles like "Smoke Without Fear" and "Go Ahead and Smoke."

Some people, including many in the news media, were skeptical of the Council. "To reporters, the Council was never independent," says Earl Ubell, a veteran science reporter at WCBS-TV in New York. "It was a wholly owned subsidiary of the tobacco industry." But in the interest of balance, journalists writing on smoking and health routinely included the Council's views.

And many smokers lacked the professional skepticism of reporters. "You would have to have lived in that era to understand—they kept providing false reassurances, so I had no idea that smoking was so very dangerous," says Janet Sackman, who once appeared in ads as Miss Lucky Strike and who now has throat cancer.

As early as 1958, however, the Council had strong intimations from studies it financed that smoking could be dangerous. "Cigarette smoke condensate is a weak mouse skin carcinogen," said a Council-financed study completed in that year.

Ensuing Council-financed research found more links to disease. In 1961, a study of 140 autopsies at a Veterans hospital in Iowa City, Iowa, said "a history of cigarette smoking is significantly related to the incidence of carcinoma." In 1963, researchers at Philadelphia General Hospital and the University of Pennsylvania linked chronic smoking to earlier coronary artery disease and a higher incidence of coronary occlusion.

The Council summarized such results in its annual reports, but it often chose other research to stress to the public. Ms. Cohen, who wrote the summaries, cites a 1965 study that said pregnant women who smoked had smaller babies and were more likely to give birth prematurely. But the industry in 1982 submitted to Congress a study the Council hadn't financed, saying that smokers had no greater risk of premature babies and that low birth weight wasn't a problem.

"In the '60s," says Ms. Cohen, "there was so much bad news about smoking that there really wasn't much the CTR could put out, but anything they could find they would use."

THE LAWYERS STEP IN

By 1964, keeping the case open was no longer just shrewd public relations; it had become a legal imperative. As more Americans came to believe smoking could kill, the number of tobacco liability suits jumped to 17 from seven the year before. And in that year, the Surgeon General labeled smoking a health hazard.

It "was a serious, stunning shock," says Mr. Bowling, the former Philip Morris director. "That's the stage at which the lawyers became a lot more involved."

Needing a defense from science as never before, yet dreading the legal exposure that adverse research would bring, the industry created within the Council a Special Projects division—with lawyers, not scientists, at the helm. Much of what it did was shrouded in mystery. "Everything was cloak-and-dagger," recalls John Kreisher, a former associate scientific director of the Council. "We weren't allowed on their floor."

The core of the lawyers' operation was a vast database, storing the world's literature on tobacco and health, data on foes and strategy documents. The lawyers began shuttling the globe, looking for research and expert witnesses. They sought out studies supporting causation of lung cancer by factors other than smoking and research suggesting the complex origin of all diseases linked to tobacco.

Overtures to scientists usually were handled by outside law firms, especially Jacob, Medinger, Finnegan & Hart in New York. It also served as counsel to the Council, and its Edwin Jacob took the lead role at the Special Projects unit. This arrangement offered crucial advantages. Notes Roy Morse, a former research chief at R.J. Reynolds: "As soon as Mr. Jacob funded" a scientific study, "it was a privileged relationship and it couldn't come into court" because of legal rules protecting attorney-client communications. "So they could do projects that they could bury if they chose."

How often they may have done that is unclear, because 1,500 Council documents are under seal in a federal suit in New Jersey, withheld under the attorney-client privilege. In any case, the industry had other options, such as halting funding after an initial phase. Mr. Jacob and the firm of Jacob Medinger declined to comment.

SCIENTISTS SIGN UP

In 1972, the Special Projects unit gave Hugh Fudenberg, an immunologist, funding to determine whether some people are genetically predisposed to emphysema. Early results indicated up to 10% might be. Dr. Fudenberg planned "to warn high-risk people not to smoke," he says, but before he could his funding was discontinued without explanation. "They may have cut me off because it would have been negative for them," he speculates.

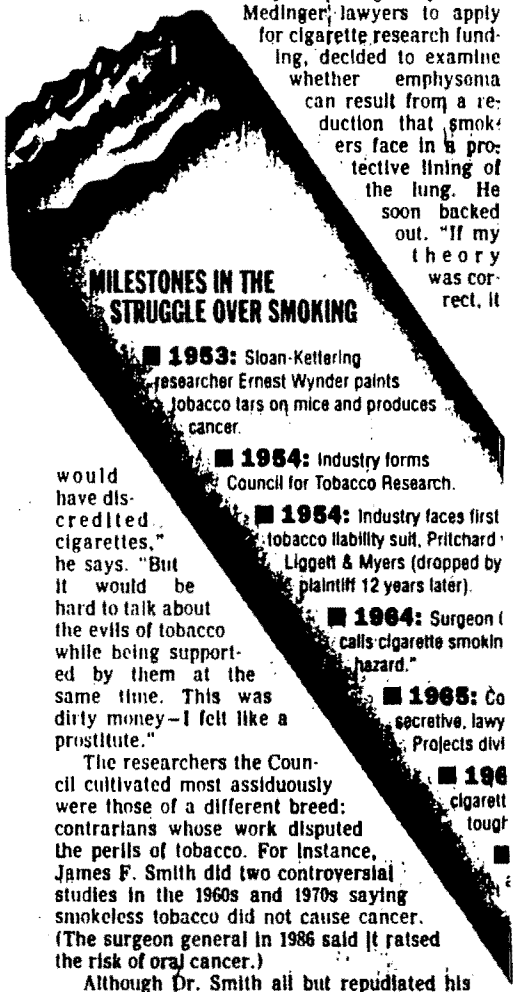
A researcher named Geoffrey Ashton learned

the limits of the Council's independence in 1976. He was invited by Mr. Jacob to study whether there might be some genetic factor underlying both smoking and certain diseases. But the study never got funded. Dr. Ashton says the lawyer told him "the presidents of the tobacco companies had turned down the proposal because they didn't think the outcome would be useful to them."

This case, like several others, points up the sometimes-perplexing relationship between scientists and the tobacco Council. Dr. Ashton says he was "very apprehensive" about casting his lot with the industry. What finally won him over? "Not to shock you, but scientists are always looking for money to further their research," Dr. Ashton says.

Likewise, a pharmacologist, Charles Puglia, did a special project for the Council's lawyers from 1979 to 1981, although he believed smoking to be dangerous. He explains: "It was early on in my career and it got me started with a laboratory."

While these scientists hesitated to accept tobacco funding but finally said yes, others, such as Theodore Finley, hesitated and finally said no. Dr. Finley, encouraged by Jacob Medinger lawyers to apply for cigarette research funding, decided to examine whether emphysema can result from a reduction that smokers face in a protective lining of the lung. He soon backed out. "If my theory was correct, it would have discredited cigarettes," he says. "But it would be hard to talk about the evils of tobacco while being supported by them at the same time. This was dirty money—I felt like a prostitute."



The researchers the Council cultivated most assiduously were those of a different breed: contrarians whose work disputed the perils of tobacco. For instance, James F. Smith did two controversial studies in the 1960s and 1970s saying smokeless tobacco did not cause cancer. (The surgeon general in 1986 said it raised the risk of oral cancer.)

Although Dr. Smith all but repudiated his own conclusions on CBS's "60 Minutes" in 1985—urging the public to avoid smokeless tobacco—a short time later he acknowledges he accepted an offer of several thousand dollars from Jacob Medinger lawyers to review scientific literature in preparation for a tobacco liability suit. The plaintiff was the mother of an Oklahoma youth who had died of oral cancer after using smokeless tobacco for seven years.

The Jacob Medinger firm and other defense lawyers won the suit, invoking Dr. Smith's studies as independent research. But there are indications he had longstanding ties to the Council; one court document shows his first study was earmarked a

earlier. Dr. Smith says the Council paid for equipment at his department's lab at the University of Tennessee when he was doing his smokeless-tobacco studies, though it didn't finance the studies.

REWARDING RESEARCH

Two other favorite scientists of the Council were Carl Seltzer and Theodor Sterling. Dr. Seltzer, a biological anthropologist, believes smoking has no role in heart disease and has alleged in print that data in the huge 15-year, 10,000-person Framingham Heart Study—which found otherwise—have been distorted by antitobacco researchers. Framingham Director William Castelli scoffs at Dr. Seltzer's critique but says it "has had some impact in keeping the debate alive."

Dr. Sterling, a statistician, disputes the validity of population studies linking smoking to illness, arguing that their narrow focus on smoking obscures the more likely disease cause—occupational exposure to toxic fumes.

For both men, defying conventional wisdom has been rewarding. Dr. Seltzer says he has received "well over $1 million" from the Council for research. Dr. Sterling got $1.1 million for his Special Projects work in 1977-82, court records show.

