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Tobacco: American Stop Smoking Intervention Study (ASSIST), National Cancer Institute (NCI)

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Jerold Mande -- OSTP -- Box #3 Tobacco

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ASSIST Program
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Nicotine
Smuggling

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REMARKS BY VICE PRESIDENT AL GORE
NATIONAL INSTITUTE ON DRUG ABUSE
Monday, July 27, 1998

There is a story people tell about Albert Einstein that has special significance for us today. When he was a child, Einstein was a late talker, and his parents were very worried. One night at the dinner table, he finally broke the silence. Looking up at his mother, he said, "the soup is too hot." Greatly relieved, his parents asked him why he had never said anything before. Einstein replied: "because up until now, everything was in order."

I am honored to be here today with the people who first shook up the established order and broke the silence about tobacco more than a decade ago. Your work hasn't just opened our eyes, it has helped save thousands of lives. I am here today to talk about how we can apply all of our scientific might to one of the greatest public health challenges of all: protecting America's children from the dangers of tobacco.

Let us start by acknowledging what we all know: tobacco kills, nicotine is addictive, and the tobacco companies lied about it for decades.

You all know the statistics: the use of tobacco products is our nation's number-one preventable cause of death. Nicotine addiction lures away 3,000 young people every day, and will cost 1,000 of them their lives. Smoking among high school students has risen by nearly a third since 1991, to an astonishing 36.4 percent. We know that if our children don't start smoking by the time they're 19, they're unlikely to start at all. But once they start, it's hard to stop: 70% of adult smokers say they want to quit, but can't.

And we know why: nicotine is every bit as addictive as heroin and cocaine. In fact, it's fair to say that the main consequence of smoking is addiction, and that causes all the other problems. The significance of this conference here today should not be lost on anybody: the worlds' best researchers from a broad spectrum of disciplines have come together to reinforce what our best science has been saying for more than a decade: nicotine is a drug, and we should treat it like a drug.

We knew back in 1964 -- when the Surgeon General released his landmark report -- that smoking causes cancer. But now we know from recently released internal tobacco industry documents that they knew nicotine was a highly addictive drug long before 1964.

In 1961, a secret report from a scientist to Liggett & Myers found, and I quote, "there are biologically active materials present in cigarette tobacco. These are (a) cancer causing; (b) cancer promoting; (c) poisonous; and (d) stimulating, pleasurable, and flavorful." A secret 1963 memo from Brown and Williamson found, and I quote, that "nicotine is addictive. We are, then, in the business of selling nicotine, an addictive drug." And in 1980, a secret memo from the British Tobacco Company put it bluntly: "B.A.T. should learn to look at itself as a drug company rather than a tobacco company."

We know from these documents that tobacco companies saw cigarettes for what they really are -- as "a vehicle for delivery of nicotine," a "dispenser for a dose unit of nicotine," and a "nicotine delivery system." Most reprehensibly, even though all 50 states prohibit selling tobacco to kids, we also know how tobacco companies saw children: as "replacement smokers," who needed to be hooked young and hooked often. It is a testament to their skill in marketing their poison that when this decade began, more children could recognize Joe Camel than Mickey Mouse.

For too long, taking on big tobacco was considered virtually impossible in Washington. But under President Clinton's leadership, what used to be a third rail is becoming a second chance for millions of American children. Eighteen months ago, we put in place the toughest measures ever to curb teen smoking. Those measures -- along with the work of the state Attorneys-General -- forced the tobacco companies to the negotiating table.

President Clinton took strong leadership and laid out five broad principles that must be part of any national tobacco legislation. He said: the bill must penalize companies if teen smoking doesn't decline; allow the FDA to regulate tobacco as a drug; disclose tobacco company information on the dangers of their products; advance other health goals through medical research; and protect the economic welfare of tobacco farmers and their communities.

When the Senate Commerce Committee considered this important issue, an overwhelming bipartisan majority -- nineteen to one -- voted for a comprehensive bill to dramatically reduce teen smoking and save over one million lives. Then something happened: the mighty tobacco industry decided to kill it. They took \$40 million that they earned selling cigarettes to kids, and used it on an advertising campaign so they could keep selling cigarettes to kids. And the Republican leadership fell in line -- lock, stock, and barrel. Because of it, we came up three votes shy of the 60 we needed to move the bill along and save lives.

I promise you: this is not the end of the fight, it's just the beginning. We are going to keep pushing this fight again and again and again until we win this victory for America's children.

At the same time, we need to do more to find out why children smoke and how we can help them stop. Government can provide the resources. But you must provide the answers.

Thanks to your research, we know a lot more about addiction than we ever did before. We know that nicotine enters the brain very rapidly, within 10 second of inhalation. We know that nicotine acts on the same pathways as other drugs, such as cocaine, heroin, and marijuana. We know that nicotine remains in the brain for a very short period of time -- about 30 minutes -- and must be consumed over and over again to sustain its pleasurable effect.

We also know that genetic factors play a critical role in addiction. A few months ago, for example, we learned that African-American smokers have higher levels of metabolized nicotine than whites or Mexican Americans, making it harder for them to quit smoking.

As you will hear at this conference, astonishing new research has identified a gene variant for the enzyme that seems to predict, at least in part, people who are more likely to become dependent upon nicotine. As you will also hear, research has been able to create a genetically mutated mouse which lacks the genes that make up the protein sites in the brain where nicotine initiates its many effects. All of this will help lead to a better understanding of addiction, and how we can prevent it.

But now, we must take the next step -- to build on what we know, so we can answer what we don't know. In business, they call them leverage points: finding those points that will lead to the greatest change overall. I believe there are certain leverage points in the debate over tobacco. They are not just roadmaps to change, I believe they are a challenge to the entire research community. Let me suggest five.

First, what makes nicotine and other substances so addictive? Although we know more than we have ever known about how nicotine affects the brain, we still don't know how nicotine produces its addictive effects on the brain. I'm told that researchers at this conference will suggest that other chemicals in tobacco also contribute to addiction. Understanding the basic neurobiology of nicotine addiction will give us important new insight -- not merely into tobacco, but other addictive substances as well.

Second, what makes a person progress from experimenting with a tobacco product to addiction? We know the relative speed with which nicotine moves through the body, but we still don't know what moves the brain to addiction. By understanding the role cultural, social, biological, behavioral, and genetic factors play -- as well as the influence of families -- we can better determine who is most vulnerable to addiction.

Third, how can we help our children resist the temptation to try tobacco products? What role can parents, communities, schools, religious institutions, and the media play in preventing tobacco use? What prevention programs are most effective? By understanding what strategies work best, we will get the most mileage from our investment dollars.

Fourth, what treatments are most effective for nicotine addiction, to help people quit? We've all seen nicotine replacement methods, like the patch and nicotine gum. What treatments work best? What factors determine what will work for some people, and not for others? New treatments based on our increased understanding must be developed so we can tailor solutions to individual needs.

Fifth, what treatments are most effective for teenage smokers? While there has been substantial focus on helping adult smokers quit, there has been little progress on cessation programs for teenagers. With more than 3,000 children beginning to smoke every day, we don't have a second or a child to waste.

These five questions may not be answered in the next year, or even the next five years.

But if we are going to stem the tide of teenage smoking once and for all, and help the millions of Americans who want to quit, we must find answers to all of them.

You are not alone in this effort. This crusade began as a partnership, and it will continue as a partnership. President Clinton and I see tobacco research not just as a policy priority, but as a moral obligation. That's why we have committed over \$200 million a year across the Institutes at NIH and CDC to find answers to these questions. Today, we take the next step.

I am proud to announce that funding for tobacco research at NIH will increase significantly in the coming year. I am especially proud to announce that over the next two years, the National Cancer Institute will dedicate \$38 million to new initiatives to help prevent smoking, and to help people quit. This represents an unprecedented increase of \$18 million, so we can better understand the nature of nicotine addiction, and ultimately do more to stop it. By funding groundbreaking new tobacco research, we will harness the full power of science and technology to protect our children, and finally turn the tide on our tobacco epidemic.

As parents, we do everything in our power to love and protect our children. We put sunscreen on them in the summer and mittens and hats in the cold. We make sure their toys are safe, and try to protect them from harm. We do all we can to protect them on the outside -- and we can no longer allow this poison to destroy them on the inside.

Three thousand children a day is a shame we all share. Together, we face it. Together, we must solve it. And we don't have a moment to waste -- because our children are waiting. Thank you.



July 27, 1998

VICE PRESIDENT GORE ANNOUNCES \$38 MILLION FOR NEW TOBACCO RESEARCH

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THE WHITE HOUSE

Office of the Vice President

For Immediate Release	Contact:
Monday, July 27, 1998	(202) 456-7035

VICE PRESIDENT GORE ANNOUNCES \$38 MILLION
FOR NEW TOBACCO RESEARCH

Challenges Researchers to Help Better Understand Tobacco Addiction and How To Prevent It

Washington, DC -- Vice President Gore announced today that the National Cancer Institute plans to allocate \$38 million for additional research into prevention and cessation programs to reduce tobacco use, and he posed five questions for researchers to help Americans better understand tobacco addiction and how to prevent it.

"These investments in more research can help turn the tide on the tobacco epidemic," the Vice President said in a speech to 600 researchers and public health advocates at the first conference on nicotine addiction sponsored by the National Institute on Drug Abuse, the National Institutes of Health (NIH), and the Robert Wood Johnson Foundation.

"President Clinton and I see tobacco research not just as a policy priority, but as a moral obligation," he added. "By funding groundbreaking new tobacco research, we will harness the full power of science and technology to protect our children."

