Tobacco Control 2003;**12**:124-132

RESEARCH PAPER

Estimating the health consequences of replacing cigarettes with nicotine inhalers

W Sumner, II

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Background: A fast acting, clean nicotine delivery system might substantially displace cigarettes. Public health consequences would depend on the subsequent prevalence of nicotine use, hazards of delivery systems, and intrinsic hazards of nicotine.

Methods: A spreadsheet program, DEMANDS, estimates differences in expected mortality, adjusted for nicotine delivery system features and prevalence of nicotine use, by extending the data and methods of the SAMMEC 3 software from the US Centers for Disease Control and Prevention. The user estimates disease risks attributable to nicotine, other smoke components, and risk factors that coexist with smoking. The public health consequences of a widely used clean nicotine inhaler replacing cigarettes were compared to historical observations and public health goals, using four different risk attribution scenarios and nicotine use prevalence from 0–100%.

Main outcome measures: Changes in years of potential life before age 85 (YPL85).

Results: If nicotine accounts for less than a third of smokers' excess risk of SAMMEC diseases, as it most likely does, then even with very widespread use of clean nicotine DEMANDS predicts public health gains, relative to current tobacco use. Public health benefits accruing from a widely used clean nicotine inhaler probably equal or exceed the benefits of achieving Healthy People 2010 goals.

Conclusions: Clean nicotine inhalers might improve public health as much as any feasible tobacco control effort. Although the relevant risk estimates are somewhat uncertain, partial nicotine deregulation deserves consideration as part of a broad tobacco control policy.

Author's Note: This commentary discusses a recent research paper published by *Tobacco Control* at *TC Online.* An abstract and the URL for that report appear above. A copy of full text for that report can be downloaded for $8.00 from *TC Online.* I highly recommend that those who have an interest in tobacco control subjects download and carefully read Dr. Sumner's report about substituting a pharnaceutical nicotine inhaler for tobacco products.

XXX Products

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June 2, 2003

"Tobacco policy radiates contempt for law."

George Will, Syndicated Columnist
"States Have Unhealthy Addiction To Tobacco"
Friday, May 23, 2003

A New Tobacco Control Research Paper

From a research paper "Estimating The Health Consequences Of Replacing Cigarettes With Nicotine Inhalers," *Tobacco Control,* 2003;12:124-132, by W. Sumner II MD, Department of Medicine, Division of General Medical Sciences, Washington University in Saint Louis:

> "Various observations suggest that the health consequences associated with cigarette smoking are infrequently caused by nicotine.[1,2] Other components of smoke are likely contributors to smoking related disease. Cigarette smoke carries thousands of reactive chemicals, including many known toxins and carcinogens.[3] Tobacco control advocates often cite these as ample reasons to quit smoking. In contrast, nicotine itself seems to be relatively safe.[1] Smoking cessation counselors increasingly encourage long courses of nicotine . . ." (Superscripts are Dr. Sumner's footnotes.)

A September 11, 2002 *Journal of the American Medical Association* (JAMA) article (Vol. 288 No. 10) reported on three California studies about smoking cessation products that included more than 21,000 smokers. The article, "Impact Of Over-The Counter Sales On Effectiveness of Pharmaceutical Aids For Smoking Cessation," stated:

> "Nicotine Replacement Therapy is heavily promoted to the general public by both the pharmaceutical industry and tobacco control advocates." and;
>
> "Since becoming available over-the-counter, NRT appears no longer effective in increasing long-term successful-cessation in California smokers."

June 30, 2001 *The Associated Press* published "Questions Raised About Nicotine Patches." The Stanford School of Medicine study that AP reported concluded that *nonsmoked* nicotine (in nicotine gums and patches) stimulates the growth of blood vessels, which can increase the growth of tumors. That action is the opposite of *smoked* nicotine, which reduces circulation. AP quoted Dr. John Cooke, director of vascular medicine at Stanford University School of Medicine:

> "This [increased blood flow to tumors] was totally a shock to us. We expected just the opposite."

January 2, 2003 CBS News reported on National Cancer Institute studies about nicotine, quoting Dr. Phillip Dennis:

> "The take-home point is that nicotine is clearly not harmless."

The institute's Dr. Dennis explained that people who use nicotine replacement products should use do so only for a short period and should not use the products for the long term.

The institute's research compared the effects of tars and nicotine on damaged cell behavior. The conclusion was that both tars and nicotine have a similar effect that can lead to cancer: DNA in damaged cells causes them to eliminate themselves, both tar and nicotine stop that process. Consequently, more damaged cells remain in the body.

The institute's research characterized that phenomenon as "an important early event in the formation of cancer."

Dr. Sumner's article presents several interesting views and recommendations regarding pharmaceutical grade nicotine. We begin with his observations about the addictiveness of deeply inhaled pharmaceutical nicotine:

> "Deeply inhaled nicotine may addict users just as efficiently as cigarettes."