In relying on such research, the tobacco industry is "exploiting the margins of science," contends Anthony Colucci, a former top researcher and later director of scientific litigation support at R.J. Reynolds. He offers an analogy: "There's a forest full of data that says tobacco kills people, and sitting on one tree is a lizard with a different biochemical and physiological makeup. The industry focuses on that lizard—that tiny bit of marginal evidence."

R.J. Reynolds is suing Dr. Colucci, an outspoken critic, to keep him from testifying in a trial or talking to the media about tobacco liability, and accuses him of demanding a big consulting contract to keep quiet. Dr. Colucci says Reynolds "manipulated the negotiations" so it can now portray them as an extortion attempt. He adds: "This is a clear demonstration of the extent to which a tobacco company will go to silence someone who is telling the truth."

The Special Projects unit worked in a variety of ways to protect tobacco companies. Lobbying in Congress against advertising curbs, the industry in 1982 submitted to Congress a researcher's statement that peer pressure, not advertising, induced young people to smoke. Congress wasn't told that the research had been funded by Council attorneys. This was no accident. At a meeting of tobacco-company lawyers the year before, Mr. Jacob explained that the reason for funding that particular research as a Special Project was to conceal the researcher's ties to the industry. "We did not want it out in the open," Mr. Jacob said, according to the meeting transcript as cited in a Newark, N.J., federal judge's opinion.

The Council's lawyers weren't content for long to confine their activities to the Special Projects division. By the late 1960s, they had begun to encroach on the smoking research emanating from the putatively independent Council itself. Often, the Council and its lawyers shared or swapped projects and scientists.

By 1968, the Council had begun putting researchers under contract for many studies. This gave it the right to control both a study's design and publication of the results. However, as a contractor, the Council could be held responsible for withholding negative findings. So its operatives would do their utmost to ensure that ugly surprises didn't arise.

This contributed to a parting of the ways with Hill & Knowlton. "The lawyers had this thing under control," recalls Loet Velmans, a former chief executive of the PR firm. It quit the account in the late 1960s, he says, out of frustration that the industry "for legal reasons felt it couldn't admit to anything [on tobacco and health] because then it would be sued out of existence."

Says Robert Kersey, a former head of tobacco research at Liggett: "Almost everything that transpired had to be done under the advice of counsel so that nothing ... would incur a potential liability."

SMOKING RODENTS

In 1968, the Council contracted with Mason Research Institute in Worcester, Mass., to evaluate smoking machines" for animal inhalation studies nd do toxicity tests on rodents. As the study drew a close in 1972, Mason researcher Miasnig agopian was astonished when scientists from the uncil and from R.J. Reynolds began turning up eekly at his lab, where he says they sat for hours king notes. They made sure that only the most netically vigorous (that is, cancer-resistant) roents were going to be used, he says, and dictated uch cigarettes and how many puffs were administered to them.

"It got to the point where they were directing e course of the study," says Dr. Hagopian. "It as nowhere near as objective as if it had been funded by" the government.

Although he did complain to Mason's president, Dr. Hagopian concedes he and other researchers mainly "looked the other way." They wanted to make sure the contract was renewed so they could do the critical experiments on whether smoke affects rodents' lung tissues. However, the Council canceled funding before Mason began the animal study.

The Council pulled out the big guns after another study, at Bio-Research Institute in Cambridge, Mass. When Syrian hamsters were exposed to smoke twice a day for 59 to 80 weeks, 40% of those of a cancer-susceptible strain and 17 of a resistant strain developed malignant tumors. Before publishing the study in 1974, the institute's founder, Freddy Homberger, sent a manuscript to Robert Hockett, then scientific director of the Council. Dr. Homberger says he had to do so because halfway through his study, the Council had changed it from a grant to a contract "so they could control publication—they were quite open about that."

Soon thereafter, Dr. Hockett and Mr. Jacob, the lawyer, hastened to Dr. Homberger's summer home in Maine. Their mission? "They didn't want us to call anything cancer," Dr. Homberger testified years later at the Rose Cipollone tobacco liability trial in federal court in Newark, N.J. "They wanted it to be pseudo-epithelliomatous hyperplasia, and that is a euphemism for lesions preceding cancer. And we said no, this isn't right. It is a cancer." Today, Dr. Homberger adds that Mr. Jacob told him he would "never get a penny more" if the paper was published without making the changes.

He compromised. At the last minute, he changed the final proofs to read "micro-invasive" cancer, meaning a microscopic malignancy. Despite this, his lab was never funded by the Council again.

Dr. Homberger would come to regret his concession. And the Council would find a use for it—on the same occasion on which it eventually would use research from another lab, Microbiological Associates of Bethesda, Md.

WHAT KIND OF CANCER?

The Council contracted with that lab to do the world's largest inhalation study, involving more than 10,000 mice. To do it, the Council spent hundreds of thousands of dollars in a quest for the perfect smoking machine, one that prevented mice from either holding their breath or overdosing on carbon monoxide. The lab initially had considerable freedom, says Carol Henry, who was its director of inhalation toxicology. But after nine years of work and $12 million, the team was told in 1982 that it could no longer meet with Council staffers unless a lawyer was present.

"We had never done science through lawyers before, and we told them it was unacceptable," says Dr. Henry. She says a Jacob Medinger lawyer told her, "That's the way it is."

The scientists knuckled under. If the Council had canceled before all phases of the first experiment were done, 40 staffers might lose their jobs and nine years' worth of data would never come to light.

In the first experiment, in which mice inhaled the equivalent of five cigarettes a day, five days a week, for 110 weeks, 19 out of 978 mice got cancer—

1964: Congress bans TV cigarette ads.

1982: Surgeon General: cigarette smoking major single cause of cancer mortality in U.S.

1983: Rose Cipollone of New Jersey sues three companies saying their cigarettes gave her lung cancer.

1984: Surgeon General calls smoking "chief, single, avoidable cause of death in our society."

1986: Surgeon General says passive smoking can caus lung cancer and smokeless tobacco can raise oral-canc risk.

1986: In Oklah U.S. Tobacco wins o smokeless-tobacc ever tried.

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...cell carcinoma," the kind usually seen in human lung cancer. And there was a 10% possibility the results were due to chance, whereas scientists prefer no more than 5%. Even so, Dr. Henry says the study built a "very strong case" that cigarettes can induce cancers in animals. This was to be the first of several experiments.

But lawyers from Jacob Medinger told Microbiological the project would go no further. "When a contract is canceled given these kinds of results," Dr. Henry says, "reasonable scientists might conclude the liability issue must have suddenly become apparent to this group." In fact, says Dr. Kreisher, the Council's former associate scientific director, Council lawyers "worried like hell" about it.

Microbiological and the Council parted ways, but the tobacco industry got plenty of mileage out of the Microbiological mice. In 1981, the Council issued a news release noting the absence of squamous-cell lung cancer in the lab's study. The timing wasn't coincidental: That year, lawyers from Liggett, Philip Morris and Lorillard began taking depositions in the landmark case of Mrs. Cipollone, a New Jersey woman whose family claimed she had died of smoking-related squamous-cell lung cancer. And at the federal trial four years later, a witness for the defense said the fact that the smoking mice didn't get squamous-cell carcinoma (although some did get cancer) showed that "cigarette smoke has not been shown to be a cause of lung cancer."

■ 1992: Federal judge in Newark, seeing possible tobacco-industry fraud, moves to let a plaintiff see Council documents protected by lawyer-client privilege; later, judge is removed and order is voided.

■ 1992: U.S. Attorney in Brooklyn, N.Y., begins criminal probe of industry.

■ 1992: Supreme Court says smokers can file suits accusing tobacco companies of deceiving public about smoking dangers despite warning-label law.

■ 1993: In first trial high court ruling, state j Belleville, Ill., finds no conspiracy to hide t dangers.

...oma City, ...nly ...o liability case

... In only damage ...nst industry, federal ...ewark orders Liggett to ...pollone heirs $400,000; ...rd is later overturned and ...lit is dropped in 1992.

The witness also put Dr. Homberger's Syrian hamsters to good use. Smoking hadn't produced any more than "micro-invasive" tumors in the hamsters, noted the witness, toxicologist Arthur Furst.

Dr. Homberger, regretting he had agreed under pressure to use this milder wording, calls this use of his report "baloney," adding: "It was cancer beyond any question, not only in our opinion but in the view of the experts who looked at the slides." Dr. Furst declined to comment.

The tobacco companies succeeded in planting doubt in some jurors. "I didn't think it was proven scientifically that smoking caused her lung cancer," says juror Barbara Reilly. She says that under pressure from other jurors, she and two other holdouts went along with a finding in favor of the Cipollones, but managed to hold the damages to $400,000 instead of the $20 million some wanted to give. The award was based on false ...safety assurances by cigarette companies in their pre-1966 advertising.