This \$38 million is part of the President's 1999 budget, which includes an unprecedented increase in funding for research at NIH. The National Cancer Institute, which is part of NIH, plans to spend this money over the next two years:

to determine if adult cessation programs, including the nicotine patch, and nicotine gum work for children; to find other successful cessation programs for children; and to enable university researchers to learn why some children can resist tobacco advertising and marketing that is targeted at them;

to work with the National Institute of Drug Abuse in genetics research to discover genetic factors that contribute to tobacco addiction;

to provide epidemiological research to track patterns in children's smoking over a longer period than ever before;

to find new, better treatments for adults addicted to nicotine; and

to extend the National Cancer Institute's American Stop Smoking Intervention Study (ASSIST) program, a joint effort with the American Cancer Society and 17 state health departments, to focus the newest tobacco control research on populations that are still smoking and those that disproportionately use tobacco products, including minorities.

- more -

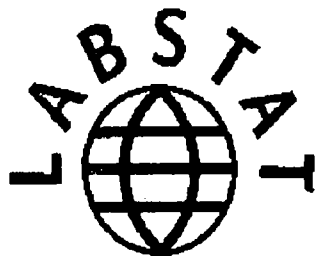
The Vice President posed five questions for researchers to help promote more understanding of tobacco addiction: (1) what makes nicotine so addictive? (2) what makes someone move from experimenting with a tobacco product to addiction? (3) how can we help children resist the temptation to try tobacco products? (4) what treatments work best for nicotine addiction? (5) what treatments work best for teenage smokers?

The Vice President also renewed his call for Congress to pass comprehensive tobacco legislation to reduce youth smoking. Each day, he said, 3,000 young people start smoking, 1,000 of whom will die prematurely from a tobacco-related disease. In addition, over three million teenagers -- over 22 percent of high school students -- smoke cigarettes on a daily basis.

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Fax Cover

To: Jerry Mande		From : Bill Rickert	
Fax Number : 1-202-456 6027		Company : Labstat Inc.	
Date : 7/23/98	Time : 6:06:58 PM	For Information Call: 748-5409	
Subject : Canada's Expert Committee		Fax Number : 1-519-748-1654	

Good Afternoon Jerry:

Thanks for giving me the opportunity of providing a bit of input on an important public health issue; namely the reduction of cigarette addiction and toxicity. In Canada the tendency has been to consider both aspects of the cigarette problem simultaneously using a number of different approaches. One has been to obtain advice from various expert committees such as the one that considered cigarette packaging and the other which considered product modification.

As a mentioned to you, I have been asked to form and chair another committee which will be addressing the issue of cigarette toxicity reduction. A draft agenda follows this letter. Participants in the last meeting were strongly in favour of the process which lead to the meeting. They were also appreciative of the meeting environment which was structured to encourage frank, in depth and meaningful discussions among individuals who would normally be adversarial. I would strongly recommend that you consider a similar process in the United States.

Please get in touch if I can be of further help.

Best regards

Bill Rickert

Draft Agenda (1)

Canada's Expert Committee on Cigarette Toxicity Reduction

1. Issues, strategies and the definition of progress in programs designed to reduce the risk associated with smoking; thoughts and general comments; an overview
2. Identification of beneficial and/or harmful modifications which have been made to cigarette construction and filler.
 - Nature of the modification(s)
 - Evidence for beneficial effect(s)
 - Evidence for harmful effect(s)
 - Conclusions
 - The Canadian Government is on record as requesting reporting on over 50 compounds in whole tobacco, mainstream smoke and sidestream smoke. Is this an adequate basis for a harm reduction strategy from a chemical toxicity standpoint or should the list be modified
3. Sidestream emissions: importance and monitoring strategies
 - How serious is the risk to health from sidestream emissions (ETS) in relation to other environmental pollutants?
 - What is the history of attempts to reduce sidestream emissions?
 - How would 'success' be measured in a program of sidestream emission reduction?
 - What sort of on-going monitoring scheme would be appropriate for monitoring and reducing exposure
 - In underage populations
 - In adult populations
4. An assessment of options for manipulating nicotine within the reduced harm context, maintain, increase, eliminate or reduce (pros and cons)
 - Is there a threshold at which nicotine addiction might begin for many smokers
 - If so what is it and how was it determined
 - If not, is it likely that one exists and if so, how might it be determined
 - Can nicotine be made either more or less addictive through the use of additives.
 - If so, what is the mode of action
5. An assessment of additives, contaminants and ammonia technologies as determinants of cigarette toxicities and usage
 - Classification of additives based on function Typical levels
 - Classification of contaminants and typical levels
 - Are there any additives used in Canadian cigarettes in sufficient quantity as to be of concern from an increased risk standpoint.
 - What additives/contaminants should be monitored on a regular basis. How might this be accomplished.
 - What is ammonia technology and its potential role in cigarette manufacture and usage.
6. Estimation of changes in nicotine exposure and various physiological endpoints resulting from the use of potentially 'reduced risk' products.
 - What are the physiological endpoints which could be used in the short term to monitor changes resulting from the usage of 'reduced risk' tobacco products (cigarettes) What would a comprehensive monitoring program entail.

- Given the evidence accumulated to date, are there any smoking-related conditions which have a 'strong' linkage to nicotine usage.
 - What are the issues involved in implementing a nicotine monitoring population based program
 - What populations should be monitored
 - How often should they be monitored
 - What should be monitored and how
 - What would constitute an increase (decrease)
 - What course of action should follow an increase (decrease)
 - What sort of sample sizes would be required to detect specific differences among products within populations. Among products and 'different' populations
7. Identification of 'cellular-based' short term tests which are available for the assessment of the potentially harmful properties of tobacco smoke.
- Properties and nature
 - Ranking in terms of specificity and relation to longer term outcomes
 - Illustration of results from innovative tobacco products
8. Identification of 'animal or organism-based' short term tests which are available for the assessment of the potentially harmful properties of tobacco smoke.
- Properties and nature
 - Ranking in terms of specificity and relation to longer term outcomes
 - Illustration of results from innovative tobacco products
9. Definition of success and suggestions for long term monitoring from an epidemiological perspective.
- What endpoints should be monitored and how often
 - Major design considerations including structure of the sample
 - For risk reduction resulting from exposure to ETS
 - For risk reduction resulting from exposure to mainstream smoke.
 - Responsibilities and potential courses of actions
 - How much reduction/increase would be defined as 'success'/'failure'
10. Monitoring strategies for the potential effect of cigarette modifications on cessation and initiation and the identification of progress.
- Models for estimating harm to society
 - Possible monitoring schemes
 - For cessation
 - For initiation
 - Issues to be addressed
 - Monitoring period
 - Course of action
 - Levels of responsibility
11. Communication of information resulting from the monitoring of a reduced risk cigarette product
- Who should be responsible for the communication of this type of information
 - How should the information be structured (ie. Under what circumstances should health claims be allowed if ever)
 - How might this information be conveyed and in what format

MASSACHUSETTS TOBACCO CONTROL PROGRAM

Department of Public Health, Bureau of Family and Community Health

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Fax Cover Sheet**DATE:** 4-17-98**TO:** Terold Mande **FAX:** (202) 456-6027**FROM:** Gregory N. Connolly, DMD, MPH**PHONE:** (617) 624 5900 **FAX:** (617) 624-5921**NUMBER OF PAGES INCLUDING COVER SHEET:** 2

Memorandum

DATE: April 17, 1998

TO: Jerold R. Mande/OSTP/EOP

FROM: Gregory N. Connolly, D.M.D., M.P.H. (

RE: VICE PRESIDENT'S REMARKS

"At a youth town meeting on tobacco I held last month in Boston I saw first-hand what ASSIST can do. Massachusetts built upon its ASSIST foundations with dedicated funds for tobacco control from a recent increase in the cigarette tax. The Massachusetts campaign is one of the largest in the world and has achieved an impressive 30% decline in cigarette consumption. At the town meeting youth told me how they were fighting back against big tobacco participating in checks to make sure stores didn't sell cigarettes to minors, ~~helping their younger brothers and sisters~~, helping their friends quit smoking, cataloging cigarette advertising in their community, and lobbying and advocating for passive or clean indoor air laws.

~~We~~^{As} the nation moves to comprehensive tobacco control legislation, the Congress looks to the success stories like Massachusetts and ASSIST to fund the programs that we need to protect our children. If the tobacco industry walks from this endeavor, they will certainly face an army at the state and local level.

Issues & Ideas

PHILIP MORRIS'S ANTISMOKING NEMESIS

BY ELIZABETH GREENSPAN



MARC MANLEY: The National Cancer Institute has "every intention of continuing tobacco-control work."

The tobacco research program ASSIST has been a rare success story among federal programs to stop smoking. Just ask Philip Morris Cos. Inc.: "ASSIST [American Stop Smoking Intervention Study] will hit us in our most vulnerable areas—in the localities and in the private workplace," warned one of the several memos that circulated through the upper echelons of the tobacco company. "It has the potential to peel away from the industry some of its historic allies."

ASSIST will end in the fall of 1999, when its eight-year trial run finishes, and its benefactor, the National Cancer Institute (NCI), a division of the National Institutes of Health, has no immediate plans to keep research like it going. (The Centers for Disease Control and Prevention, however, has slated a spin-off of ASSIST.)

What is most worrisome is that despite the apparent effectiveness of such studies, funding for all community-based, tobacco-control research initiatives are in peril.

Antismoking campaigners are timing over the NCI's lack of support for this type of research, and are still pressing for ASSIST-like programs to be put in place.

Many antismoking advocates believe that NCI director Rick Klausner isn't open to tobacco-intervention research because he has little interest in work that strays from the conventional biomedical lab research that is more common at the institute.

"It has been trench warfare between the health community and Klausner," said Stanton Glantz, a prominent anti-tobacco activist and professor of medicine at the University of California (San Francisco). "There has been continued foot-dragging at NCI."