We therefore start our analysis of the research paper with clear understandings: we are talking about pharmaceutical nicotine products that are highly addictive and that have known health risks. The purpose of Dr. Sumner's paper is described on page 125 as:

> "This paper has two purposes. First, it introduces the DEMANDS program (Differences in Expected Mortality Adjusted for Nicotine Delivery Systems), a spread sheet combining SAMMEC 3 data and methods with adjustable estimates of risk sources and exposures . . . Second, this paper contrasts the long term consequences of achieving the [CDC] Healthy People 2010 goals [12% adult smoking prevalence] with an alternative policy in which a clean, fast acting nicotine inhaler completely displaces tobacco cigarettes. Although this analysis highlights some questions about the safety of nicotine and acceptability of a nicotine inhaler, it also suggests that widespread use of clean nicotine inhalers could have tolerable public health consequences." (Brackets added.)

That is a remarkable viewpoint from a medical practitioner and a public health advocate: products that are now deemed to be no longer effective in increasing long-term smoking cessation, that have unique effects that may stimulate the growth of tumors, are highly addictive, and which the National Cancer Institute reports are clearly not harmless, present "tolerable public health consequences" with wide spread public use.

Lest we miss the point, in the "Discussion" section of his paper on page 129 Dr. Sumner says:

> "On average, eight nicotine users may be healthier than one smoker and seven non-smokers."

Should nonsmokers begin using nicotine inhalers, so we can have a healthier society? To be certain we get it, Dr. Sumner further informs us on page 129 that the benefits of promoting pharmaceutical nicotine replacement products could be underestimated:

> "Third, DEMANDS does not quantify never-smokers mortality benefit from elimination of environmental tobacco smoke, which may total tens of thousands of YPLL85. This benefit would be larger in nicotine inhaler scenarios, which eliminate environmental tobacco smoke, than in the Healthy People 2010 scenario, which continues to expose some nonsmokers to environmental smoke. The benefits of a clean nicotine inhaler that displaces cigarettes might be larger than this analysis predicts."

Among the "tolerable public health consequences" are fatal diseases, which Dr. Sumner discusses on age 130:

> "Although nicotine replacement therapy is generally free of serious adverse consequences,[60] nicotine might induce fatal diseases not anticipated in the SAMMEC software. Nicotine causes a distinct acute toxicity syndrome typified by green tobacco sickness.[61] [62] However, nicotine poisoning deaths are remarkably unlikely in tobacco harvesters, children ingesting nicotine or tobacco,[63] or adults attempting suicide with nicotine patches.[64] If nicotine use were to increase other substance abuse, then a clean nicotine inhaler could lead to increased death from alcohol and drug abuse. Current literature may not have explored complex pathways leading from nicotine use to human death. For instance, Heeschen and colleagues report that nicotine is angiogenic,[65] and might promote tumor growth, but even this hypothetical harm might be offset by accelerated wound healing.[66] Synergism between nicotine and environmental risk factors other than cigarettes is conceivable. For example, chronic exposure to pure nicotine and polluted air might cause chronic obstructive lung disease."

Regarding other risks, Dr. Sumner says on page 130:

> "DEMANDS does not estimate morbidity from tobacco use. Nicotine might impair quality of life or productivity by altering growth and function of the nervous system, with consequences potentially including depression, anxiety, or addiction.[5] These require further elaboration, separate analysis, and disclosure to smokers and other potential nicotine users.

Dr. Sumner's preceding statements raise a troubling question: Who are the "other potential nicotine users"? The answer to is Dr. Sumner's model assumes that availability of a nicotine inhaler product may induce nonsmokers and never smokers to use the product. On page 129 Dr. Sumner says:

> "As with tobacco pipes and cigarette packages, the nicotine industry could produce myriad variation on the appearance of inhalers, so that users could select inhaler designs based on image. These images might even replicate successful smoking themes, such as rugged individuality, suave character, and pleasure. Pharmaceutical companies would then promote the images and real advantages of a modern nicotine inhaler to potential users, *beginning* with current smokers." (Italic added.)

The above statement leaves little room for doubt: the strategy would not only replace cigarettes with nicotine inhalers, but it also includes promotion of the "images and real advantages of a modern cigarette inhaler" to new nicotine users *who are not current smokers.* Practices employed to market cigarettes based on image and satisfaction would be employed to sell nicotine inhalers. Marlboro Man has met his match: suave, sophisticated, satisfying Nellie Nicotine.

From Master Settlement Agreement, Section VI. (h):

"The National Public Education Fund shall be used *only* for public education and advertising regarding the addictiveness, health effects, and social costs related to the use of tobacco products . . ." (Underline, italic added.)

"Koop Predicts Nicotine Inhalers, Sprays"
United Press International, Feb. 15, 1998 Michael Smith

"Within the next five years, America's nicotine addicts increasingly will get their fix without the dangers of smoking cigarettes, former surgeon-general C. Everett Koop said."

"Koop said he foresees nicotine nasal sprays and inhalers joining the currently available chewing gum and nicotine patch products. Said Koop: 'Nicotine is not the dangerous part of a cigarette.'"

"Within the next five or 10 years, Koop said, 'we will still have a tremendous number of nicotine addicts, but we will have smoking nicotine addicts and nonsmoking nicotine addicts.'"

"Drug Makers Find A Risky New Role For Nicotine"
The Wall Street Journal, February 27, 1998 Suein Hwang

"Cigarette makers may be facing an unusual rival as long term suppliers of nicotine fixes: the pharmaceutical industry"

"I'd rather see people dependent on nicotine than tobacco." Dr. Neal Benowitz, technical editor of Dr. Koop 1988 report that declared nicotine to be addictive.