An appeals court overturned the verdict, saying the plaintiffs had to prove Mrs. Cipollone had relied on the ad claims. In December, the Cipollones withdrew the suit rather than retry it, citing the cost.

The advent of this suit had coincided with the end of the Council's contract and Special Projects research, as well as the waning influence of Jacob Medinger, which departed under pressure in 1981. Tobacco industry lawyers say privately that executives and attorneys grew fearful that the Council, though designed to deflect liability, would wind up incurring just that, because it could be portrayed as having breached a public pledge to do independent research.

LEGAL LANDSCAPE SHIFTS

In fact, by the mid-1980s, the industry had begun to face the very suits against the Council that it feared. In one, the Cipollone family's lawyer, Marc Edell, sued the Council in 1984 on behalf of Susan Haines, the daughter of a lung-cancer victim.

To prove his claims of fraud and conspiracy, Mr. Edell has been trying to get access to the 1,500 Council documents the industry has kept secret by invoking attorney-client privilege. Such privilege can be abrogated in case of fraud, and last year a federal judge in Newark, citing possible evidence of fraud, set in motion the process of making documents available to Mr. Edell. The judge, H. Lee Sarokin, who had been hearing tobacco lawsuits for a decade, wrote a scathing opinion saying that the tobacco industry may be "the king of concealment and disinformation."

A federal appeals court removed him from the case last September for failing to maintain the appearance of impartiality. A new judge will decide the critical issue of whether the industry must divulge any of the 1,500 Council documents.

In the meantime, plaintiffs' attorneys are pinning their hopes on the Supreme Court's ruling last June. The ruling, which grew out of the Cipollone case, said that although cigarette warning labels prevent smokers from bringing "failure to warn" cases, plaintiffs may file suits alleging that cigarette makers intentionally hid or misrepresented tobacco's health hazards. This has led some to view the Council for Tobacco Research as the key to recovering damages from the industry.

But doing so may not be easy. At the end of January, a state court jury in Belleville, Ill., rejected the allegation that companies had conspired to play down tobacco's dangers. Some say winning such a case may depend on getting access to sealed Council documents.

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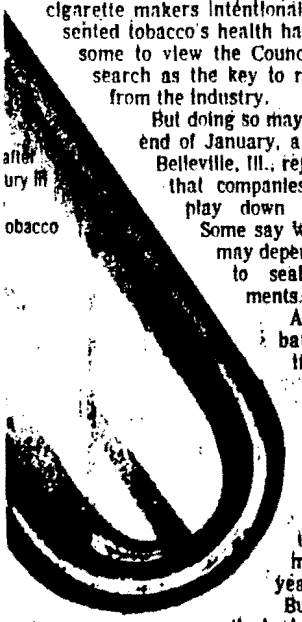

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Also facing an uphill battle is the criminal investigation by the U.S. Attorney in Brooklyn, N.Y. Prosecutors are facing statute-of-limitations problems because the Special Projects unit was disbanded more than five years ago.

But what may prove the best protection for the tobacco industry is the readiness of certain scientists to read the evidence differently from the majority. Says Dr. Colucci, the ex-Reynolds employee: "The scientists can come from Mars, but no matter how obscure or how misbegotten, as long as they are willing to tell the scientific lie that 'it's not proven,' the tobacco industry is off the hook." ♦

TOBACCO PLAINTIFFS FACE A GRILLING

LAUREL, Miss. – Days after Burl Butler filed suit accusing six tobacco companies of causing his lung cancer, a call came in to the barber shop he'd owned for 30 years. "Is Burl still chewing and smoking?" the anonymous caller asked.

A young barber who picked up the phone volunteered that although Mr. Butler had never smoked, he did have a taste for Levi Garrett chewing tobacco. With that, the line went dead. But Mr. Butler, who claims he got his cancer from second-hand smoke at his barber shop, thinks there is no mystery. "We know that was an enemy from the tobacco side," he says. "They were trying to intimidate us."

Burl Butler

The lead tobacco industry attorney in the case, James Kearney, declines to comment on any aspect of the case.

The tobacco industry's great success against litigants lies not only in convincing jurors that tobacco-disease links remain unproved but also in tactics that scare off or wear down plaintiffs before the cases ever come to trial. Now, as the industry faces a fresh round of suits, those tactics will be put to the test once more.

THOROUGH SEARCH

A company accused of causing someone's cancer clearly has an interest in probing for alternative causes. But "the tobacco industry makes a plaintiff feel as if everything in his life is exposed," says Thomas F. Johnson, a Philadelphia attorney. "It can be debilitating and scary."

Sleuths seek out anyone plaintiffs have known in quest of gossip and clues, says Doug Baldwin, an investigator in 1984-88 for George L. Barnes & Associates in Los Angeles, the industry's favorite gumshoe firm. He says none of the work the firm did while he was there – for hundreds of thousands of dollars per plaintiff – was used in court. So why bother? "We know details about plaintiffs that would have forced them to drop the suits," he says.

Jim Barnes of the Barnes firm says, "There can be lots of reasons for why people drop cases – litigation is expensive."

Although plaintiffs' attorneys say some clients give up in the face of the ordeal, most steel themselves and proceed. In one case, tobacco lawyers asked plaintiff John Gunsalus and his friends about a gun-possession charge he had faced 10 years earlier, a burglary prison term he had served and allegations of marital infidelity. Attempts to present this in Philadelphia federal court were blocked. But the judge did allow evidence about how police once beat an intoxicated Mr. Gunsalus after he broke into the bar where he worked while it was closed.

COURTROOM HARDBALL

"One of the issues in that case was if a warning had been on a cigarette package prior to 1966, would it have made a difference in this person's behavior," explains Edward Mannino, a tobacco industry attorney. The fact that Mr. Gunsalus, despite the beating, later broke in again "indicates what this gentleman's reaction would have been to a warning on a pack of cigarettes."

If a case makes it to trial, the hardball continues. Mr. Mannino sought a judge's permission to tell a Philadelphia federal jury that a witness for Mr. Gunsalus once served in the Nazi army. The judge said no. Mr. Mannino says he merely argued his right to cite the information to combat a motion from the plaintiff, and "it never occurred to me to use it."

The industry is also known for blanketing the courtroom with 30 or 40 lawyers, a tactic called "the wall," says New Jersey plaintiff's attorney Marc Edell. A 1988 memo by an outside lawyer for R.J. Reynolds, J. Michael Jordan, describes another strategy.

"The aggressive posture we have taken regarding depositions ... continues to make these cases extremely burdensome and expensive for plaintiffs' lawyers," he wrote. Mr. Jordan, who declines comment, continues in the memo to other lawyers: "To paraphrase General Patton, the way we won these cases was not by spending all of Reynolds's money, but by making that other son of a bitch spend all his."

For Mr. Butler in Mississippi, the emotional toll is the worst part (his lawyers are paying for the litigation and will get part of any damages). For one thing, industry lawyers managed to delay the videotaping of his testimony for weeks in spite of his worsening condition.

Customers smoked so much that Mr. Butler's barber-shop ceiling turned brown and the silver ashtrays built into the old-fashioned barber chairs were usually full. But lawyers hoping to weaken the lung-cancer victim's case have probed Mr. Butler's school records, checked whether he had a cigarette vending machine in his shop (he didn't), grilled him about risks he took by hunting and using power tools, and asked what he ate. They even requested his mother's recipe for "smothered gravy."

– Laurie P. Cohen and Alix M. Freedman

American Heart Association

AMERICAN LUNG ASSOCIATION®
The Christmas Seal People®

AMERICAN CANCER SOCIETY®

Coalition on Smoking OR Health

LEVELING THE REGULATORY PLAYING FIELD
THE CASE FOR FDA REGULATION
OF TOBACCO PRODUCTS

FACTS:

- o Cigarette smoking is a major cause of cancer, cardiovascular disease, emphysema, chronic obstructive lung disease and stroke, and accounts for over 430,000 deaths each year.
- o Tobacco products are as addictive as cocaine and heroin.
- o Tobacco products have been exempted from every major health and safety law enacted by Congress to protect consumers from dangerous products.
- o No federal regulatory agency has the authority to regulate the manufacture, distribution, sale, labeling, advertising and promotion of tobacco products.
- o Tobacco industry promises of self regulation for the last 30 years have been a dismal failure resulting in huge economic profits for the tobacco industry at the expense of millions and millions of American lives.