ASSIST is the largest program the federal government has ever funded to reduce smoking, and in the 17 trial sites, statistics show that it has reduced tobacco consumption between 7 and 10 per cent, or 50 mil-

lion packs of cigarettes per month. Many medical experts say that the key to ASSIST's success is its emphasis on changing the social environment of smoking. The research program specifically advocates higher cigarette taxes, stricter smoking regulations in public and reduced teen access to cigarettes.

ASSIST workers are convinced their research has produced a unique set of guidelines for kicking the habit, and consider it a badge of honor that the tobacco industry has been trying to destroy them for years. Their suspicions were recently confirmed when a Minnesota judge ordered a series of Philip Morris memos onto a company Web site in connection with a civil lawsuit against the tobacco industry. One memo details how Philip Morris even sent a disguised company employee ("I signed in as a student and hoped that my baggy clothes and backpack would make this credible," the memo read) to at least one local ASSIST meeting in Ft. Collins, Colo. In the memo, dated Dec. 9, 1992, the employee outlined the meeting, including the ideas discussed to reduce smoking in the state, and described ways company "plans" could avoid attracting attention.

"Philip Morris took this program very seriously; they did everything they could to stop us. But despite them, we succeeded," said Jerrie Jordan, who supervises the American Cancer Society's work with ASSIST.

But to date, the NCI has not decided whether it will fund follow-up research along the lines of ASSIST. Marc Manley, chief of the public health applications branch at NCI and program director of ASSIST, says the institute has "every intention of continuing tobacco-control work," but that "there are no firm decisions made." However, the Tobacco Research Implementation Plan detailing NCI's next cycle of tobacco research will be released in September.

Impact of the American Stop Smoking Intervention Study on cigarette consumption

Marc W Manley, John P Pierce, Elizabeth A Gilpin, Bradley Rosbrook, Charles Berry, Lap-Ming Wun

Abstract

Objective—To obtain an early estimate of the effectiveness of the American Stop Smoking Intervention Study (ASSIST).

Design, setting, and participants—Seventeen American states funded through ASSIST are compared with 32 others regarding per capita cigarette consumption from 1989 to 1995. California, which already had an extensive tobacco control programme, was omitted. ASSIST states were selected competitively (not randomly) based on their proposals' merit, state smoking prevalence, and geographical distribution.

Interventions—Comprehensive tobacco control programmes, emphasising policy interventions, were implemented in the ASSIST states beginning in 1993.

Main outcome measures—Trends in aggregated per capita cigarette consumption and inflation-adjusted average price/pack of cigarettes in the intervention states were compared. Percentage change in per capita consumption is also compared with percentage change in inflation-adjusted cigarette price by state in each group from 1992 to 1994.

Results—Per capita consumption and inflation-adjusted cigarette price were nearly identical in both groups of states before 1993, when full funding for the ASSIST interventions began. However, by 1996 smokers in the intervention states were consuming about 7% less cigarettes per capita ($P < 0.05$, beginning in 1994), and in 1994 the average price was over \$0.12/pack higher in the intervention states. All but three states (all intervention) showed decreases in cigarette price. Nonetheless, 76% of the intervention and 55% of the comparison states showed some decrease in consumption despite decreases in price. The relationship between changes in price and consumption was considerably diminished in the intervention group.

Conclusions—These interim results suggest that the ASSIST programme is associated with a substantial difference in tobacco consumption in a third of the United States, and that increased price from taxation may not be the only programme influence.

(*Tobacco Control* 1997;6 (suppl 2):S12-S16)

Keywords: ASSIST programme; cigarette consumption; tobacco tax

Introduction

Tobacco use has been identified as the leading preventable cause of death.¹ The National Cancer Institute (NCI) has sponsored more than a decade of research aimed at identifying the most effective ways to reduce tobacco use. This research suggests that comprehensive programmes that emphasise media and policy are the most promising intervention approaches in the current environment.² Such statewide comprehensive programmes have been associated with a reduction in smoking in two states in Australia,³ and in California⁴ and Massachusetts.⁵

The American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) is a phase V research initiative to develop, implement, and evaluate statewide tobacco control projects. Phase V projects are designed to demonstrate that interventions are widely applicable to the population of the United States. It is one of the first demonstration projects of its kind that has been supported by the NCI.

In 1989, proposals for tobacco control programmes from state health departments were sought and reviewed both for their scientific merit and their ability to mobilise community coalitions. The selection process yielded 17 intervention states with a population base of 91 million people, closely reflecting the total American population in ethnic and geographical diversity. The ASSIST project began in 1991 under the direction of both the NCI and the American Cancer Society (ACS).

Funding to support tobacco control programmes in each of the intervention states was set at a developmental or planning level for 1991 and 1992. Each state was required to have a coalition of organisations to guide the project under the leadership of the state health department and the state division of the ACS. Each state coalition developed a five-year comprehensive smoking control plan specifically tailored to the needs of the state, but within the scientific guidelines provided by the NCI. The plans included goals related to public policy (clean indoor air, youth access, advertising, and tobacco taxes), mass media, and programme services (such as smoking cessation classes). All states emphasised policy advocacy as the most effective and efficient type of activity. Programme staff and volunteers received extensive training in policy advocacy, media advocacy, coalition development, and other tobacco control topics. From 1993 to 1998 budgets were increased to

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approximately \$1 million/year per state for programme implementation. All the intervention states were encouraged to use other funding to supplement this implementation budget whenever possible.

Evaluation of the effectiveness of tobacco control interventions in this phase V research project is complicated by the presence of other tobacco control interventions. For example, tobacco excise taxes have been increased in many states in the past five years,⁷ in some instances ostensibly for revenue generation. In a few states, additional elements of a comprehensive tobacco control programme have been funded by increased state tobacco taxes. The most prominent examples are the large programmes in California,⁸ Massachusetts, and Arizona. In addition, other agencies concerned with public health provide state-level funding for tobacco control programmes. The Centers for Disease Control and Prevention (CDC) and the Robert Wood Johnson Foundation (RWJ) provide such support for state programmes at a more modest annual level of \$74 000–\$300 000 per state.^{10,11}

In this article, we present data depicting trends in per capita cigarette consumption and inflation-adjusted average cigarette price for the ASSIST intervention states and a comparison group of states. As California implemented a large and ongoing tobacco control programme funded by a substantial increase in its cigarette tax in 1989, we have omitted it from our comparison. Documentation of similar trends for the two groups of states in cigarette consumption and price before the start of this research project is important to the final evaluation of the effectiveness of the ASSIST interventions. We also examine the trends in per capita consumption through 1995 to identify whether the early years of the ASSIST intervention were associated with a significant difference in per capita consumption levels. Finally, we examine cigarette prices between 1989 and 1994 to assess differences between the two groups of states in this important aspect of the ASSIST intervention.

Methods

CIGARETTE CONSUMPTION AND PRICE DATA

The Tobacco Institute compiles and reports data on tax payments from all packages of cigarettes removed from wholesale warehouses to retail outlets within each state on a monthly basis.¹² The reporting unit is the number of cigarette packs on which taxes were paid in any given month. Data from December 1984 through January 1996 are included in the present analysis. Although consumption estimates from this source are subject to monthly and seasonal variations that are business related rather than reflecting variation in consumption patterns, these data are gathered in a uniform manner across states and are the usual source for reporting national per capita consumption. Both the US Department of Agriculture and the US Surgeon General's reports on smoking and health use this data source.^{13,14}

In this analysis we aggregate the consumption data from all states that received ASSIST funding (intervention group) and contrast it with the aggregated consumption data in states not receiving such funding (comparison group). We excluded California, which had a very large tobacco control programme during this period that was funded by an increase in its tobacco excise tax.⁸ Although Massachusetts, an ASSIST participant, also funds a tobacco control programme partly by a tax increase, it is retained in the analysis, because the impetus for the tax increase resulted from policy encouraged by the ASSIST intervention.⁶ The 17 states participating in ASSIST are: Colorado, Indiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Rhode Island, South Carolina, Virginia, Washington, West Virginia, and Wisconsin (see map on page S8). The data for the District of Columbia were included in the comparison group of states.

The average price of a package of cigarettes (including state and federal excise taxes) as of 1 November of each year is published for each state annually, again by the Tobacco Institute.¹⁵ Data from November 1989 through November 1994 (the last year for which it was available) were analysed.

DATA ANALYSIS

Changes in total cigarette sales within a state may not be related to changes in smoking behaviour if the state population changed during the study period. We estimated per capita consumption for a given state in any given year using census estimates for the state population aged 18 years and older. We followed the Surgeon General's age criterion¹⁷ of 18 years because only about 1% of cigarettes sold in the United States are consumed by people aged 18 and younger.^{16,17} Decade census population data are as of 1 April for 1980 and 1990, and supplemental within-decade estimates are as of 1 July of each year.^{18,19} To obtain monthly estimates of state populations, we fit regression lines to the yearly data and interpolated.

Business-related variance in tax data occurs because of increased inventory clearance in the final month of any quarter (especially December) and corresponding reduced clearance in the first month of the quarter (particularly January). To partly remove this consistent pattern from the trend analyses, we consider six data points in each 12-month period which are computed by averaging the monthly results for December and January, February and March, ... October and November. Further, to assess trends over time, we applied the SABL seasonal and calendar adjustment procedure, available in the statistical package S-plus,^{20,21} to these averaged bimonthly raw data points. The results from this procedure are called "deseasonalised" data.