"If it's the nicotine that people want, why not give it to them?" Dr. Karl Fagerstrom, former director of scientific information for Pharmacia & Upjohn.

"To be crass about it, virtually every pharmaceutical company sees a tremendous market here." Dr. David Sachs.

We look back several years to 1998 (see center): when executed in 1998 the MSA contained explicit and restrictive language that said its National Public Education Fund shall be used *only* for public education and advertising regarding *the addictiveness*, health effects, and social costs of tobacco nicotine; in 1998 Dr. Koop was predicting that we will have a tremendous number of smoking *and nonsmoking* nicotine addicts; Dr. Neal Benowitz, with the University of California at San Francisco, was of the opinion that he would rather see people dependent on nicotine than tobacco; Dr. Fagerstrom, formerly with Pharmacia & Upjohn, inquired why we shouldn't give people the nicotine they wanted, and Dr. David Sachs hit a central point for tobacco control advocates and their pharmaceutical nicotine sponsors: "To be crass about it, virtually every pharmaceutical company sees a tremendous market here."

Dr. Sumner says it best in "What This Paper Adds" on page 130 of his paper:

> "For a wide range of plausible inputs, DEMANDS estimates that the health consequences of completely displacing cigarettes with a widely used, deeply inhaled, highly addictive, pharmaceutical grade nicotine inhaler are comparable or superior to reducing smoking prevalence to 12%. Public health advocates and pharmaceutical companies could adapt tobacco control techniques to encourage smokers to replace cigarettes with nicotine inhalers."

A differing view of Dr. Sumner's statement is: "Now that we have a stable nicotine consumer base we can foist our addictive products on addicts that we created, and do so in the name of public health."

Common Interests, Conflicts Of Interest

Perhaps—years after-the-fact—we now understand the importance of Dr. Koop and Dr. Benowitz sitting as comembers of the Society for Research on Nicotine and Tobacco *alongside representatives from R.J. Reynolds Tobacco Company* during the 1990s. Not only do they share a common vested interest with tobacco companies in the sale of nicotine products, but for their products to be self-sustaining pharmaceutical nicotine distributors share the same *source consumer base* as tobacco companies: youth who begin to smoke.

Beyond the obvious, an interesting question raises more potential conflicts: Where does the nicotine in pharmaceutical patches, gums, lozenges, sprays and inhalers come from? Nicotine is a natural substance that comes from the tobacco plant. Collectively, tobacco companies have centuries of experience cultivating, harvesting and curing that plant. Moreover, genetically engineered seeds that produce greater nicotine potency were exported to South America during the 1990s. Are there tobacco plantations in South America today, and if there are who is managing them? It is intuitively obvious that the demand for nicotine will dramatically increase if Dr. Sumner's model comes to fruition, and it is transparent that tobacco companies could be both skilled and likely suppliers.

As we look back today to 1991 to 1998 Project ASSIST years we face a stunning reality: those who we parents trusted to reduce youth smoking rates during the 1990s are today the same folks that the Journal of the American Medical Association says heavily promoted Nicotine Replacement Therapy to the general public (pharmaceutical companies and tobacco control advocates.) Those who also financed in large part and presided over youth smoking interventions that increased teen daily smokers 43 percent 1992 to 1997 now stand to benefit handsomely from the expansion of the nicotine source consumer base.

A Political, Regulatory And Economic Competitive Strategy

How would one conduct a comprehensive strategy to substitute pharmaceutical nicotine for tobacco nicotine? Dr. Sumner provides the answer on page 129 of his paper:

> "The first policy step would be to allow the pharmaceutical industry to privately develop and market increasingly clean *and fast acting* nicotine delivery systems. For example, adapting an existing metered dose powder inhaler or adopting the design patented by Rose [Prof. Jed E. Rose of Duke University] and colleagues. Policies to encourage substitution of nicotine inhalers for cigarettes would reflect established principles of community level tobacco control policy, such as raising tobacco product prices, informing customers of risks, counter advertising, restricting youth access and marketing, and limiting opportunities to smoke." (Italic, brackets added.)

The first steps of that competitive strategy to replace cigarettes with nicotine inhalers are what we have observed in anti-tobacco campaigns over the past several years: promoting new taxes on cigarettes and mandating smoking bans. Those two central elements of tobacco control advocacy *increase the parity price* (and therefore profitability) that can be charged for pharmaceutical nicotine and create a *coerced consumer choice* of "Tobacco Free" nicotine products to be used in "Smoke Free" work and public facility environments mandated by tobacco control advocates and their supporters.

Dr. Sumner continues to describe the competitive nicotine strategy on page 129 of his paper:

> "Taxation and product liability costs are already raising the price of cigarettes, and could create a significant price difference between cigarettes and less hazardous nicotine delivery systems. Governments should tax all nicotine delivery devices at rates that at least recover their regulatory and health costs."