FDA REGULATION OF TOBACCO PRODUCTS IS FAIR AND EQUITABLE:

- o Providing the Food and Drug Administration with the necessary authorities it needs to regulate this addictive killer would be an effective of way of significantly discouraging tobacco consumption by both children and adults without banning the product.
- o By providing the FDA the authorities it needs to regulate the manufacture, distribution, sale, labeling, advertising and promotion of tobacco products, in a manner comparable to the way in which other legal products are regulated for their health and safety, the FDA would be able to ensure the following:

  a) That tobacco products are not sold or dispensed to minors and that such laws are effectively enforced.
  b) That tobacco products are effectively labeled with information about addiction, environmental tobacco smoke, stroke, and other health ramifications not on the package.
  c) That all chemical additives are disclosed to the public and are tested for safety.
  d) That dangerous constituents in tobacco smoke be disclosed to the public (i.e. benzene, arsenic, etc.)
  e) That tobacco advertising and promotion be held to the same standards that other legal drug products are held to.
  f) That no implied or direct health and safety claims are made unless they are scientifically substantiated.

1150 Connecticut Avenue, NW, Suite 820, Washington, DC 20036
Telephone: (202) 452-1184 FAX: (202) 452-1417

American Heart Association

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Coalition on Smoking OR Health

TOBACCO PRODUCTS: AMERICA'S MOST UNREGULATED ADDICTIVE KILLERS

	FDA Authorities to Regulate Foods, Drugs and Cosmetics	Federal Authorities to Regulate Tobacco
NICOTINE	**Yes**	**No** (except when health claims are made, however, FDA has failed to use those authorities since the 1950's)
RESTRICTION ON ADVERTISING AND PROMOTION	**Yes**	**No** (except general authorities under Sec. 5 of the FTC Act)
ADDITIVES	**Yes**	**No** (no agency can require disclosure or testing of the hundreds of additives used in tobacco products)
DISPENSING SALE, DISTRIBUTION	**Yes**	**No**
LABELING	**Yes**	**No** (only Congress has authority, i.e. warning labels which are incomplete compared to drugs, foods and cosmetics)
DESCRIPTORS/ CLAIMS REGULATIONS	**Yes**	**No**

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ORGANIZATIONS SUPPORTING ADMINISTRATIVE AND LEGISLATIVE EFFORTS TO REGULATE TOBACCO PRODUCTS

Academy of General Dentistry
Akron GASP
American Academy of Family Physicians
American Academy of Otolaryngology
American Academy of Pediatrics
American Association for Cancer Research
American Association for Respiratory Care
American Association of Dental Schools
American Cancer Society
American Chiropractic Association
American College of Cardiology
American College of Chest Physicians
American College of Physicians
American College of Preventive Medicine
American College of Sports Medicine
American Council on Life Insurance
American Dental Hygienists' Association
American Heart Association
American Licensed Practical Nurses Association
American Lung Association
American Medical Association
American Medical Student Association
American Medical Women's Association
American Nurses Association
American Public Health Association
American Society of Addiction Medicine
American Society of Clinical Oncology
American Society of Internal Medicine
American Speech-Language-Hearing Association
Association for Nonsmokers-Minnesota
Association of Women's Health Obstetrical and Neonatal Nurses
American Veterans Committee
Association of Black Cardiologists, Inc.
Association of State and Territorial Chronic Disease Program Directors
Association of State and Territorial Health Officials
Asthma and Allergy Foundation of America
Cancer Care, Inc.
Carter Center of Emory University
Center for Science in the Public Interest
Christian Science Committee on Publication
Church of the Brethren Washington Office
Committee for Children
Committee to Prevent Cancer Among Blacks (Philadelphia)
Consumers Union
Doctors Ought to Care
Evangelicals for Social Action, Inc.
Fox Chase Cancer Center
General Board of Church and Society of the United Methodist Church
General Conference of Seventh-day Adventists
General Federation of Women's Clubs
Health Insurance Association of America
International Council for Coordinating Cancer Research
Interreligious Coalition on Smoking or Health
Joint Council on Alergy and Immunology
Lawyers for Consumer Rights
March of Dimes Birth Defects Foundation
Massachusetts GASP
Minnesota Coalition for a Smoke-free Society
National Association of Community Action Agencies
National Association of County Health Officials
National Association of Elementary School Principals
National Association of Nonsmokers, Inc.
National Black Leadership Initiative on Cancer of Philadelphia
National Coalition for Cancer Research
National Coalition of Hispanic Health and Human Services (COSSMHO)
National Council for International Health
National PTA
National Perinatal Association
New Jersey GASP (Group Against Smoking Pollution)
Oncology Nursing Society
Pride (National Parents' Resource Institute for Drug Education)
Smokefree Educational Services, Inc.
Uptown Coalition for Tobacco Control and Public Health
Washington Institute

American Heart Association

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Coalition on Smoking OR Health

HISTORICAL OVERVIEW OF CIGARETTE AND NICOTINE REGULATION

1930s: Congress expands definition of "drug" under the Food, Drug and Cosmetic Act to include "articles intended for use in the cure, mitigation, treatment or prevention of disease," and "articles intended to affect the structure or function of the body."

1950s: Courts uphold the Food and Drug Administration's authorities to regulate cigarette products as drugs when implied or direct health claims are made and when the cigarettes are sold not just for "smoking pleasure only."

1970s: Action on Smoking or Health (ASH) files petitions with the FDA seeking (among other things) to classify all nicotine cigarettes as "drugs" under the FDC Act. The FDA states that ASH has failed to show any intent on part of manufacturer to sell cigarettes as "drugs."

1980s: Courts uphold the FDA actions in the ASH petitions. (see above.) Consumer intent to buy the products as "drugs" is not enough, intent on the part of the manufacturer must be shown.

1984: The FDA approves drug application for prescription drug Nicorette, a gum containing nicotine.

1987: The FDA issues a regulatory letter to Advanced Tobacco Products, Inc. indicating that their product "FAVOR" a non-conventional, non-tobacco cigarette is a "drug" under the FDC Act.

1988: The Coalition on Smoking OR Health (comprised of the American Heart Association, the American Cancer Society and the American Lung Association) file a petition with the FDA asking the agency to regulate all low tar/low nicotine products as "drugs" under the FDC Act. (Petition remains pending.)

1988: The Coalition on Smoking OR Health and the American Medical Association file petitions with the FDA and the FTC seeking to classify "Premier" cigarettes (the so-called cleaner, heating cigarette) as a "drug" under the FDC Act. R.J.R. withdraws the product from the market.

1989: The FDA issues a regulatory letter to Masterpiece Tobacs indicating that a chewing gum containing tobacco was a "food" under the FDC Act and because tobacco is a dangerous, hazardous, unapproved substance for use in food, the product was "adulterated" and could not be marketed.

1991: The Coalition on Smoking OR Health file petitions with the FDA and the FTC seeking to classify Benson and Hedges "De-Nic" cigarettes as "drugs" under the FDC Act. (Petitions remain pending.)

1991: The FDA approves drug applications for marketing of transdermal nicotine patches.

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February 27, 1992

INTRODUCTION OF THE TOBACCO AND NICOTINE HEALTH AND SAFETY ACT

MR. SPEAKER, Today I am introducing legislation to correct a serious omission in the regulatory authority of the Food and Drug Administration. While the FDA has jurisdiction to protect consumers from unsafe foods, drugs, cosmetics and medical devices, it is powerless to do anything about one of the deadliest consumer products -- tobacco. It is time correct this situation.

Each day 1200 Americans die from cancer, heart disease, chronic obstructive lung disease and stroke as a result of cigarettes. Some 50,000 scientific studies on the relationship between smoking and disease have been conducted. The results are conclusive. Tobacco use is the single most preventable cause of death. Tobacco products are implicated in the deaths of 434,000 people each year.

Although the FDA has the authority to regulate foods, drugs, cosmetics and medical devices, the first law establishing the agency did not list tobacco in the legislation's narrow definition of a drug. While the definition of what is a drug has been expanded several times since, cigarettes themselves have never been classified as drugs. However, in two court cases the FDA has been found to have "indirect" authority to regulate tobacco products when the advertising implies that the product is intended for some purpose other than smoking pleasure. Specifically, when the product in question is being sold for the purpose of mitigating or preventing disease or is intended to affect the function or structure of the body, the FDA can regulate tobacco as a drug.

The FDA has exercised this limited authority in the past. For example, the agency classified a non-tobacco cigarette-like device which delivered nicotine to the system of the user in a similar fashion and appearance to a cigarette as a drug because it was intended to satisfy a nicotine dependence and to affect the structure or, one or more functions of the body. Nevertheless, there are numerous petitions urging the FDA to take action on other tobacco products which have not been acted on.

Even if the FDA exercised its limited authority in every case, it would not be enough. The FDA still would not have the jurisdiction to regulate nicotine, additives and other

constituents in tobacco products, or sales of cigarettes to minors. Excluding tobacco products from the FDA's comprehensive regulatory scheme makes no sense.