To assess trends in the difference between the intervention and comparison states, the raw bimonthly data points for the intervention group were subtracted from those for the

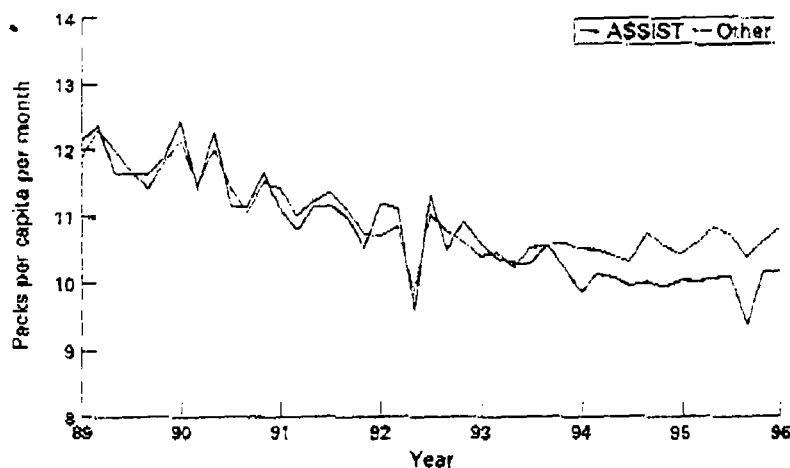


Figure 1 Deseasonalised per capita cigarette consumption for intervention and comparison states (excluding California).

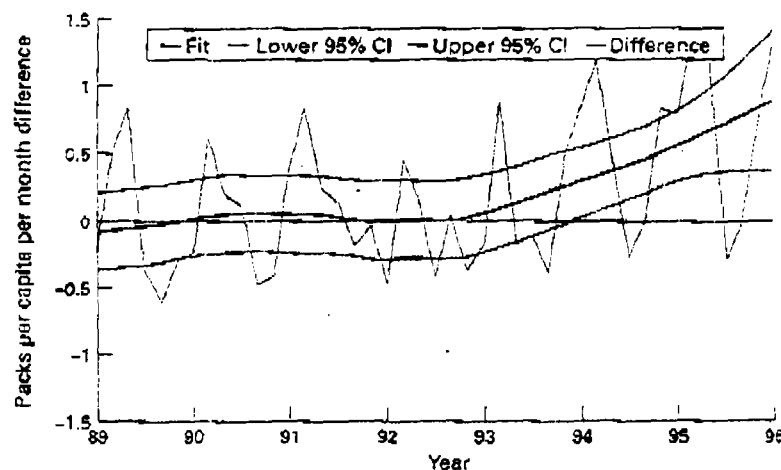


Figure 2 The thin line is the difference in raw per capita cigarette consumption between intervention states and comparison states (excluding California). Positive values indicate lower consumption in intervention states than the comparison states for that period. The thick line is the smoothed difference (with 95% confidence limits) in per capita cigarette consumption for the two groups of states. Where the lower confidence limit exceeds zero, the difference between the two groups of states is significant at $P < 0.05$.

comparison group, a procedure that also directly removes most of the seasonal variation. Finally, we used a smoothing algorithm (Loess procedure from S-plus) which employs a bootstrap procedure allowing 95% confidence intervals (CI) to be calculated for the smoothed trend lines.²² Although data from before 1989 were used to increase the precision of the estimates of seasonal variation for the calculation of Loess trends, the two groups of states had identical trends so these data are not included in the figures.

For the analysis of the price data, we computed the weighted yearly average inflation-adjusted price/pack of cigarettes for the intervention and comparison groups. The weights were the state adult populations, as in the per capita consumption analysis. Inflation adjustments were to 1989 dollars using regional consumer price index adjustments applied to the data from appropriate states.²³ In addition to examining the trends in price for the intervention and comparison groups, we plotted the percentage change in consumption versus the percentage change in price from 1992 to 1994 for each state individually. As price is reported as of 1 November each year,

we use the October–November per capita consumption data point for each state. We chose this time interval because 1992 is the last year of the planning phase for the ASSIST states and 1994 is the last year price data was available. The simple linear regression of percentage change in price versus percentage change in consumption was computed for each group of states.

Results

DESEASONALISED PER CAPITA CONSUMPTION TRENDS

There appears to be no difference in the deseasonalised per capita consumption data between the intervention and comparison groups through at least mid 1993 (figure 1). In 1989, consumption in both groups was approximately 12 packs per person per month and by 1991 it had decreased to 11 packs per person per month. However, starting in late 1993, the consumption trends start to diverge. The intervention states maintained a lower consumption rate through 1995, but the comparison group appears to show an increase in consumption.

CONSUMPTION DIFFERENCES BETWEEN GROUPS

Figure 2 shows the difference in raw per capita consumption (thin line) between the intervention and comparison groups. If there is no difference between these groups of states, the data should show random fluctuation about the zero difference line. However, beginning in 1993, there appears to be more positive than negative differences. The smoothed difference (thick line) in per capita consumption shows that 1993 was the beginning of a consistent pattern of lower per capita consumption in the intervention states. By 1994, the lower limit of the 95% CI for the smoothed trend is above the zero difference line, indicating that the difference between the two groups of states, is statistically significant ($P < 0.05$). At the beginning of 1996, consumption in the intervention group was about 7% less than that in the other group.

CIGARETTE PRICE TRENDS IN THE INTERVENTION AND COMPARISON GROUPS

The weighted average inflation-adjusted price per pack for the intervention and comparison groups of states was similar from 1989 to 1992 (figure 3). Both groups experienced a drop in price from 1992 to 1993. By 1994, the price per pack appeared to have returned to its 1992 level in the intervention group of states, although it was lower than the 1992 level in the comparison group. In 1993 the inflation-adjusted price per pack for the intervention group was \$0.066 higher than the comparison group, and this differential increased to \$0.126 in 1994.

PRICE VERSUS CONSUMPTION CHANGES, 1992–1994

Figures 4 and 5 present the association between the percentage change in the inflation-adjusted price per pack of cigarettes versus the percentage change in per capita consumption between 1992 and 1994 for each individual state. In the comparison group of

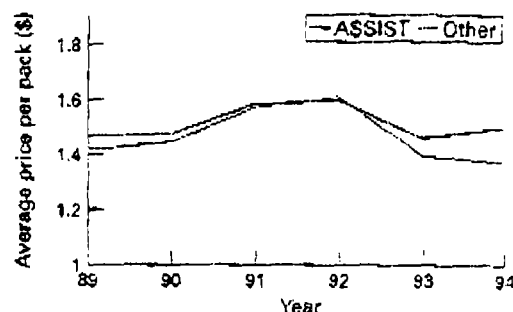


Figure 3 Trends in inflation-adjusted price/pack of cigarettes for interventions and comparison states (excluding California).

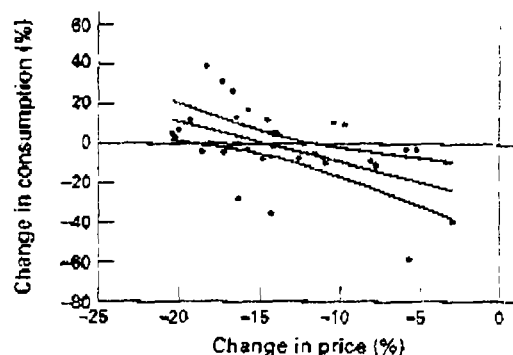


Figure 4 The percentage change in inflation-adjusted price/pack of cigarettes from 1992 to 1994 plotted against the percentage change in per capita cigarette consumption for comparison states (excluding California).

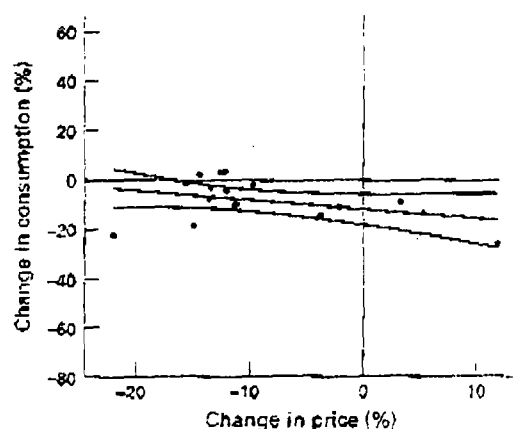


Figure 5 The percentage change in inflation-adjusted price/pack of cigarettes from 1992 to 1994 plotted against the percentage change in per capita cigarette consumption for ASSIST states.

states, the 1994 real price of cigarettes is 5–20% lower, with 18 states showing $\geq 15\%$ price decrease from 1992. No comparison state had a price increase, yet 55% showed a decrease in consumption. The slope of the regression line for percentage change in price versus percentage change in consumption was -2.11 (95% CI = -3.34 to -0.80).

Three intervention states show real price increases between 1992 and 1994, and only one had a price decrease of greater than 15%. In each of the three intervention states with a price increase, consumption decreased as expected. In the 14 intervention states with a decrease in price, 11 (76%) also had decreased consumption. In the remaining three states, the

increase in consumption was very small. The slope of the regression line was -0.39 (95% CI = -0.87 to 0.11) which was not significantly different from zero.

Discussion

Phase V demonstration projects such as ASSIST cannot usually be randomised, controlled trials, so it is important that the intervention group be similar to the remainder of the population on the major study measures at the time it is selected. There were no differences between the intervention and comparison groups of states in either cigarette consumption or cigarette price before state selection (1989–1990) and through the planning phase (1991–1992) of the ASSIST project. Thus, any differences observed are unlikely to be greatly influenced by selection bias.

Coincident with the beginning of the ASSIST implementation period in 1993, per capita cigarette consumption levels started to diverge between the ASSIST and comparison groups of states, becoming statistically significant in 1994. This difference has persisted through to the beginning of 1996, at which time consumption in the ASSIST states was about 7% below that of the other states. A difference is also present when Massachusetts is excluded from the ASSIST intervention group. Furthermore, the slope of the regression line in figure 1 with Massachusetts excluded is still not statistically different from zero, so the conclusions of this report are unchanged.