The above subject is about as cold-blooded mercantile as one can get: if government is to tax all nicotine delivery devices *at rates that at least recover their health costs,* then it is axiomatic that *those products will predictably cause illness and health consequences among their consumers.* Wilfully distributing nicotine products with known health risks for mercantile profit appears to be acceptable, so long as government is reimbursed in advance for the costs that it will incur in treating nicotine-related illness. But what about the suffering and death caused by pharmaceutical companies that "replicate successful smoking themes, such as rugged individuality, suave character, and pleasure" in their advertising to induce *smokers and nonsmokers alike* to use their nicotine products? Is suffering now reduced to calculated collateral damage, mere human cost that is expediently sidestepped in pursuit of mercantile gain?

Dr. Sumner continues his strategy points on page 129:

> "Governments would then tax safer nicotine delivery devices at a lower rate than hazardous tobacco products.[6] Legislation could shield the nicotine and tobacco industries from liability for the health effects of nicotine use, on the theory that even addicted individuals bear some responsibility to weigh the known risks against the perceived benefits of nicotine,[51] and in recognition of the historical futility of efforts to fully eradicate nicotine use.[52]"

Through tobacco control we have progressed from recovering damages from tobacco companies to shielding them from liability. Under Dr. Sumner's model not only would tobacco companies and pharmaceutical nicotine suppliers actively distribute addictive products with known health risks, but they would be able to do so with immunity from liability for the suffering and death their products may cause.

Dr. Sumner's model says on page 129 that liability standards for pharmaceutical nicotine and tobacco would differ:

> "However, the same legislation should recognize that corporations can best anticipate, control, and manipulate perceptions of the harms inherent in their nicotine delivery systems. Legislation holding companies accountable for those harms could maintain higher liability costs for cigarettes than for clean inhalers. Labels on all nicotine

products should inform consumers of risks, including addiction, and enumerate the product's chemical constituents. Product specific labels on cigarettes will list more chemicals and carry more warnings than the labels on clean nicotine inhalers."

A medical practitioner and a public health advocate asserts that corporations are best able to *control and manipulate* perceptions of harms inherent in their nicotine products. Note the wording: *to control and manipulate perceptions of harms,* not to control and reduce the harms, of their products. Few statements could more aptly illustrate a fundamental truth of tobacco control advocacy: it's about *controlling the perception* of what occurs, what actually occurs is not relevant. How else but through manipulating perceptions could an organized nationwide special-interest enterprise get away with increasing high school senior daily smokers 43 percent under the auspices of its programs, in the name of "Saving the Children" from tobacco use? The only way that could be accomplished is to manipulate a public perception that their programs accomplished something positive, which they did not.

The final element in the competitive strategy is to substitute pharmaceutical nicotine for tobacco nicotine. On page 129 of Dr. Sumner's paper presents another familiar tobacco control activity, control of public advertising for products:

> "As a special form of counter-advertising, legislation could permit promotion of clean nicotine delivery systems as an alternative to cigarettes, perhaps with fewer constraints than we apply to tobacco products."

We parents of teens can see it coming now: thirteen-year-old Sally sits with her parents in the living room one evening, watching her favorite sit-com. On the commercial break suave, sophisticated, ruggedly independent, and satisfying Nicotine Nellie sidles up to the screen. Nellie deeply inhales her nicotine as she extols the "real advantages" of sucking on her "modern nicotine inhaler" to get a hit. In the background Marlboro Man leers with an approving glance as he nonchalantly takes a drag off of his plastic nicotine delivery pseudo-cigarette. And, of course, a special disposal tray for used inhalers is a common courtesy in every home, just as ash trays were scant decades ago. The commercial ends with the two embracing, each holding up their nicotine stick in an offhand way that kids can emulate.

No, that scenario is not a stretch of the imagination. What Dr. Sumner proposes is to apply what tobacco companies have proven to be successful in marketing nicotine products, and what is described above is similar to tobacco company advertising during the 1950s and 1960s. Moreover, Dr. Sumner proposes that such promotion of pharmaceutical nicotine be allowed *with fewer restrictions* than on tobacco. Finally, in 1998 when Dr. Benowitz and Dr. Koop were making public statements about addicts being dependent on nicotine instead of tobacco Johnson & Johnson was advertising its Nicotrol inhaler in television commercials that included a suave young man in a flashy red convertible who inhaled deeply from his Nicotrol inhaler. That suave young man was congratulated by an attractive young lady for his intelligent consumer choice.

On page 130 of his paper Dr. Sumner cautions us about undesirable public health consequences if nicotine inhalers do not succeed in replacing cigarettes:

> "Some undesirable public health scenarios might unfold if a clean nicotine inhaler did not succeed in replacing tobacco cigarettes. First, the inhaler could simply disappear from the market, leaving the prevalence of cigarette use and nicotine addiction unchanged or even increased. Second, the inhaler could recruit new users, but not replace enough cigarette smoking to offset the harms to the new users. However even this short term public health failure would create legislative opportunities to demand lower nicotine content in cigarettes while raising taxes aggressively.[6 53] Relatively satisfying inhalers could then supplant expensive and unsatisfying cigarettes and provide an alternative to black market cigarette purchases.[54]"

So there we have it: a complete and comprehensive plan to use tobacco control's legislative influence and pharmaceutical political clout to muscle in on tobacco companies' nicotine market share. The competitive plan even anticipates harm to consumers from widespread distribution of highly addictive pharmaceutical nicotine delivery device products, but addresses that risk by using influence with legislators to legislate *pharmaceutical immunity from liability.*