Three-wheeled All Terrain Vehicles (ATV's) were implicated in far fewer deaths and yet the Consumer Product Safety Commission and the U.S. Justice Department acted swiftly to protect the public's safety by placing conditions on sales of the vehicle. When the EPA discovers that a pesticide may cause cancer in humans, it is quickly pulled from the market. When the FDA determines that a medical device poses health risks, such as the silicone breast implant, severe restrictions on its sale are proposed. In contrast, the sale, manufacture, and promotion of tobacco products continues unregulated despite the scientific evidence that the products cause death, disability and disease.

The Tobacco and Nicotine Health and Safety Act of 1992 would give the FDA the authority to regulate tobacco products in a manner consistent with other comparable products.

Specifically the bill would do the following:

* Create a new section in the Food, Drug and Cosmetic Act authorizing FDA regulation of tobacco products.

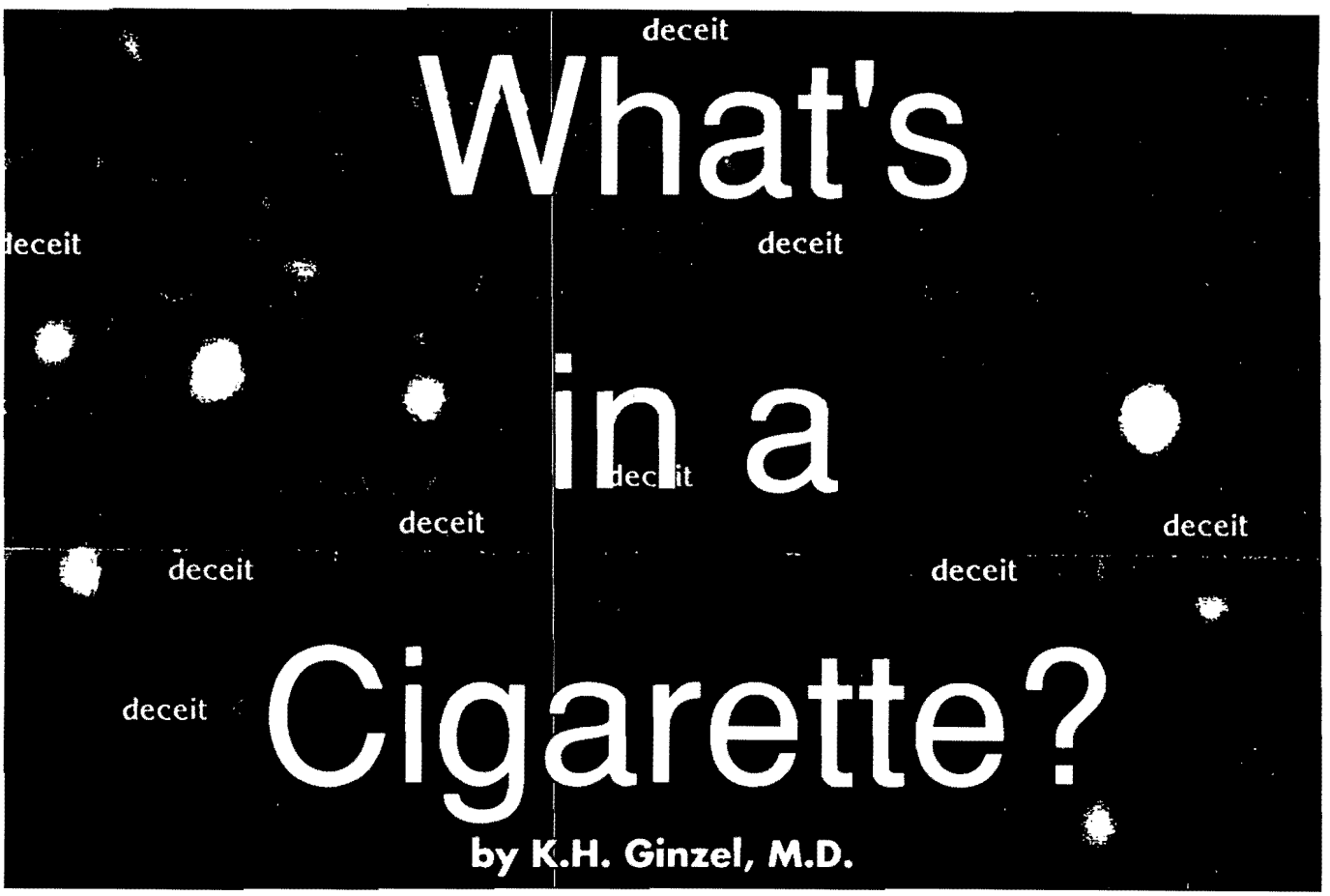
* Require tobacco manufacturers to fully disclose all chemical additives in tobacco products.

* Give the FDA the authority to reduce the level of harmful additives or to prohibit the use of those additives altogether.

* Prohibit the sale of tobacco products to any person under the age of 18.

There is simply no justification for treating tobacco differently than comparable consumer products. If tobacco is to remain on the market, it should be regulated by the FDA. Why should the FDA have the power to regulate nicotine in every circumstance except tobacco? Why should the tobacco industry be exempt from the FDA's disclosure and safety requirements regarding chemical additives? Why should the implied or direct health claims about tobacco products, which no agency requires be substantiated by medical science, be treated any differently than the implied health claims of corn flakes? The obvious answer to all of these questions is: it shouldn't. If anything tobacco deserves closer scrutiny than cereal or orange juice. The Tobacco and Nicotine Health and Safety Act is long overdue.

I am pleased that my colleagues Don Ritter, Dick Durbin, Mike Andrews and Wayne Owens are joining me in this effort.



For those who still don't know—let me emphatically state that cigarette smoking is a true addiction, more powerful than a dependence on alcohol, heroin or cocaine. To grasp this well-documented fact, one really doesn't have to study all the supporting scientific evidence. One simply needs to consider that no other drug is self-administered with the persistence, regularity and frequency of a cigarette. At an average rate of ten puffs per cigarette, a one to three pack-a-day smoker inhales 70,000 to 200,000 individual doses of mainstream smoke during a single year. Ever since its large scale industrial production early in this century, the popularity of the modern cigarette has been spreading like wildfire. Here is the first, and perhaps the most significant answer to the title question: Addiction is in a cigarette.

Probing into what makes a cigarette so irresistible, we find that much of the recent research corroborates earlier claims: It is for the nicotine in tobacco that the smoker smokes, the chewer chews, and the dipper dips. Hence, nicotine is in a cigarette.

In contrast to other drugs, nicotine delivery from tobacco carries an ominous burden of chemical poisons and cancer-producing substances that boggle the mind. Many toxic agents are in a cigarette. However, additional toxicants are manufactured during the smoking process by the chemical reactions occurring in the glowing tip of the cigarette. The number is staggering: more than 4,000 hazardous compounds are present in the smoke that smokers draw into their lungs and which escapes into the environment between puffs.

The burning of tobacco generates more than 150 billion tar particles per cubic inch, constituting the visible portion of cigarette smoke. According to chemists at R.J. Reynolds Tobacco Company, cigarette smoke is 10,000 times more concentrated than the automobile pollution at rush hour on a freeway. The lungs of smokers, puffing a daily ration of 20 to 60 low to high tar cigarettes, collect an annual deposit of one-quarter to one and one-half pounds of the gooey black material, amounting to a total of 15 to 90 million pounds of carcinogen-packed tar for the aggregate of current American smokers. Hence, tar is in a cigarette.

But visible smoke contributes only 3-8% to the total output of a cigarette. The remaining bulk that cannot be seen makes up the so-called vapor or gas phase of cigarette "smoke." It contains, besides nitrogen and oxygen, a bewildering assortment of toxic gases, such as carbon monoxide, formaldehyde, acrolein, hydrogen cyanide, and nitrogen oxides, to name just a few. Smokers efficiently extract almost 90% of the particulate as well as gaseous constituents (about 50% in the case of carbon monoxide) from the mainstream smoke of the 600 billion cigarettes consumed annually in the U.S. In addition, 2.25 million metric tons of sidestream smoke chemicals pollute the enclosed air spaces of homes, offices, conference rooms, bars, restaurants, and automobiles in this country. Hence, pollution is in a cigarette.

The witch's brew of poisons invades the organs and tissues of smokers and nonsmokers, adults and children, born as well as unborn, and causes cancer, emphysema, heart disease, fetal growth retardation and other problems during pregnancy. The harm inflicted by all other addictions combined pales in comparison. Smoking-related illness, for example, claims in a few days as many victims as cocaine does in a whole year. Hence, disease is in a cigarette.