One possible explanation for the difference in consumption between intervention states and the others is cross-border sale of cigarettes. Cigarette companies have claimed that increases in cigarette excise taxes will result in people buying cigarettes from neighbouring states. All comparison states (except Alaska and Hawaii) border at least one intervention state. Five ASSIST states (Massachusetts, Michigan, New York, Rhode Island, and Washington) had price increases of greater than \$0.15/pack in 1993 or 1994. In only one neighbouring state, New Hampshire, was there an increase in consumption during this time. Thus, it is unlikely that the overall consumption trends for the two groups of states we analysed are greatly influenced by cross-border purchasing.

As mentioned previously, the ASSIST intervention is a comprehensive tobacco control programme coordinated at the state level that included guidelines for raising cigarette excise taxes as one method of reducing consumption. However, only about 40% of ASSIST states were actually able to increase taxes in 1993 or 1994, and in this same period, nearly a third of the comparison states also increased their tobacco taxes.⁷ Most of those tax increases were not reflected in long-term increases in real cigarette prices. In April 1993, Phillip Morris announced an unprecedented 20% reduction in the price of premium cigarettes, and other tobacco companies quickly matched this.²⁴ This drop in the inflation-adjusted price in both the intervention and comparison

groups of states is reflected in figure 3. This price decline is responsible, at least in part, for the first increase in the total American cigarette consumption observed in 1995 since the mid 1970s.¹⁵ Figure 1 shows that the decline in consumption was arrested in the ASSIST states and reversed in the comparison states after 1993.

Given the known relationship between cigarette price and consumption, that is, the price elasticity of demand, it is very likely that the consumption differences between the two groups of states were caused at least in part by the differences in price. However, our data suggest that price may not be the only influence on cigarette consumption in many states. The slope of the regression line for percentage change in price versus percentage change in consumption was significantly different from zero in the comparison group, but appears much diminished in the ASSIST group. Thus, compared with the other states, price seems to be a weaker correlate to consumption in the ASSIST group, which suggests a role for other influences. Such influences may be the result of other tobacco control programme elements besides taxation that may decrease tobacco consumption. As mentioned earlier, these other policy areas included worksite smoking restrictions, mass media campaigns, and smoking cessation programmes. In California, per capita cigarette consumption dropped when the increased excise tax went into effect and then dropped further when programmes supported by the new tax revenue were implemented.¹⁶ Future analysis will examine patterns of consumption in Massachusetts and other individual states.

In addition to public health programmes, cigarette consumption is influenced by tobacco company actions, including cigarette marketing. In 1993, tobacco companies spent more than \$6 billion on marketing and promotion, compared with \$1.9 billion a decade earlier.²⁰ The fact that cigarette consumption is no longer decreasing in many states may be related to this enormous marketing budget that dwarfs the budgets of publicly funded tobacco control programmes. In addition to these marketing efforts, the tobacco industry has also disrupted the efforts of many state tobacco control programmes apparently to diminish their effect.²¹ This interference may continue.

At the time it was conceived, ASSIST was unprecedented in its magnitude and ambitious goals. The consumption trends observed this early in the intervention phase are very encouraging. No tobacco control effort has ever been associated with this level of difference in such a large population. Although conclusions from these trends can only be tentative, one plausible inference, which evidence from California and Massachusetts supports,²² is that reductions in tobacco use in very large populations can be achieved through comprehensive public health programmes.

This study was supported by contract 89-97872 from the California Department of Health Services, Tobacco Control Section, and by Contract CN-05295 from the National Cancer Institute.

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TOBACCO CONTROL

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Studies in Community Tobacco Control: Projects COMMIT and ASSIST

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From: Stanton Glantz

COMMENTARIES

Below we are publishing a commentary by Professor Stanton Glantz, in which he lays out his views on the appropriate role of the National Cancer Institute (NCI) in supporting tobacco control research. The National Cancer Institute is part of the National Institutes of Health, which is the lead federal agency funding biomedical research in the United States. Following Glantz's commentary, we publish five replies from seven others involved in tobacco control research and practice.

This discussion is particularly timely for two reasons. First, it takes place as the NCI is winding down a large demonstration in tobacco control: the American Stop Smoking Intervention Study (ASSIST). ASSIST followed the NCI's first large-scale community study in tobacco control: the Community Intervention Trial for Smoking Cessation (COMMIT). Second, publication of this issue of Tobacco Control coincides with publication of a special supplement to the journal, which is devoted to research related to COMMIT and ASSIST.

We invite readers to share their own views with us in the form of letters to the editor. Instructions for letters to the editor appear in our Instructions to Authors, which were published in our Spring 1997 issue and which are available on our web site <http://www.tobaccocontrol.com>. —ED

After ASSIST, what next? SCIENCE

While the US Food and Drug Administration's (FDA's) efforts to regulate tobacco products and the deal made by the attorneys general with the tobacco industry to "settle" their suits over smoking-induced disease have dominated the headlines in the United States, the federal government's most successful effort to curb tobacco has been the National Cancer Institute's (NCI's) American Stop Smoking Intervention Study (ASSIST). ASSIST, a state-based programme built around local coalitions and media advocacy, has reduced per capita consumption of cigarettes by 7% compared with non-ASSIST states.^{1,2} This seemingly modest change amounts to about 50 million packs of cigarettes a month not being smoked. Indeed, the ASSIST "market share" now exceeds that of all other brands of cigarettes except Marlboro³ (table). This represents a stunning accomplishment for the public health, particularly in light of efforts by the tobacco industry to cripple ASSIST.⁴

Given this success, it is remarkable that the NCI has no approved plan for a follow-on trial to build on ASSIST's success. Instead, the current plan is to simply transfer the programme to the US Centers for Disease Control and Prevention's (CDC's) Office on Smoking and

Health. It would appear that NCI plans to abandon large-scale, population-based intervention studies and return to bench and behavioural research and small-scale, investigator-initiated projects. Although there is no question that such small-scale projects are important and worthy of NCI support, it is simply unacceptable for NCI to abandon this most promising line of research and development in tobacco control.

While CDC should expand its state efforts based on the ASSIST model (including much larger funding levels for individual states than CDC currently provides), expansion of CDC efforts does not obviate the need for NCI to develop and evaluate the next generation of large-scale tobacco control interventions. After all, the NCI's primary function is the development of new knowledge and the CDC's function is promotion of strong public health practice once it has been developed. Failing to recognise this distinction by coupling the issues of the future of large-scale tobacco control research at NCI and expansion of the CDC's state-based tobacco control programme, IMPACT, has confused the question of what the new research agenda should be. The issues of NCI's future research agenda for large-scale tobacco control interventions and the CDC's future expansion are fundamentally different questions which need to be addressed independently.

New research and development work on large-scale tobacco control is all the more important because a growing number of states have funded multi-million dollar tobacco control programmes as well as the possibility that national policy making may lead to more resources being devoted to tobacco control. The ASSIST programme is scheduled to end in 1999, so it is long past the time that the NCI should have started planning the follow-on research and development programme to continue to improve the effectiveness of population-based tobacco control interventions.

Market share of different brands of cigarettes, 1996¹

Brand	Market share (%)	Company
Marlboro	32.3	Philip Morris
ASSIST*	7.0	National Cancer Institute
Newport	6.1	Lorillard
Dorco	5.9	RJ Reynolds
CPC	5.8	Brown & Williamson
Winston	5.3	RJ Reynolds
Basic	4.8	Philip Morris
Camel	4.6	RJ Reynolds
Kool	3.6	Brown & Williamson
Salem	3.6	RJ Reynolds
Virginia Slims	2.4	Philip Morris
Merit	2.3	Philip Morris
Benson & Hedges	2.3	Philip Morris

*ASSIST is not a brand of cigarettes, but by reducing consumption by 7%, it has the same effect on the other cigarette brands as if it were a brand attracting new customers.

The rate of tobacco use is not identical in all states. States that have made investments in comprehensive tobacco prevention and control programmes have consistently out-performed other states in reducing tobacco use. The state of California implemented a large-scale comprehensive programme beginning in 1989 and saw a tripling in the rate of decline of tobacco consumption.¹¹ There were major reductions in adult smoking rates, and no increases in teenage smoking rates (until the programme was narrowly focused on young people, when adult smoking stopped dropping and teenage smoking increased.¹²) Massachusetts implemented a similar programme two years later and since then Arizona and Oregon have followed suit. ASSIST was the model for the development of these state-based tobacco control interventions as well as the model for the CDC's IMPACT programmes and the Robert Wood Johnson Foundation's Smoke-Less States programme.

The field of tobacco control is undergoing fundamental change. Litigation by states and other groups may change the way tobacco is advertised and sold.¹³ Maine (through a doubling of the state's cigarette excise tax) and Wisconsin (through the normal budgeting process) are also beginning state-funded tobacco control programmes. Florida and Mississippi have obtained millions of dollars for tobacco control programmes as part of their state settlements with the tobacco companies. The number of states receiving such funds will increase. The discussions about a national deal with the tobacco industry may generate a large pool of federal funds for tobacco control, and this may occur even if a deal is not enacted because public health groups demand adequate funding. The death toll of tobacco clearly justifies greater government resources.¹⁴ These developments highlight the importance of continuing research and development designed to improve the effectiveness of large-scale tobacco control interventions.

The promising results of the current ASSIST programme indicate that these programmes can be effective, and they challenge NCI to develop a follow-on programme that will be even more effective in reducing tobacco consumption and the associated cancer and heart disease toll. Although the effectiveness of state tobacco control programmes has been demonstrated, fundamental research questions about these programmes remain unanswered. It is clear, however, that such large-scale media and population-based tobacco control programmes are the most promising approach to reducing the toll of tobacco.