Given Dr. Sumner's references to established principles of tobacco control policy, the use of smoking bans to reduce opportunities to use *competitive* tobacco products, and promoting taxes on cigarettes to create a price disadvantage for cigarettes versus nicotine inhalers, his paper reveals tobacco control for what it is and always has been: a systematic long-term plan to artificially substitute pharmaceutical nicotine products for tobacco products in the U.S. consumer market. Part and parcel of that plan was a scheme to stabilize the tobacco source consumer market, which optimizes the target population for nicotine inhalers, and to use tobacco consumer money to finance pharmaceutical nicotine's encroachment in the nicotine market. Considering Dr. Sumner's carefully planned campaign to give pharmaceutical nicotine vast price, use, and regulatory advantages over tobacco, I believe we can safely say that a mercantile product substitution scheme is what tobacco control advocacy shall ever more be, as well.

Blind faith is not necessary to accept the preceding observations about the motivations and consequences of tobacco control advocacy. Through Dr. Sumner's research we have a clear analysis of the current nicotine market and a bold statement of what can be done to assure that tobacco control advocates and their pharmaceutical sponsors seize the mercantile opportunity the market provides. That the current nicotine market has been socially engineered by tobacco control over the past decade is evident from the results of its own programs: *increased* youth smoking and *stabilized* adult smoker populations, compared to consistent declines before anti-tobacco conducted its policy interventions. Today we observe tobacco control aggressively promoting new tax and ban policy that assures their special-interest enterprise will capture the maximum economic benefit from a nicotine market that has been crafted to benefit itself at the public's expense.

Important Disclosures

Dr. Sumner is with Washington University in Saint Louis. That university is the beneficiary of several current grants from the Robert Wood Johnson Foundation:

Grant ID No. 036026	$ 500,000
Grant ID No. 045448	$ 300,000
Grant ID No. 048030	$ 688,690
Grant ID No. 045782	$ 631,937
Total Current Grants:	$ 2,120,627

According to *Value Line*, the RWJ Foundation owns 5.4 percent of Johnson & Johnson, the company that advertised its Nicotrol inhaler on television in 1998. The foundation's assets are reportedly worth more than $7 billion. The foundation is therefore in a unique position to fund those like Washington University and Dr. Sumner who advocate policy that benefits Johnson & Johnson, and other drug companies.

Who could we speculate is developing or has developed new "deeply inhaled, highly addictive" nicotine delivery technology? Time will tell. When a nicotine inhaler as described by Dr. Sumner is introduced the answer will be obvious.

Nicotrol products that were distributed by Johnson & Johnson under license from Pharmacia during the 1990s are now distributed by Pharmacia Consumer Care. Pharmacia became a part of Pfizer through a recent merger. Has Johnson & Johnson left the nicotine market, or was termination of its licensing agreement with Pharmacia a precursor to introducing new nicotine inhaler technology described by Dr. Sumner?

Considering that Dr. Sumner's paper was written at a university that is the beneficiary of $2.1 million from Johnson & Johnson's advocacy-funding foundation, we may have an indication of one economic power behind the throne of tobacco control's product development and promotion efforts.

Successful introduction of new nicotine inhaler technology that does not carry the overhead of licensing by Pharmacia would be financially attractive to Johnson & Johnson. The company also has long-established financial ties to tobacco control advocates through the RWJ Foundation. Combining the economic advantages of license-free inhaler technology with the political influence of tobacco control to virtually mandate its use could assure a highly successful product launch.

A key point on page 129 in Dr. Sumner's paper raises the possibility of mandates for use of nicotine inhalers at work:

> "Local ordinances that curtail public smoking already create settings where a nicotine inhaler could be the most satisfying alternative for current smokers. Lacking a burning tip and side stream smoke, an inhaler should present no risk to by bystanders, and requires no restriction on public use. Employers could even abolish outdoor smoking areas and smoking breaks if addicted employees could inhale nicotine indoors." (Underline added.)

The above statement in Dr. Sumner's paper assumes several facts that are not in credible evidence: first that people only smoke to ingest nicotine; second, that there is bona fide risk from side stream smoke; and third that it is acceptable public policy to widely distribute highly addictive products that credible research says may present significant health risks.

Perversely, many smokers would thank tobacco control advocates for abolishing work smoking breaks and areas, and for the opportunity to purchase the new nicotine inhaler. They could return from smoking outside in the elements, to suck on Johnson & Johnson's inhaler at their work station. That is the ultimate "Stockholm Syndrome," thanking those who have abused you for crafting a more comfortable form of abuse.

Perhaps we already see the initial steps to Johnson & Johnson's product launch in play. The RWJ Foundation has generously funded health advocacy organizations such as the American Lung Association and Campaign for Tobacco-Free Kids, that recently sponsored nationwide initiatives to increase taxes on tobacco products. We have also observed a sharp increase in proposed local and state legislation for smoking bans, such as Washington's failed attempt to extend our state's smoking ban beyond offices to restaurants, taverns, etc., as well as New York City's recent mandate of smoking bans. Foundation and other special-interest dollars are already hard at work to bring to fruition Dr. Sumner's vision of a nicotine-dependent future *that includes smokers and nonsmokers alike* as prospective customers for pharmaceutical nicotine.