The irony is that many of the poisons found in cigarette smoke are subject to strict regulation by federal laws which, on the other hand, specifically exempt tobacco products. "Acceptable Daily Intake," ADI, is the amount of a chemical an individual can be exposed to for an extended period without apparent detriment to health. A comparison of the actual intake of selected chemicals in mainstream smoke with their ADIs (see table, pg 12) reveals the enormity of toxic exposure incurred by the smoker (note the presence of methyl isocyanide, the toxicant of the Bhopal disaster).

In addition, there is the chemical burden from sidestream smoke, afflicting smokers and non-smokers alike. Based on the reported concentrations in enclosed, cigarette smoke-polluted areas, the estimated intakes of nicotine, acrolein, carbon monoxide, nitrogen dioxide and formaldehyde peak at 200, 130, 75, 7, and 3 times the ADI, respectively. The high exposure to acrolein is especially unsettling. This compound is not only a potent respiratory irritant, but qualifies, according to current studies, as a carcinogen.

HOWEVER EAGERLY THE GOVERNMENT TRIES TO PROTECT US FROM OUTDOOR POLLUTION AND THE CARCINOGENIC RISK OF CONSUMER PRODUCTS, IT BLATANTLY SUSPENDS CONTROL IF THE OFFENDING CHEMICAL IS IN, OR COMES FROM, A CIGARETTE. HENCE, HYPOCRISY IS IN A CIGARETTE.

Regulatory policy aims at restricting exposure to carcinogens to a level where the lifetime risk of cancer would not exceed 1 in 100,000 to 1,000,000. Due to a limited database, approximate upper lifetime risk values could be calculated for only 7 representative cigarette smoke carcinogens. The risk values were extraordinarily high, ranging from 1 in 6,000 to 1 in 16. Because of the awesome amount of carcinogens found in cigarette smoke and the fact that carcinogens combine their individual actions in an additive or even multiplicative fashion, it is not surprising that the actual risk for lung cancer is as high as one in ten. Hence, cancer is in a cigarette.

Among the worst offenders are the nitrosamines. Strictly regulated by federal agencies, their concentrations in beer, bacon, and baby bottle nipples must not exceed 5 to 10 parts per billion. A typical person ingests about one microgram a day, while the smokers' intake tops this by 17 times for each pack of cigarette smoked. In 1976, a rocket fuel manufacturer in the Baltimore area was emitting dimethylnitrosamine into the surrounding air, exposing the local inhabitants to an estimated 14 micrograms of the carcinogen per day. The plant was

promptly shut down. However eagerly the government tries to protect us from outdoor pollution and the carcinogenic risk of consumer products, it blatantly suspends control if the offending chemical is in, or comes from, a cigarette. Hence, hypocrisy is in a cigarette.

But there is still more in a cigarette than addiction, poison, pollution, disease, and hypocrisy. A half century of aggressive promotion and sophisticated advertising that featured alluring role models from theater, film and sport, has invested the cigarette with an enticing imagery. Imagery which captivates and seduces a growing youngster. The youngster, indispensable for being recruited into the future army of smokers, does not start to smoke cigarettes for the nicotine, but for the false promises they hold. Hence, deceit is in a cigarette.

SMOKERS' DAILY INTAKE OF SELECTED MAINSTREAM SMOKE POISONS

Chemical Substance	Range* in Multiples of the AcceptableDaily Intake
Nicotine	400 - 3.600
Acrolein	50 - 370
Carbon monoxide	50 - 250
Methyl isocyanide	6 - 60
Formaldehyde**	9 - 40
Hydrogen cyanide	8 - 30
Acrylamide**	7 - 20
Cadmium**	3 - 9
Ammonia	1 - 5

** Encompassing both the range of cigarette consumption (1 to 3 packs/day) and the weight range of mainstream smoke constituents.*
*** Established carcinogen (International Agency for Research on Cancer)*

In summary, no drug ever ingested by humans can rival the long-term debilitating effects of tobacco; the carnage perpetuated by its purveyors; the merciless irreversibility of destiny once the victim contracts lung cancer or emphysema; the militant denial on the part of those who, with the support of stockholders and the sanction of governments, legally push their lethal merchandise across borders and continents killing every year two and one-half to three million people worldwide. All things added together: death is in a cigarette. ❑

K.H. Ginzel, M.D., is Professor of Pharmacology and Toxicology at the University of Arkansas. His work is concentrated in the area of nicotine and its effects.

FROM JOHN CHANCELLOR, NBC, Feb. 15, 1990

One of the subjects of today's drug summit is: How to keep cocaine out of the United States. Here's a quiz: how many Americans does cocaine kill in a year? If you don't count those killed by drug criminals—cocaine itself kills two thousand people. How many Americans are killed in a year by cigarettes? 390 thousand. For every American who dies of cocaine, 195 die because of tobacco.

We ought to keep this in mind when we try to stop the sale of dangerous drugs around the world. The fact is—the United States is a big exporter of that dangerous drug called tobacco. It's a three and a half billion dollar export business for American tobacco companies.

Some of these companies are trying to sell more overseas. They have targeted Thailand. Thailand wants to keep them out to protect its state-owned tobacco monopoly—and also because Thailand has mounted a serious campaign against smoking. The companies want the Bush Administration to force Thailand to allow the sale of American cigarettes—and to allow cigarette advertising on television—which is forbidden in Thailand. If Thailand doesn't give in—the tobacco companies want retaliation against Thai products sold here.

So—we have the President going to Colombia on a mission to keep cocaine out of the United States while tobacco companies in the United States are trying to enlarge their world market for something even more dangerous and addictive. Want to think about contradictions? That's a big one.

Disease prevention must be a major part of health system reform. Stopping tobacco deaths is our first priority.

In the spirit of openness expressed by President Clinton, the 300,000 members of the American Medical Association (AMA) are working to forge a new partnership with the Administration and members of Congress on behalf of our patients.

Our goal: comprehensive reform of America's health care delivery system. The AMA's agenda for change is defined in our proposal, *Health Access America.*

One of the recommendations in our proposal calls for an effective disease prevention program. Every year, hundreds of thousands of our patients die from preventable diseases. Cancer, heart disease, AIDS, TB, domestic violence. And the biggest killer of all is tobacco.

We believe that any reform measures must place our patients first.

435,000 deaths a year

Tobacco is a legal product that is *deadly* when used as directed.

It is as addictive as cocaine or heroin. Every year 435,000 Americans die prematurely because they smoke cigarettes.

The financial drain on our health system is staggering — over $50 billion a year.

And the numbers are growing. Three thousand teenagers begin smoking *every day*. More than one million a year. Ninety percent will become regular smokers before age 18.

Additionally, 40,000 *nonsmokers* die every year from secondhand smoke. The Environmental Protection Agency considers environmental smoke to be as deadly as asbestos and has reclassified it as a known carcinogen.

But, unlike diseases for which there are no known cures, the cancer and heart disease caused by cigarettes *can* be prevented.

Our agenda for change

The AMA supports an increase in the federal excise tax on tobacco, which will dramatically reduce smoking. A $2 per pack cigarette tax increase would discourage teenagers from beginning to smoke and encourage current smokers to quit. This alone would save two million lives over time — more than all American losses from all U.S. wars combined.

Increased cigarette taxes would also generate billions of dollars annually. These revenues could be applied directly to deficit reduction, health system reform and educating the public, especially our children, on the dangers of smoking.

We also recommend that tobacco be placed under the control of the Food and Drug Administration. Of all the misbranded, adulterated, and potentially dangerous products under the FDA's jurisdiction, tobacco is conspicuous by its absence.

Eleven key issues

Smoking and disease prevention are only one part of the AMA's agenda for change. Over the course of the new Administration's first 100 days, America's physicians will enter a dialogue with legislators and other members of the Clinton team on *eleven key issues* leading to total health system reform.

To stay fully informed, watch for additional messages in this series in *The Washington Post*. And send for our comprehensive proposal, *Health Access America.* We will also send you our fact sheet on disease prevention. Write Dr. John Clowe, Dept. 2009, American Medical Association, 515 North State Street, Chicago, IL 60610. Or call us today at **800 262-0411.**

American Medical Association

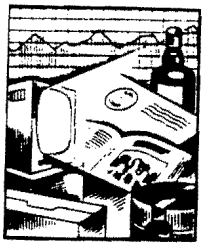
Physicians dedicated to the health of America

ADVERTISING / By Laura Bird

Bold Tobacco Ad on Ingredients Planned

Liggett Group, the smallest of the major cigarette makers, is betting $20 million on a folksy print ad campaign that it hopes will breathe life back into Chesterfield, an 80-year-old brand that hasn't been advertised in 25 years.

But the effort, which introduces a filtered version of the vintage smoke, may ultimately prove hazardous to the tobacco industry's health.