As ASSIST draws to an end, it is imperative that NCI implement a new population-based research programme involving 15-20 states to develop and study the impact of innovative tobacco prevention and control interventions at the community, state, and multi-state level. Such a programme might be called SCIENCE—Smoking Control Innovation and Evaluation in New Community Environments. This research programme should build on the

success of ASSIST and should simultaneously provide resources to research institutions and state and local tobacco control coalitions to undertake multiple studies collaboratively. All states should include a paid counter-advertising campaign as one of their interventions. Policy interventions at the state and local levels should also be required. This programme should be new, including an open competition with awardees selected through peer review, not simply a continuation of the existing ASSIST programme. The results of this research will provide knowledge that can be used to improve tobacco control programmes in the remaining states and throughout the world.

ASSIST has taught us about the value of public policy interventions to reduce tobacco use. In contrast to its predecessor, NCI's Community Intervention Trial for Smoking Cessation (COMMIT), which expressly prohibited public policy activity, ASSIST stressed it. Policy interventions designed to change the environment (ASSIST) work better than education (COMMIT). SCIENCE should be designed with this lesson in mind.

SCIENCE should begin the day after ASSIST ends. Many different aspects of the interventions are appropriate subjects of research. The following are examples of broad research questions that might be addressed through this project.

- In the context of a state-wide programme, what is the impact of a large counter-advertising campaign on attitudes toward tobacco advertising, tobacco use, and the tobacco industry?
- What themes of counter-advertising campaigns are most effective in achieving the goals of the campaign?
- How do state laws that preempt local tobacco control legislation influence the public's knowledge, attitudes, and behaviour related to tobacco?
- How should tobacco control programmes be modified to be most effective in tobacco-growing states?
- How should tobacco control programmes be modified to meet the needs of special population groups?
- How can new funds be used to reduce tobacco use as rapidly as possible?
- What is the optimum level of per capita spending on tobacco control programmes?
- Which public policies are most strongly predictive of reductions in tobacco use?
- How will the tobacco industry respond and what are the best strategies for countering their response?
- What are the most appropriate methods for researching a rapidly changing field such as tobacco control, when traditional randomised trials are no longer possible?

NCI should seek to coordinate these large-scale research activities with CDC's IMPACT programmes to ensure the most efficient technology transfer and the most effective use of CDC's epidemiological surveillance capabilities. Moreover, the existence of different levels of tobacco control programmes

(CDC IMPACT states funded at current ASSIST levels of at least \$1 million per state, SCIENCE states with significant programmes in addition to IMPACT, and the states with very large tobacco control programmes such as California and Massachusetts) will provide an opportunity to study the "dose-response" relationships for tobacco control programmes.

This SCIENCE proposal simply represents a logical follow-up to the demonstrated success of ASSIST. If the NCI conducted a clinical trial of a breast cancer treatment that reduced mortality by 7%, it would immediately begin a follow up designed to test better treatments. Tobacco should be treated no differently. Lung cancer is the leading cause of cancer deaths and tobacco causes almost all lung cancer.

It is important that researchers recognise that tobacco control has become sufficiently high profile and dynamic that traditional randomised controlled-trial models probably will not be applicable. It is more likely that research models based on econometrics, political science, law, and epidemiological surveillance will be most appropriate. In the special supplement to this issue of *Tobacco Control*, NCI director Richard Klausner acknowledges the success of ASSIST and the need for new forms of evaluation for such programmes beyond the traditional randomised clinical trial.¹⁰ This recognition makes the NCI's abandonment of such research all the more remarkable.

Development of the SCIENCE population-based programme is not the only area in which NCI needs to strengthen its activities related to tobacco control. Despite the fact that tobacco accounts for about 30% of all cancer deaths,¹¹ NCI, by its own accounting, spends less than 3% of its \$2.3 billion budget¹² on tobacco research (including ASSIST and tobacco-related biomedical research); these numbers are clearly out of balance. Less than 1% of NCI's budget goes to investigator-initiated research grants related to tobacco control (and NCI is doing better than the rest of the National Institutes of Health).

NCI must also increase funding for a broad range of tobacco control research and see that appropriate mechanisms for peer review of grant applications are put in place.¹³ Several

years ago NCI issued a request for proposals on policy research and ended up funding several important projects, and it recently solicited and funded grants related to young people and smoking. These actions were good first steps that demonstrated a pool of good ideas worthy of funding. It is time for NCI to initiate a large, broad-based programme of investigator-initiated tobacco control grants. Such a programme can only complement SCIENCE.

The NCI cannot be allowed to walk away from its responsibility to continue developing and evaluating large-scale tobacco control interventions as well as putting in place a substantial programme of investigator-initiated grants that deal with tobacco control. It is up to the public health community to see that the NCI and the Clinton Administration go the next step.

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When SCIENCE doesn't make sense

When asked why he robbed banks, the legendary Willie Sutton replied, "Because that's where the money is!" One is tempted to interpret Dr Glantz's plea for a sequel to ASSIST in much the same light: in the United States, the National Institutes of Health are "where the money is", and the largest single share of it is in the vaults of the NCI. I have no quarrel with Glantz's proposition that more tobacco control research is needed; nor do I

disagree with him that well-funded, state-based tobacco control activities may be effective deterrents to smoking. But I do differ with him in concluding that NCI should follow up ASSIST with yet another large-scale population-based programme involving multiple states and tens or hundreds of millions of dollars.

Intentionally or otherwise, Glantz's commentary omits important history explaining

the origins and purpose of ASSIST. Indeed, the naïve reader of the commentary will be forgiven for not appreciating that ASSIST is not and never was a research project. To the contrary, ASSIST was designed to serve as a *demonstration* project, intended to demonstrate the *application* of tobacco control interventions researched (and presumably shown to be effective) in an earlier project, COMMIT, the Community Intervention Trial for Smoking Cessation, designed to reduce heavy smoking.¹⁴ The origins of ASSIST lay in an ambitious five-phase cancer control research model developed by NCI to carry a research theme from basic research through to readiness to apply research findings nationwide.¹⁵ ASSIST represented the last of the five phases, "Demonstration and Implementation", intended to spur dissemination of findings into practice in the broader health services and health policy communities.

For a variety of non-scientific reasons, ASSIST was pushed into existence prematurely, before the results of COMMIT were known. As it turns out, COMMIT failed to achieve its primary research objective: heavy smoking did not decline significantly more in the experimental communities than in the non-intervention comparison communities.^{16,17} Thus, had NCI adhered to its original scientific design, in which ASSIST would follow success in COMMIT, ASSIST would never have seen the light of day.

But ASSIST did see the light of day. And according to one analysis, ASSIST states have experienced a decline in per capita cigarette consumption 7% greater than that in non-ASSIST states.¹⁸ If this relationship is causal (other explanations come readily to mind), this surely represents a monumentally important achievement, one that should be reproduced in the remainder of the states, with dissemination to other countries as well. But herein lie two essential reasons why more large-scale, population-based NCI research is not the appropriate mechanism for following up on the success of ASSIST. First, no-one knows how to design an effective sequel that would have the fundamental community-intervention tobacco control characteristics of ASSIST and yet be amenable to investigating the kinds of research questions that Glantz poses.

Second, the early evidence, cited by Glantz, indicates that ASSIST is succeeding in its demonstration and dissemination objectives. This raises the question of whether NCI funding is needed to promote large-scale, population-based tobacco control interventions; indeed, it begs the question of whether strictly experimental community intervention research could work in the present environment. Other states, and indeed other national programmes (CDC's IMPACT programmes and the Robert Wood Johnson Foundation's SmokeLess States programme), are following the lead of ASSIST in developing state-based community interventions; Glantz tells us that ASSIST was the model for these new programmes. Led by Glantz's home state of California, a few states have developed sub-

stantial state-financed programmes that have been documented to decrease smoking.¹⁹ Other states, already including Mississippi and Florida, stand poised to receive millions of dollars for tobacco control as a result of successful legal actions against the tobacco industry.

If congressional tobacco control legislation now under consideration is adopted, all states will have ample resources to conduct aggressive and (one would hope) innovative tobacco control programmes. If such legislation is not adopted, one can indeed make a case that the federal government should be subsidising the further development of state-based programmes. But mounting such programmes should not be the responsibility of the NCI, an organisation dedicated to biomedical and health research. Rather, this should be done under the auspices of the Centers for Disease Control and Prevention, the nation's leading organisation responsible for monitoring and improving the health of the public. CDC likely would need a significant infusion of new resources to fulfill this role. But ceding it to the NCI simply because that's where the money is would not represent government budgeting at its finest. The questionable logic aside, we would incur a large opportunity cost in terms of other forms of research not undertaken, such as the small-scale investigator-initiated bench and behavioural research that Glantz acknowledges as important and worthy of NCI support.

This brings us full circle. Glantz is correct that important community-intervention research questions remain. Clearly, the more effectively and efficiently state-based funding is deployed, the more the scourge of tobacco will be contained. The form that community-intervention tobacco control research can and should take now, however, is precisely that at which Glantz himself has excelled: evaluation of the multitude of natural experiments that arise as a result of the burgeoning business of population-based tobacco control.²⁰ Such research is not necessarily expensive, because it exploits the numerous opportunities for evaluation presented by a world actively engaged in programmatic efforts to combat our modern plague of tobacco-produced disease. NCI has a clear obligation to support such investigation, precisely because it is important and potentially very valuable health research. NCI support of such research would be consistent with its path-breaking history of encouraging behavioural research germane to tobacco control²¹ and with its recent initiative in the domain of tobacco policy research.²² A wonderful example of well-conceived, important tobacco policy research is Glantz's recent study of the economic implications of smoke-free restaurant and bar ordinances,²³ which NCI funded.