GlaxoSmithKline distributes Nicorette gum, NicoDerm CQ patches, and COMMIT lozenge nicotine products. Those products are manufactured by Pharmacia with license to GlaxoSmithKline, which was formed through merger of Glaxo Wellcome and SmithKline Beecham.

Similar to Johnson & Johnson, GlaxoSmithKline also finances tobacco control advocates. For an example, examine a box of Nicorette or NicoDerm CQ. You will find the American Cancer Society receives an annual grant from Glaxo for use of the society's seal in promoting its nicotine products.

A logical question rises from the preceding five pages of discussion about Dr. Sumner's research paper: Would we be discussing that subject at all if allegedly anti-tobacco programs had accomplished what they publicly proclaimed their goals to be, *material and sustaining reductions in tobacco use?*

Considering that question raises a short course in the history of tobacco control. Under Project ASSIST 1991 to 1998 youth smoking rates dramatically *increased,* adult current smokers *stabilized,* and adult former smokers *declined.* 1993 Project ASSIST Action Plans included objectives to support passing smoking bans (page 6). At the time state tobacco control advocates were promoting smoking bans before our legislature the State of Washington Office of Financial Management received a $1.4 million grant (page 7) and the State of Washington Department of Health received a $1.3 million grant from the RWJ Foundation (page 8). In 1993 the American Cancer Society received $500,000, the American Lung Association received $1.1 million, and Washington DOC received $649,967 from the foundation (page 9). The state and its policy advocates received a total of $5,013,102 in grants from the RWJ foundation while they promoted smoking bans.

Based on the foregoing, it seems fair to assume that states and tobacco control advocates are already hard at work using foundation money to produce another handsome return on pharmaceuticals' investments in smoking ban promotion.

Redmond WA June 2, 2003

ANNUAL ACTION PLAN

Year 1 Interventions
October 1, 1993 - September 30, 1994

CHANNEL: **Community Environment/Policy**

ASSIST NATIONAL OBJECTIVES:

By 1998, sites will substantially increase and strengthen public support for policies which a) mandate clean indoor air; b) restrict access to tobacco by minors; c) increase economic incentives and taxation to discourage the use of tobacco products; and d) restrict the advertising and promotion of tobacco.

ANNUAL OBJECTIVE #1:

Work to pass Department of Labor and Industries' regulations on eliminating Environmental Tobacco Smoke from nonindustrial worksites.

JUSTIFICATION:

The Washington Clean Indoor Air Act does not address environmental tobacco smoke (ETS) in the workplace. The recent release of the EPA report on ETS provides the necessary justification to potential opposition, i.e, restaurant owners, small business owners, and smokers for requiring workplaces to eliminate the health hazards of ETS in the workplace. Clearly, comprehensive L & I regulations on ETS in the workplace would be a significant accomplishment for tobacco control advocates. It is important to have a statewide strategy, statewide dissemination of information and grass roots collaboration and support. L & I is currently developing the regulations and will be holding public hearings for input on the regulations. Tobacco control advocates have an opportunity to present their views and influence policy changes.

ACTIVITIES:

Activity: In collaboration with the other Worksites and Policy Task Forces around the state, work to ensure that Labor and Industries passes strict regulations regarding smoking in the workplace.

NOTE: When this Action Plan was published the American Cancer Society was the nationwide manager of Project ASSIST, the American Cancer Society was a Tobacco-Free Washington Coalition member, and Dr. Robert Jaffe of Washington DOC was the president of the coalition. All three organizations received grants from Nicotrol distributor Johnson & Johnson's Robert Wood Johnson Foundation in 1993 (see page 9). According to proceeding transcripts, all three organizations actively lobbied for, and testified in support of, the Washington Department of Labor and Industries prohibition on smoking in office work environments. That Washington smoking ban Administrative Order of Adoption 93-18 affirmatively declared that all proposed Indoor Air Quality regulations other than the smoking ban were ". . . not appropriate at this time."

Access, Cost Containment

STATE OF NORTH CAROLINA, NORTH CAROLINA HEALTH PLANNING COMMISSION
Raleigh, NC
$95,045
(17 months)
Access, Cost Containment

COMMONWEALTH OF PUERTO RICO, PUERTO RICO HEALTH INSURANCE ADMINISTRATION
San Juan, PR
$287,642
(1.5 years)
Access, Cost Containment

STATE OF VERMONT, HEALTH CARE AUTHORITY
Montpelier, VT
$342,993
(1 year)
Access

STATE OF **WASHINGTON**, OFFICE OF FINANCIAL MANAGEMENT
Olympia, WA
$1,459,632
(2 years)
Access (Box Added)

COLUMBIA UNIVERSITY, SCHOOL OF PUBLIC HEALTH
New York, NY
$359,404
Evaluation of the State Initiatives in Health Care Reform program
Access, Cost Containment

STATE INITIATIVES IN LONG-TERM CARE
Supports state reform of long-term care financing and service delivery systems and development of comprehensive strategies to broaden access to long-term care coverage
(for the periods indicated).
Chronic Health Conditions, Cost Containmen

t STATE OF COLORADO, DEPARTMENT OF HEALTH CARE POLICY AND FINANCING
Denver, CO
$199,376
(1.5 years)