The campaign does what practically no other cigarette ads dare to do: It breaks the six U.S. tobacco companies' collective silence about the actual ingredients in their cigarettes by boasting about the quality of Chesterfield tobacco and trashing the competition. At a time when anti-smoking activists are readying a push to have cigarettes treated as pharmaceuticals and be newly regulated by the Food and Drug Administration, Liggett's ad points out tactlessly just how little puffers really know about what goes into their lungs.

Gerry Reid, Liggett senior vice president of sales and marketing, makes no bones about it. "For something that people put into their mouths 20 or 30 times a day, it's surprising that no one tells them more about it," he marvels. Large manufacturers have a "vested interest in not telling. We, being the little guy, might as well tell the truth and make hay with it."

The brazen campaign is likely to cement the reputation of Liggett, the cigarette manufacturing unit of **Brooke Group** Ltd., as the tobacco industry's spoiler. Created by **WPP Group's** Ogilvy & Mather, New York, the campaign swipes at competitors' cigarettes in homespun prose, explaining how Chesterfield painstakingly cleans tobacco of "coarse stems" while other companies "chop 'em up and put 'em back in." The ad goes on to tell how Chesterfield puts "a generous wad of tobacco" into every cigarette. "We reckon it flat-out makes a better smoke," the ad drawls.

Liggett's corny tone and its unabashed description of tobacco-rolling mark an unusual departure from the fashion and status statements favored in most tobacco ads. Most of the best-known campaigns – including **Philip Morris's** Marlboro man and **RJR Nabisco's** cartoon Camel – focus on abstract illustrations of adventure and glamour; they certainly don't boast about specific ingredients and often don't even show people smoking.

In sharp contrast, the Chesterfield ads show a wistful scene of a Durham, N.C., factory loading dock, where workers take a good old-fashioned cigarette break. "The fact is, American cigarettes all have significant quantities of filler ingredients – stems, reconstituted and puffed tobacco," Mr. Reid says. Liggett decided a cigarette without such detritus could be "the basis for a legitimate product."

The ads, however, could spark a controversy. Industry critics and marketers say that, by harping on the inferior ingredients of competing smokes, Liggett is exposing one of the industry's dirtiest but best kept secrets. Even smokers, they say, would be unpleasantly surprised to find out what tobacco companies put in their cigarettes.

Tobacco ads seldom if ever tell the "quality story," according to Anthony Regensburg, a Boca Raton, Fla., consultant to tobacco wholesalers because tobacco "has been so adulterated over the years that no one has that story to tell."

The campaign "exposes the fault line that cigarettes are a highly manufactured product with all kinds of additives," says Richard Daynard, chairman of the Tobacco Products Liability Project, a Boston group that encourages lawsuits against tobacco companies. In some recent tobacco liability cases, Mr. Daynard says, "the tobacco industry's basic defense has been that this product is natural."

Liggett's Mr. Reid says the Chesterfield campaign strategy was meant to go after competitors on the topic of tobacco quality, not flavoring additives. Common additives, he says, include cocoa, sugar, and licorice – "normal kinds of household flavoring food ingredients. Nothing that you'd call nasty," Mr. Reid says.

Critics suspect that more insidious ingredients also are routinely added to cigarettes, to change their flavor or retard the burn of the flame. Carbon monoxide, formaldehyde, arsenic and a host of other unsavory compounds turn up in tobacco smoke under analysis, according to Stanton Glantz, professor of medicine at the University of California in San Francisco. But such analyses don't tell whether the compounds originated in the tobacco, or were formed as a result of being burned.

Cigarette companies are required to disclose their ingredients only to the U.S. Department of Health and Human Services, in a top-secret composite list that doesn't include specifics on brands or quantities. The reason for the secrecy, according to the Tobacco Institute, is to guard each brand's recipe from the competition. "It's a little like how Coke tastes different than Pepsi," says Institute spokeswoman Brennan Dawson.

This isn't the first time that Liggett has broken ranks with its rivals for the sake of marketing. In 1988, Liggett thumbed its nose at the lock-step pricing practices in the tobacco industry and introduced Pyramid, then the nation's lowest-priced cigarette. That move touched off an era of price wars and discounting that continue to undercut the industry's profits to this day.

Even if Chesterfield catches fire, it isn't likely to revive the fortunes of Liggett. Best known for making "no name" generic smokes, Liggett is a faded player in tobacco, holding a meager 3.2% share of the total cigarette market, according to tobacco analyst John Maxwell of Wheat First Securities in Richmond, Va. Chesterfield, in its non-filter version, holds a microscopic 0.1% market share.

Startling as the new campaign is, an earlier version was even more spine-tingling. It was centered, Liggett's Mr. Reid says, on "guys in white coats in laboratories, diagnosing the ingredients." Even for Liggett, that idea may have gone too far; it never saw the light of day.

George F. Will

Smoking Gun

Bad habits and the health care crisis.

At Barnes Hospital in St. Louis in 1919, a doctor summoned some medical students to an autopsy, saying the patient's disease was so rare that most of the students would never see it again. It was lung cancer.

That story, from Dr. John A. Meyer's article "Cigarette Century" in the December American Heritage, illuminates like a lightning flash this fact: Much—probably most—of America's hideously costly health care crisis is caused by unwise behavior associated with eating, drinking, driving, sex, alcohol, drugs, violence and, especially, smoking. Therefore, focusing on wellness—on preventing rather than curing illness—will reduce the waste inherent in disease-oriented, hospital-centered, high-tech medicine. The history of the connection between cigarettes and lung cancer illustrates the fallacy of associating health with the delivery of medicine.

One of those 1919 medical students later wrote that he did not see another case of lung cancer until 1936. Then in six months he saw nine cases. By the 1930s advances in immunology and public health measures (sanitation, food handling etc.) were reducing the incidence of infectious diseases. But the nation was about to experience an epidemic of behaviorally driven disease.

The lung-cancer epidemic can be said to have sprung from the 1881 invention of a cigarette-making machine. Prior to that, commercial manufacturing of cigarettes was, Meyer says, a cottage industry. But by 1888 North Carolina's James Buchanan Duke (whose fortune endowed the university) was selling nearly a billion cigarettes annually. Next, war, the shaper of our century, worked its transforming force. Duke's company and the National Cigarette Service Committee distributed cigarettes free to soldiers in France during World War I. So important were cigarettes thought to be to morale that Gen. Pershing demanded priority shipment for them.

Between 1910 and 1919 U.S. cigarette production increased 633 percent, from 10 billion to almost 70 billion annually. Meyer notes that O. Henry's meticulously observed short stories, written at the turn of the century, almost never mention cigarettes, but the expatriates—men and women—in Hemingway's "The Sun Also Rises" smoke constantly. By the 1930s physicians were struggling with the consequences of the new, "emancipated" behavior.

In 1930 the lung cancer death rate among men was less than five per 100,000 per year. By the 1950s, after another war, in which cigarettes were sold for a nickel a pack and were distributed free in forward areas and were included with K rations, the death rate among men was more than 20 per 100,000. Today it is more than 70 per 100,000, women's lung cancer rates are soaring, and lung cancer is far and away America's leading cause of cancer death.

We have come a long way from the early days of television, when the sponsor of anchorman John Cameron Swayze's "The Camel News Caravan" required him to have a lit cigarette constantly visible. The aggressiveness of today's anti-smoking campaigns is attested, paradoxically, by a "smokers' rights" movement trying to protect from employment discrimination those persons who only smoke away from the job.

The American Cancer Society is testing the tolerance of the magazine industry, which last year got $264.4 million—4 percent of its revenue—from tobacco advertising. Some magazines may flinch from running ACS advertisements that say, "Smoking promotes zoo breath" or "More Americans die each year from illness related to smoking than from heroin, crack, homicide, car accidents, fires and AIDS combined." (A current idiocy: the loud, abrasive entertainer Denis Leary, who harangues MTV's young viewers about the dangers of crack, smokes while haranguing.)

The social disaster of the smoking addiction illustrates why behavior modification, especially education, is the key to cost-containment regarding health. And journalism can help, as The Post's Jay Mathews deftly demonstrated in his reporting on the Liggett company's campaign to revive the Chesterfield brand of cigarettes, a brand that has not been advertised for decades.

Launched 80 years ago, Chesterfield flourished when smoking was most glamorous, from the 1930s into the 1950s, when the "Chesterfield Girl" was a television fixture. Today 50 million addicted Americans still pay $26 billion for almost a half-trillion cigarettes each year, so if Chesterfield wins one-half of 1 percent of the market (2.4 billion cigarettes), it will be a success.