Supporting research on the effects of tobacco control and funding tobacco control *per se* are two different activities that should be kept distinct. Given the remarkable recent history of the development of state-based programmes, described by Glantz, we are well beyond the point at which we can or should attempt to construct state-based interventions

as scientifically pned controlled trials. COMMIT, the most touted such intervention to date, fell short in this endeavour several years ago. ASSIST, IMPACT, and the Smoke-Less States programme have taken us past it.

Glanz does not draw the line between the funding of tobacco control activities *per se* and support of research on its consequences. His proposed SCIENCE programme comprises large-scale interventions and evaluation research. I heartily endorse the latter. Given our current understanding of the limitations of community intervention research,^{23,24} and the expanding dissemination of tobacco control programmes, I find the former indefensible. When it comes to funding tobacco control evaluation research, we should hold NCI's feet to the fire. We will burn ourselves, however, if we hold NCI responsible for footing the bill for more population-based, large-scale tobacco control programmes.

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Building on the foundation of ASSIST

Tobacco control activities continue to raise more questions than they answer.

- How high must a cigarette tax be to decrease consumption?
- Does strong emphasis on measures to reduce access by young people result in a "forbidden fruit" effect, which results in more, not less, smoking in the young?
- Can small amounts of counter-advertising impact cessation rates?
- Have the contents of cigarettes been altered recently to make them more addictive?
- Does reducing access to tobacco products have any effect on adult smokers?
- How should coalitions be structured to achieve maximum tobacco control policy change?

Tobacco control policy research in the United States remains limited even as the opportunities to apply the research results are increasing. Within the past two years, Oregon and Maine have earmarked cigarette tax dollars for tobacco control programmes, and Mississippi and Florida have received settlement funds counted in billions of dollars. Health professionals in these places found themselves putting together comprehensive statewide programmes in very short time frames.

As more funds become available, this situation will be repeated. Health professionals will be allocating new monies and launching interventions without the benefit of the best scientific information on the effectiveness of tobacco control strategies.

The tobacco industry, in contrast, uses up-to-the-minute research in every aspect of its comprehensive approach to designing, advertising, marketing, pricing, and selling tobacco products and reinforcing use through the policies it promotes and those it blocks. The Tobacco Institute studies, understands, and takes advantage of the political system in ways that health advocates find difficult to counter.

Calculating how much the industry spends on all its research would be a herculean task. Even if we knew the final amount, we could not begin to match it. But when we see smoking rates in the young increase despite all our attention and efforts, it is clear we understand far less about how to reach the next generation than do the tobacco companies.

Certainly, the NCI has an obligation to the citizens of the United States to play a major role in reducing the epidemic of tobacco-caused cancers. We have entered a new era where prevention research by the NCI must involve large populations, diverse cultural and ethnic groups, policy interventions, and measurements of media impact. We need to know how to influence the outcome of reduced smoking prevalence by designing the best interventions possible. We need to understand culture change surrounding smoking and to do that requires entering the culture.

The American Cancer Society has been the NCI's partner of record for the eight years of the ASSIST project. During this time, we have seen the effects of the NCI's resources devoted to systematic and innovative approaches to

tobacco control. The laboratories for this great experiment are the states and local communities; the studies are being conducted by health advocates using tools of advocacy and media.

Now is the time to continue those studies. Now is the time for the National Cancer

Institute to build on the foundation of ASSIST and move to the next level of tobacco control research.

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The future of NCI's smoking research agenda

Stan Glantz has joined a small chorus beseeching the National Institutes of Health in general and the NCI in particular to greatly expand its tobacco control research agenda.^{25,26} As usual, Glantz does it provocatively and articulately and puts forth his own proposed agenda.

Glantz is correct in asserting that the NCI has not had a programmatic tobacco research programme since the Smoking and Tobacco Control Program developed by Joe Cullen culminated in the ASSIST programme. It is also hard to avoid the implications of the huge discrepancy Glantz noted between the impact of tobacco on cancer morbidity and mortality and the proportion of the NCI's budget devoted to tobacco control research. The NCI may well feel that, given the relatively large expenditures for the COMMIT²⁷ and ASSIST community and state-level trials, tobacco research has been taken care of and it is time to move on to other risk factors. I strongly agree with Glantz's argument that such a move would be greatly premature and unfortunate. There are major gaps in our knowledge about tobacco control that need to be addressed via research. Given the size of its budget and its prior history, the NCI should take the lead in developing a plan for tobacco research.

Glantz's particular "wrinkle" is to argue for large population studies that would take off from the accomplishments of ASSIST and capitalise on variation in state activities—which exist in part because some states are now engaged in tobacco control funded by dedicated tax monies—to learn about the relative effectiveness of population-level tobacco control interventions. Glantz has, in effect, drafted the essentials of a persuasive Request for Proposals (RFP) that the NCI might issue. It is an RFP that would

likely have an expensive price tag attached. Such research would be worth paying for, given the mortality and morbidity stakes that are involved.

Some of the elements in Glantz's RFP are consistent with research directions that I proposed²⁸ in a paper that was commissioned by the NCI. Both Glantz's recommendations and mine could and should be addressed through investigator-initiated proposals. I would urge investigators to take on portions of Glantz's agenda. Building upon the accomplishments of ASSIST, however, requires that ASSIST submit its methods and results for review by the science community. As Glantz notes, the CDC has important evaluation expertise to contribute, and state health divisions are getting into the act as they monitor the smoking control programmes supported by dedicated tax monies. But the NCI retains primary responsibility for advancing the science of population-based tobacco control. Glantz is correct in noting that innovative methodologies will be needed to tease out causation in population studies where experimental control may be quite limited. Let us hope that NCI's newly reorganised Division of Cancer Control and Population Science takes the latter part of its new name seriously.

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Tobacco control in the United States: the next generation of demonstration and research projects

As noted in the above commentary by Glantz, the landscape for tobacco control in the United States is changing dramatically due to unprecedented leadership in our national government,^{29,30} state-based efforts to increase tobacco taxes and to sue tobacco companies,^{30,31} and local measures to restrict

the use of and access to tobacco.³² Based largely on the favourable evaluation results of the NCI's ASSIST trial, Glantz calls for a new NCI-coordinated programme (SCIENCE) for tobacco control research and development.

It is worth noting that the primary goal of ASSIST is to "reduce smoking prevalence

among adults to 17 percent in ASSIST states by 1998"²⁸ (from a baseline of 24.1% in 1992–1993). This indicator is being measured by surveys at baseline (1992–1993), midpoint (1995–1996), and endpoint (1998–1999). To support his recommendation to launch SCIENCE, Glantz relies mainly on the work of Manley *et al.*²⁹ examining per capita cigarette consumption in ASSIST states, compared with non-ASSIST states. This research showed a promising 7% difference in consumption between intervention and comparison states.³⁰ Despite this suggestive evidence, final data on the main outcome endpoint noted above will not be available for two to three years. As observed earlier in COMMIT,³¹ secular (decreasing) trends in comparison states' smoking rates may lessen the likelihood that differences in smoking patterns between ASSIST and non-ASSIST states will be detected.

In light of these issues, does the evidence suggest that we should wait several years before deciding whether dissemination or a new round of demonstration and research trials, or both, are warranted? On this point, we agree with Glantz that the answer is emphatically "No". Plans for further work in this area should be developed with great urgency.

In conjunction with this urgency, consideration of strategic planning issues is needed. Glantz contends that "The issues of NCI's future research agenda for large-scale tobacco control interventions and the CDC's future expansion are fundamentally different questions which need to be addressed independently." However, we suggest it is essentially impossible to "un-couple" these issues—resources are always finite and public health efforts to control tobacco use relate to numerous federal agencies. The follow up to ASSIST should be a strategic national initiative in tobacco prevention and control, initially coordinated at the level of the US Secretary of Health and Human Services (HHS). Major input is essential from the Surgeon General, the relevant federal agencies, policy makers, academic researchers, public health practitioners (within and outside state and local public health agencies), and other community health advocates. Planning should consider numerous factors and programmes currently in the field, including ASSIST, COMMIT, the CDC's IMPACT programme, and the Robert Wood Johnson Foundation's SmokeLess States programme. The Secretary of HHS should articulate an agenda of explicit research questions that clearly outline the complementary roles of NCI and CDC. For example, the NIH and the CDC are jointly supporting a series of focused, competitive grants within the Community Prevention Study of the Women's Health Initiative.³² A similar model should be considered for the present issues in tobacco control.

Glantz argues for new SCIENCE awards to research institutions and state and local tobacco control coalitions. We believe a clearer distinction is needed between roles in tobacco

control demonstration (public health intervention) and those in tobacco control research.

Separate from research needs, tobacco control is a core public health function deserving of more attention from state and local health agencies due to the health burden from tobacco use and the availability of effective interventions.³³ In all likelihood, research institutions will have less "savvy" about day-to-day policy considerations, and public health agencies will be less inclined to conduct research. Therefore, careful consideration must be given to the design and programmatic structure of new grants and contracts. In a given geographical location (a state or large city), two parallel awards could be provided—one to a public health agency for intervention activities and another to a research institution for evaluation of interventions. Such a funding arrangement should accelerate the diffusion of research to practice. Widespread dissemination is especially appropriate following the completion of ASSIST because it represents the logical next phase after the conclusion of phase V research (demonstration and implementation).³⁴

We will also highlight two related points. First, in developing the next generation of tobacco control demonstrations, it is critical that the array of potential interventions be evidence-based. These should take into account the "lessons learned" to date. For example, Oregon has developed a "toolkit" of best practices in tobacco control that illustrates the increasing sophistication of public health agencies.³⁵ A set of guidelines for community preventive services, currently under development, should augment these efforts.³⁶ Second, we are supportive of Glantz's notion to study the potential "dose-response" relationships between the size of various state-based tobacco control programmes and performance indicators. Such an evaluation should also take into account qualitative factors that may predict programme initiation and success.