4/25/98 3:33:14 PM

Grant Information Retrieved From Web Site Of The Robert Wood Johnson Foundation

NOTE: Receipt of the above Robert Wood Johnson Foundation grant by the State of Washington was confirmed to me in 1998 correspondence from the Washington Secretary of Health, Mary C. Selecky. In her correspondence she dismissed my objection to the $1.4 million grant because it was for health care access. The direct relevance of that grant to tobacco control initiatives and agendas became apparent in 2001, when the American Lung Association (a member of the Tobacco-Free Washington Coalition that operates under the auspices of the Washington Department of Health) sponsored I-773. That successful initiative levied a new tax of 60 cents per pack on cigarettes to fund expansion of health insurance for children and the poor. 10 percent of I-773's revenues are earmarked to fund tobacco control programs, revenues that benefit the American Lung Association in Washington. Pharmaceuticals, such as Johnson & Johnson, directly benefit from such initiatives because they increase insurance revenues available to purchase pharmaceutical products as prescribed by physicians.

PROJECT LIST

GRANT INFORMATION

NATIONAL PROGRAM
Improving Child Health Services: Removing Categorical Barriers to Care

NATIONAL PROGRAM OFFICE
State of Washington, Department of Health (Olympia, WA)
$1,303,503 (May 1990 to October 1997) ID#s 018804, 019690, 021203, PC219, 023455, 024762
Contact
Program Director: Maxine Hayes, MD, MPH
(360) 753-7021
mdh0303@hub.doh.wa.gov
Deputy Director: William D. Hobson, MS
(206) 616-1506
mcna@u.washington.edu

(Box Added)

EVALUATOR
University of California, San Francisco Institute for Health Policy Studies (San Francisco, CA)
$587,054 (September 1991 to September 1995) ID# 016641
$244,687 (October 1995 to April 1997) ID# 023359
Contact
Principal Investigator: Paul Newacheck, PhD
(415) 476-3896

Authorized by the Board of Trustees for $4,874,043 in June 1991.

RWJF GOAL AREA
Chronic Care — To improve care and support for people with chronic health conditions.

THE PROBLEM

Most public funding for child health services flows from distinct programs that are separately regulated by federal and/or state agencies. In many cases, the vital health services funded through this rigid categorical system have given rise to agencies and programs that provide only a single service or narrow set of closely related services. This system evolved from the tendency of Congress to act on specific health problems as opposed to broad health care needs. As such, communicable diseases, chronic diseases, and preventive health services have been separately funded through numerous pieces of legislation. Today, entirely separate programs exist for preventive health services, maternal and child health services, and family planning services. Such categorical funding provides Congress and states with the ability to target limited resources to specific health problems. It also affords policymakers with an opportunity to champion or to be identified with funds for a specific disease or service deemed to be a national or state priority.

The heightened visibility afforded each categorical health program in federal and state budgets has helped assure the survival of funding that otherwise might have been lost to public spending reductions. Advocates for a particular categorical program have been able to effectively organize a constituency bound by common interests or concerns. Public funding trends and legislative action can be readily tracked in the current system. This precise targeting and legislative visibility, however, has contributed to the fragmentation of services for children and has created burdensome logistical problems for their parents.

The structure of publicly supported health programs is one of two major problems addressed by the ICHS initiative. The second problem is that an increasing number of children have multiple health care needs. Low-income US children, particularly, have needs for primary medical care, mental health counseling, substance abuse counseling, and preventive health services. In

NOTE: The above grant to the State of Washington Department of Health from the Robert Wood Johnson Foundation placed the department in the position of being a national program coordinator for a private foundation special-interest at the time the state was also sponsoring smoking ban legislation advantageous to the foundation's financial interests. Children's health is related to state Project ASSIST tobacco control advocacy that focused on children. The results of Project ASSIST nationwide and in Washington were 40 percent-plus increases in high school daily smokers, an outcome that benefitted Nicotrol smoking-cessation product distributor Johnson & Johnson. The foundation is the largest single shareholder of Nicotrol distributor Johnson & Johnson.

Robert Wood Johnson Foundation $34,997,194 1996 Tobacco Control Grants
Source: RWJ Foundation 1996 Annual Report
(1996 Tobacco Control Grants Only, 1993 To 1999 Total Is More Than $200 Million)

According to *Value Line* The Robert Wood Johnson Foundation is the largest single shareholder of Johnson & Johnson. During ASSIST years Johnson & Johnson distributed Nicotrol smoking cessation products through its McNeil Consumer Products subsidiary.