To achieve that, Liggett is merchandising Chesterfields with a $50 million advertising campaign featuring soft, 1930s-style photography. Mathews reported that—and this, too:

"Janet Sackman, who was the Chesterfield Girl on 'The Perry Como Show' in the late 1940s, said she was not impressed. She speaks with difficulty because of surgery for both throat and lung cancer, which she blames on 33 years of smoking urged by a Chesterfield executive who thought she would look more authentic. 'People who smoke ought to take a look at me,' she said."

And at the trajectory of the epidemic from 1919 until now.

BY JOHN OVERMYER

Washington Post, 12-24-92

HEALTH

Federal Control of Tobacco: A Smoldering Issue Heats Up

By MARLENE CIMONS
TIMES STAFF WRITER

WASHINGTON—Should the Food and Drug Administration—which has the authority to regulate dangerous or misleading consumer products in the marketplace—have power over what health experts consider one of the most toxic items sold today: tobacco?

While tobacco companies respond with a resounding no, many anti-smoking groups, lawmakers and others believe that it should—and even insist that it already has some authority to regulate tobacco use.

"We've seen recent action on the part of the FDA with respect to silicone breast implants, food labeling and a host of other products," said Scott D. Balin, of the Coalition on Smoking OR Health. "It's time for action on tobacco products."

The coalition does not expect federal regulators to ban tobacco, only "to get it regulated in the way that is consistent with other products," said Joe Marx, a spokesman for the American Heart Assn. "We believe that if the crackdown is heavier, public perception will be more acute" as to its dangers, he said.

BACKGROUND: Public health officials have long complained about the dangers of smoking and in recent years have waged an unrelenting campaign that has been, by any measure, enormously successful. Societal attitudes have undergone dramatic changes toward smoking in public.

Regulation at the local level has become especially aggressive, with the widespread enactment of numerous ordinances that ban or restrict smoking in public places, such as restaurants and job sites. Nationwide, smoking has been on the decline in certain segments of the American population.

At the same time, despite its well-established risks, tobacco has been untouchable at the federal level, due to, among other things, the influence of the powerful tobacco lobby, the loyalties of congressional lawmakers from tobacco-producing states and continued consumer demand for tobacco products.

As a result, Congress and regulatory agencies have typically exercised a "hands-off" attitude toward cigarettes.

The coalition—made up of the American Heart Assn., the American Lung Assn. and the American Cancer Society—believes the FDA as well as the Federal Trade Commission, which regulates advertising claims, already have the power to do something about cigarettes but lack the will.

Recently, the coalition petitioned the FDA to use its existing authority to regulate cigarettes as "drugs" when implied health claims are made about them—for example, when a specific brand claims that it suppresses appetite and can help control weight, or that one brand is safer than another because it has less tar and nicotine.

And Rep. Mike Synar (D-Okla.) recently introduced legislation that would create a section in the Food, Drug and Cosmetic Act that would clearly give the FDA jurisdiction over cigarettes.

The tobacco industry intends to fight the legislation, as well as any attempt on the FDA's part to regulate tobacco. Industry officials have predicted that the FDA will never move on its own against tobacco.

"It's a terrible idea," Walker Merryman, vice president of the Tobacco Institute, said of efforts to involve the FDA. "The coalition clearly intends to try to ban cigarettes by bringing the FDA into the picture. If the FDA asserts itself, it will end up in court."

OUTLOOK: While federal health officials are quick to condemn cigarettes, they are reluctant to step into the politically charged issue of increasing federal regulation.

Dr. William Roper, director of the Centers for Disease Control, which runs the federal office of smoking and health, said he supports "anything that will eliminate smoking in the United States." But he and Surgeon General Antonia C. Novello said they would defer to the FDA on this issue.

For its part, the FDA, which has become extremely aggressive under the leadership of its new commissioner, Dr. David A. Kessler, seems just as reluctant as every other federal agency to take on tobacco.

"We don't have the resources to do what we're supposed to do now," one FDA official said. "We have an enormous public health responsibility—but we're not supposed to be God."

Won't the FDA curb this drug, too?

It's a product that kills 1,200 Americans a day. In a year, that toll comes to eight times as many victims as died in the entire Vietnam War.

Even people who never use this product can still be injured or killed just by coming into close, regular contact with users while they are consuming it. As many as 40,000 of these innocent bystanders lose their lives each year in the United States.

Measured in dollars, the toll exacted by this product — including reduced economic output — comes to $50 billion a year.

What's more, medical studies indicate the product can be addictive.

Yet, incredibly, advertising tries to equate this product with health, vigor and sex appeal.

Under the circumstances, shouldn't the U.S. Food and Drug Administration treat this product the same way it would any other dangerous substance?

Of course it should. And that's just what likely would happen if this were a comparatively new product.

But cigarettes have been around for centuries. Consequently, human nature and political inertia being what they are, don't hold your breath waiting for Washington to heed this week's request from the American Heart Association, the American Lung Association and the American Cancer Society — which joined in asking that tobacco be regulated like any other dangerous drug.

Despite such inertia, the health organizations should keep pushing their new request. It took years of campaigning, but Washington finally heeded demands for a ban on TV commercials for smoking and imposed health warning labels on cigarette packages and printed tobacco ads. And it took more years of such bans and warnings before the public started to curtail its smoking.

But eventually those messages got through — and so can the latest one, with enough patience and prodding.

The disease and death linked to tobacco are preventable. Caring members of an often lethargic but usually responsible country should keep pricking the government's conscience and educating the public for as long as it takes.

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The missing entree in regulatory menu

ELLEN GOODMAN

The story began, like a typical American breakfast, with a bracing dose of orange juice. In April, the Federal Drug Administration seized a batch of o.j., saying that it carried a false label. Citrus Hill Fresh Choice wasn't "fresh," dear Breakfast Clubbers and Wordsmiths; it was concentrated.

Having gotten the business folk to swallow that, the regulators went after cooking oil next. They told three manufacturers they couldn't put those cute little hearts and no-cholesterol signs on bottles of high-fat vegetable oil. The labels weren't exactly false, but they were misleading. They suggested that you could fry a path to good health.

These two moves sent a message that the regulators are back in the business of regulating. And that it isn't only linguists who are interested in the labels. Soon, we may be unraveling the mysteries of low-fat, low-salt and lite confusion that reign in the marketplace.

But there is still a missing entree in the regulatory menu. Every day 50 million Americans put something into their mouths that is exempt from the safety, health or truth-in-labeling laws that affect virtually every other product: Tobacco.

Tobacco remains the glaring renegade. It is the absolute outlaw on the American market.

Consider, for example, NEXT cigarettes, which are brazenly promoted for their "de-nicotined" tobacco. De-Nic has that nice decaf ring about its name. It promises all the flavor with none of the evil buzz.

But NEXT has nicotine, .1 milligrams a smoke, about the same amount as the older cigarettes, Carlton and NOW. It also has a mystery recipe of additives to give it that "rich flavor." But the maker doesn't say what they are or if they're bad for you.

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In short, the makers of low-tar and low-nicotine cigarettes do precisely what the vegetable-oil folk did. They make an implied health claim in their ads. But they get away with it.

This has not escaped the anti-smoking coalition, which has now petitioned both the FDA and the Federal Trade Commission to treat tobacco messages the way they treat orange juice or vegetable oil. Nobody dies, after all, from concentrated o.j.

"The FDA is in the process of defining low-fat and low-salt," says Scott Ballin of the American Heart Association. "At the same time we have cigarette companies making claims that their products are de-nicotine and low-tar and nobody is setting standards."

The complaint about De-Nic and Lo-Tar is just the filter tip of the issue, of course. Tobacco, the love child of politics, has been exempt from every federal health and safety act since the surgeon general's first report on the dangers of smoking.

Today, as anti-smoking activist Greg Connolly says, we regulate cigarette lighters but not the cigarettes they light. We regulate the toxic agents in every household product except the one dangling from someone's lips.

By now, we just assume everyone knows what the tobacco companies deny: that smoking is addictive and lethal. There is an almost casually judgmental attitude toward people who are dumb or dependent enough to keep smoking. On the other side, those who want to regulate cigarettes and cigarette advertising are often regarded as closet prohibitionists.

But you don't have to be in favor of the futile – a tobacco ban – to believe that smokers should know what it is they're lighting up. What happens to the hundreds of additives and chemicals in tobacco products when they burn? How do they interact with each other? What are their health implications?

The tobacco people always defend their product by saying that it's legal. But if that's true it should be treated like every other legal product. It should be regulated.

If the government can define what's lite, then it can define what's ultra-light. If ads for cholesterol-free oil make false safety claims, what about the ads for Merit Free? And how about the ads that associate Virginia with slimness and Camels with cartoons aimed at kids?

At the moment, there is one cigarette manufacturer who tells it like it is in smoking country. From California, we have a brand bearing its dire message in a neat black pack with a skull and crossbones. It's called "Death."

Now that's truth in advertising.

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