In summary, we are in the midst of a critical period in the history of tobacco control in United States. We thank Glantz for stimulating more dialogue on future intervention and research in tobacco control—this discussion is critical for ensuring that public health opportunities are not missed.

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In support of SCIENCE

Americans for Nonsmokers' Rights (ANR) is the country's only national organisation representing individuals seeking to enforce their right to breathe clean air, free of the toxins of secondhand smoke. Through its long history, tireless efforts, and continuous application of the trial-and-error method, ANR has learned the important basic rules of how to achieve this goal. We humbly offer that vast body of knowledge and experience as part of our petition for continued federal support of ASSIST-like programmes.

The NCI, charged with leading the nation's war against cancer, spent at least a decade searching for the "safe" cigarette. Then NCI came to understand that it would be much more effective and efficient simply to help people not to smoke. The Institute spent the next 15 years researching effective interventions toward this goal. What that research demonstrated, and what tobacco control advocates everywhere now understand, is that, while we approached tobacco use in the traditional disease model—attempting to "cure" one smoker at a time through cessation programmes, and to forestall initiation through prevention programmes similarly aimed at individuals—we were doomed to fail. With tobacco advertising and promotional expenditures reaching as high as \$6 billion per year, we would never be able to "unsell" cigarettes nearly as quickly as the industry could sell them.

Great insights have come from our understanding the limitations of these approaches based on the individual disease model, which ignored the control that tobacco companies maintained over the social environment in which individuals made their decisions whether or not to smoke. Tremendous advances in tobacco control have come from our more recent efforts not to change individuals, but to alter the environments in which individuals make healthy or unhealthy decisions.

For the past seven years, NCI has funded large-scale intervention research, under the acronym ASSIST, that has proven this approach to be effective. ASSIST should be thought of as a clinical trial representing a unique partnership among the NCI, the American Cancer Society (ACS), state health departments, and public and private organisations across the country. ASSIST has applied the body of research on tobacco use prevention and control toward reducing the prevalence of smoking (and incidentally, cleaning the air that non-smokers are also forced to breathe), with amazing success.

Although ASSIST is the largest and most comprehensive tobacco control project ever sponsored by the federal government, and although tobacco control is involved in a third of all cancer deaths, ASSIST comprises only 1% of NCI's total budget. In fact, the total annual budget of ASSIST is only 0.0002 of the \$100 billion in direct healthcare services and lost productivity that tobacco use costs this country each year. Given the incredible reductions in tobacco consumption during the first half of the intervention phase, ASSIST represents one of the greatest, and most cost-effective, successes ever supported by the federal government for improving the health and lives of our citizens.

If ASSIST were a drug or a vaccine, pharmaceutical manufacturers in the private sector would be competing fiercely for the right to conduct further research and development, and then to market it for profit.

However, the ASSIST clinical trial is different. Although the profits in selling cigarettes are almost unfathomable, there is no profit in programmes that successfully reduce tobacco use. This is why the federal government's role in continuing to support research and development of community-based interventions is absolutely indispensable.

The federal government, in particular the NCI, must take what we have learned in ASSIST to the next level by supporting

SCIENCE. This is the primary and indispensable role for federal government—to support the basic research that would not be effective or cost efficient for any individual state to conduct, but the results from which could support all state efforts.

This is our best advice from the trenches of tobacco control. We do not need any more bench research on the deleterious health effects of tobacco, nor ways to make smoking less

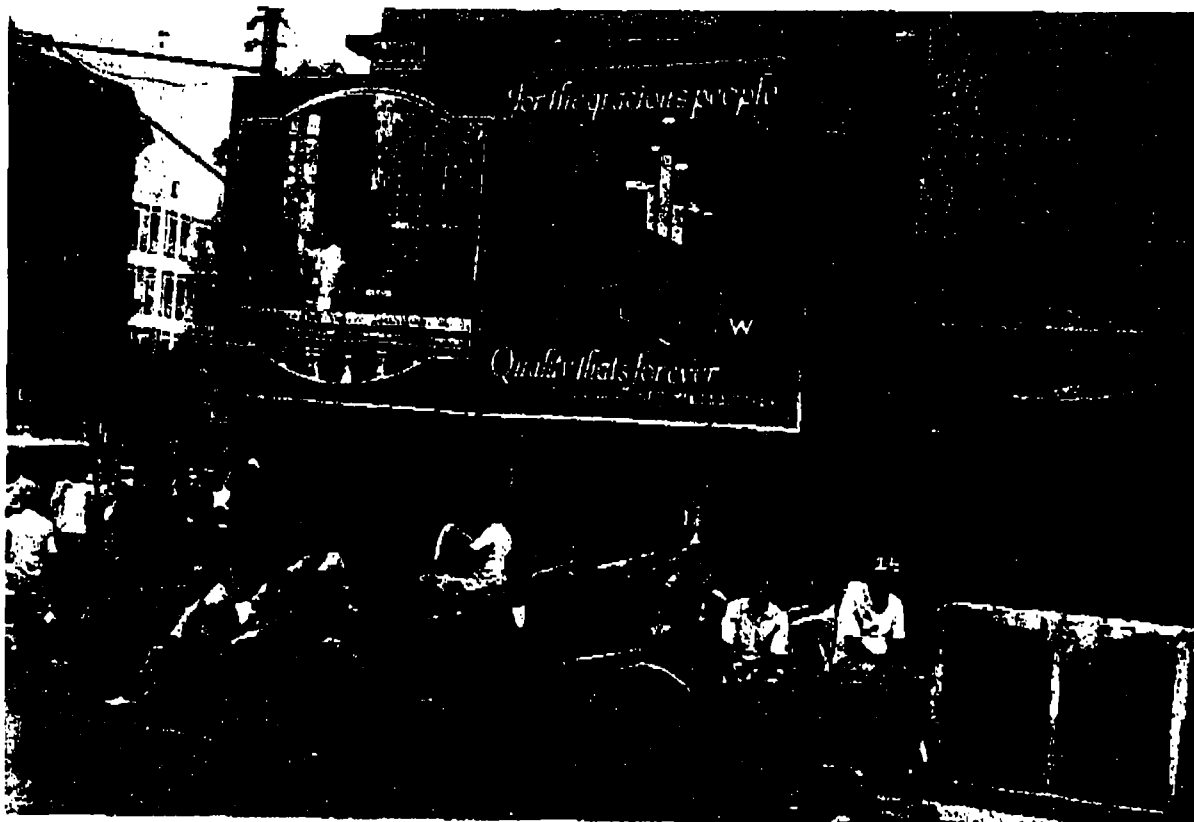
deadly. We need to know how to get even better at countering the tobacco industry's ubiquitous promotion of cigarettes, and helping people not to smoke.

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ROBIN HOBART

Americans for Nonsmokers' Rights



Draft

**Vice President Al Gore's Video-taped Address to the ASSIST Information Exchange
April 21, 1998
Detroit, Michigan**

I would like to send you -- the partners, staff and volunteers of the American Stop Smoking Intervention Study (ASSIST) -- my heartfelt congratulations for your hard work on the front lines of our battle against youth smoking. You have taken on the tobacco industry in the trenches of communities across our country and slowly but surely, you are winning the war against tobacco use, the most preventable cause of death and disability in our time.

ASSIST is one of the most successful research projects ever undertaken by the National Cancer Institute. We have seen tobacco consumption reduced by 7 percent in the 17 states which run ASSIST programs. This 7 percent reduction represents approximately 50 million packs of cigarettes each month that are not sold because of ASSIST.

The heart of ASSIST, the reason for its success, and our hope for the future of tobacco control is the partnerships this program represents. Leading scientists at the National Cancer Institute offer scientific and technical support, state public health department leaders support the infrastructure of the state programs and local public health advocates are supporting these programs. I wish to thank each of you for your contribution to bringing down tobacco consumption rates.

Specifically, I would also like to offer my thanks to the American Cancer Society (ACS), who have been our close partner in ASSIST. Through its national organization and its many divisions and units, ACS has contributed invaluable in-kind resources, volunteers, moral suasion and support.

Since its inception, ASSIST has organized hundreds of state and local coalitions, involving thousands of organizations and individuals. ASSIST works because it invests federal resources in the communities of our country where the toll that tobacco takes is felt most dearly, and the desire to win this public health battle is most fervent. ASSIST works because it turns the targets of the tobacco industry - especially our children and teenagers - into advocates for health. This is why ASSIST has accomplished so much, and why, in the end, we will win the battle over tobacco.

NCI has extended the ASSIST program for an additional year, and we wish you continued success during this time. But ASSIST has started something that will not end at the end of that year. ASSIST has built a community-based public health infrastructure that will endure. ASSIST has empowered people to organize for control over the longevity and quality of their own lives. That is what will live on.

~~and so~~ Because of your hard work and
success it is time to take the next step.

Secretary Shalala has announced that programs like ASSIST will be expanded to all 50 states, through funding from the Centers for Disease Control and Prevention. Today I want to reiterate our pledge for increased funding for CDC to adequately support ASSIST nationwide.

The President and I are committed to passing comprehensive tobacco legislation this year which will dramatically reduce smoking, especially among young people. It is our strong belief that comprehensive legislation which significantly raises the price of tobacco products, imposes tough penalties on the industry for not reducing youth smoking, gives the FDA the authority to regulate tobacco, funds smoking cessation and local anti-smoking programs will result in a drastic improvement in the nation's public health. Such legislation would allow us to fund successful programs like ASSIST all over the country.

Thanks again to all of you, the ASSIST workers, for all that you have done for us and for future generations. You are some of our most successful, if least heralded, American heroes.