ID No.	Recipient	Grant Amount	Grant Purpose	Location
30499	Allina Health System	48,171	Smoking Cessation	Minneapolis, MN
29319	American Bar Association	482,219	Substance Abuse Law	Washington, DC
30066	American Cancer Society	500,000	SmokeLess States	Atlanta, GA
29549	American Heart Association	1,063,392	SmokeLess States	Portland, OR
28494	American Lung Association	200,000	Local Preemption Law	Washington, DC
30065	American Lung Association	900,000	SmokeLess States	Louisville, KY
28189	American Medical Association	748,595	SmokeLess States	Chicago, IL
28586	American Medical Association	95,300	Media Briefing on Tobacco	Chicago, IL
29398	American Medical Association	29,855	11th World Conf. on Tobacco	Chicago, IL
29466	American Medical Association	70,983	Primary Care Dist. AHCPR	Chicago, IL
30691	American Society of Addiction Medicine	197,844	Alt.Nicotine Delivery Syst.	Chevy Chase, MD
27340	Battelle Memorial Institute	105,870	Minors' Access to Tobacco	Baltimore, MD
28367	Boston University	50,000	Tobacco Control Website	Boston, MA
30308	Burness Communications	17,000	Communications, Conf. on AHCPR	Bethesda, MD
28757	Center for the Advancement of Health	49,699	Managed Care Tobacco Prev.	Washington, DC
28495	Creighton University	182,399	Smoking Cessation Videos	Omaha, NE
29471	Dana-Farber Cancer Institute	49,981	Distribute AHCPR Org. Labor	Boston, MA
30695	Foundation for State Legislatures	19,137	Survey of Medicaid	Denver, CO
29718	George Washington University	37,615	Eval. Tucson Youth Tob. Proj.	Washington, DC
29386	Girl Scouts of America	17,500	Girl Scouts Against Smoking	New York, NY
30825	Governor's Partnership	826,021	Worker Protection	Hartford, CT
28635	Harvey J. Weiss and Associates	449,344	National Inhalant Prevention	Austin, TX
29283	Hayes, Domenici & Assoc.	65,622	Conf. Women and Smoking	McLean, VA
30067	Health Education Inc.	782,317	SmokeLess States	Lincoln, NE
28040	Hedrick Smith Productions	150,000	PBS Series on Tobacco Lobby	Bethesda, MD
26857	Institute for Public Policy Advocacy	147,529	Tech. Assist. SmokeLess States	Washington, DC
29514	Jacksonville Jaguars Foundation	332,802	NFL Youth Anti-Tobacco	Jacksonville, FL
29558	Lehigh Valley Hospital	50,000	Comm. Alcohol/Tobacco Policy	Allentown, PA
30068	Medical & Chirurgical Facility	823,476	SmokeLess States	Baltimore, MD
29831	Miller & Associates	8,000	Econometric Model Review	Oakland, CA
30069	Minn. Coalition for Smoke-Free Society	1,199,987	SmokeLess States	Minneapolis, MN
29050	Miriam Hospital	46,816	Nurse Smoking Cessation Implem	Providence, RI
29600	National Center for Tobacco-Free Kids	19,510,110	National Youth Campaign	Washington, DC
30145	National Foundation for CDC	451,185	Race/Gender Smoking Resrch.	Atlanta, GA
30531	New Jersey Nets	164,000	NBA Health Risks of Tobacco	East Rutherford, NJ
30298	New Sounds Inc.	27,000	Anti-Tobacco Radio Spots	New York, NY
28191	Oral Health America	767,986	Major League Baseball Init.	Chicago, IL
27474	Pinney Associates	72,000	Implementing AHCPR Guidelines	Bethesda, MD
29354	Pinney Associates	36,750	Tobacco Dependence Work Group	Bethesda, MD
30465	Pinney Associates	35,500	AHCPR Conf. Proceedings	Bethesda, MD
30055	Pyramid Communications	197,843	Conf. Preventing Tobacco Use	Seattle, WA
29060	Roswell Park Cancer Institute	23,309	RWJF Tobacco Control Policy	Buffalo, NY
30235	Scholastic Inc.	20,000	Teacher Panels - Tobacco Educ.	New York, NY
27123	St. Peter's Medical Center	46,531	Exhibits About Tobacco Prod.	New Brunswick, NJ
28627	St. Peter's Medical Center	27,833	Alternative Nicotine Delivery	New Brunswick, NJ
30735	Strategic Consulting Services	12,175	RWJF Science Conf. Facilitator	Portage, WI
31072	The Lewin Group	83,830	Tobacco Policy Assessment	Fairfax, VA
27375	University of Alabama	484,167	Smoke Free Families	Brimingham, AL
28946	University of Arizona	146,061	Reduce Youth Tobacco Use	Tucson, AZ
29273	University of Arizona	792,565	Reduce Youth tobacco Use	Tucson, AZ
28042	University of California	597,012	Study Tobacco Marketing	San Diego, CA
28676	University of Illinois	54,858	Adolescent Tobacco Use	Chicago, IL
29015	University of Kentucky	253,347	Research Etiology of Tobacco	Lexington, KY
30070	University of Virginia	749,992	SmokeLess States	Charlottesville, VA
29389	University of Wisconsin	45,699	Distribute AHCPR Guidelines	Madison, WI
30072	Washington DOC	649,967	SmokeLess States	Seattle, WA

Notable Grants: $500,000 to Project ASSIST's nationwide manager, the American Cancer Society; $900,00 to American Lung Association and $19,510,110 to National Campaign for Tobacco-Free Kids, who sponsored Washington's 2001 I-773, adding 60 cents per pack new cigarette taxes to finance anti-tobacco programs and expanding medical insurance; $649,967 to Washington DOC that participated in ASSIST's Washington youth interventions; $826,021 to Governors Partnership; and $451,185 to CDC. The Campaign for Tobacco-Free Kids was awarded and additional $50 million RWJ foundation grant 1999. Additional foundation grants (beyond those to expand health insurancer coverage) include those for reducing exposure to seconhand smoke, whch is to say to promote smoking bans.