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August 1, 2002

Delivery By Hand

J. Howard Beales III Director, Bureau of Consumer Protection Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, DC 20580

Re: U.S. Smokeless Tobacco Company's Request for an Advisory Opinion

Dear Mr. Beales:

Prior to our meeting with you and the FTC staff on Friday, August 2, 2002, we wished to bring to your attention two additional items which we believe are relevant to your consideration of USSTC's request for an advisory opinion. The items are attached and are discussed below:

The first is a copy of an article and related commentaries that recently appeared in the journal *Addiction*, published by the Society for the Study of Addiction to Alcohol and Other Drugs. *See* Attachment A. In response to an article by P. Anderson, entitled "Public-private partnerships to reduce tobacco dependence," *Addiction*, 97, 951-955 (2002), is a commentary by Dr. K. Michael Cummings of New York's Roswell Park Cancer Institute, in which he points out:

Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in tobacco products really contribute to disease risk. Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as fairly minor compared to the difference in disease risk between smoked and smokeless products (Stratton *et al.* 2001). *Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain.* Capitalism, and not governmental regulation, has the greatest potential to alter the world-wide epidemic of tobaccorelated disease. Cummings, *Addiction* 97 (2002) at 957 (emphasis supplied). J. Howard Beales III August 1, 2002 Page 2

The second item is a set of excerpts from a presentation by Dr. Cummings at the National Conference on Tobacco or Health in November 2001, entitled "Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products." See Attachment B. There, as background and support of the statements cited above, Dr. Cummings demonstrates that 82 percent of smokers in his survey believe that "chewing tobacco is just as likely to cause cancer as smoking cigarettes." See p. 10 (unnumbered).

We hope that this information will assist you and the Commission staff in considering USSTC's request. We look forward to the opportunity you have given us to meet with you on Friday on this subject.

Sincerely yours,

Daniel C. Schwartz

Lydia B. Parnes, Deputy Director, Bureau of Consumer Protection cc: C. Lee Peeler, Deputy Director, Bureau of Consumer Protection Heather A. Hippsley, Acting Associate Director, Bureau of Consumer Protection Gerard Butters, Assistant Director, Bureau of Economics Thomas B. Pahl, Assistant Director, Bureau of Consumer Protection Michael P. Ostheimer, Staff Attorney, Bureau of Consumer Protection Rosemary Rosso, Staff Attorney, Bureau of Consumer Protection Joseph P. Mulholland, Staff Economist, Bureau of Economics

Attachment A

1.1.1

Public-private partnerships to reduce tobacco dependence

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ABSTRACT

Four-fifths of the estimated one billion deaths that will be caused by tobacco dependence over the next 100 years will occur in low-income countries. Along with other tobacco control policy measures, the treatment for tobacco dependence is a cost-effective policy measure in low-income countries. In public health, public-private partnerships for drugs and vaccines and incentives for commercial private sector engagement are proposed to tackle the communicable diseases of the poor. This paper will argue that public-private partnerships are also an appropriate and important vehicle to reduce the harm caused by tobacco. For the pharmaceutical sector to engage in the marketing of tobacco dependence treatment products in low-income countries the incentives must be aligned, and a self-sustaining market must be developed. A rational market would be large, characterized by high volumes and low margins. The framework convention on tobacco control of the WHO provides a global infrastructure for taking public sector action to reduce the harm caused by tobacco. The convention could call for a proportion of tobacco tax from high-income countries to be used to fund tax credits and other incentives for increasing the access to tobacco dependence treatment in low-income countries.

KEYWORDS Public-private partnerships, treatment of tobacco dependence.

INTRODUCTION

Increasing attention is being given to the need to reduce the global disparities in health caused by tobacco dependence. Globalization has been accompanied by a reassessment of the strengths and limitations of the public sector, the private sector and civil society institutions in grappling with tobacco dependence. It is becoming recognized that there is not just a need for better coordination of existing roles but also new ways of working together in order to achieve a synergistic combination of the strengths, resources and expertise of the different sectors.

Public-private partnerships are receiving increased discussion and development in public health, particularly for private-sector engagement in the communicable diseases of the poor (Feachem 2001). This paper will argue that tobacco dependence is becoming increasingly a disease of low- and-middle income countries; that public-private partnerships are an appropriate and important vehicle to reduce the harm caused by tobacco; and that such partnerships can focus on increasing access to dependence treatments, thereby increasing the return on investment for health gain in low- and middleincome countries.

THE PUBLIC HEALTH BURDEN OF TOBACCO DEPENDENCE

Over 1.2 billion people in the world are current smokers, four-fifths of whom live in low- or middle-income countries (Gajalakshmi *et al.* 2000). Over the next 100 years, it is estimated that tobacco will lead to one billion deaths, four-fifths of which will occur in low-income countries.

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Within 20 years, tobacco dependence will become the world's single largest cause of disability adjusted lifeyears. Tobacco products are a considerable health and economic burden to individuals, families and societies and are a major deterrent to the health, social and economic development of low- and middle-income countries (World Bank 1999). A recent study in Bangladesh demonstrated that expenditure on tobacco products, particularly cigarettes, was a major burden for impoverished households. It was estimated that the lives of 350 Bangladeshi children could be saved each day if money on tobacco was spent on food instead (Efroymson *et al.* 2001).

Epidemiological analysis demonstrates that it is not possible to reduce tobacco-related deaths over the next 30–50 years, unless adult smokers are encouraged to quit (World Bank 1999). Price measures, non-price measures and the treatment of tobacco dependence are all cost-effective options to reduce adult smoking rates (World Bank 1999). Raising tobacco taxes and increasing smoke-free places will increase pressure to quit smoking. This will cause considerable difficulties for many smokers, in view of the addictiveness of tobacco products, classified as a dependence disorder by the 10th revision of the international classification of diseases and related health problems (WHO 1992).

Treatments for tobacco dependence have high safety, efficacy and utility (Novotny *et al.* 2000). With the specific example of pharmacological products, nicotine replacement therapy (NRT) doubles a smoker's chance of quitting with or without other therapy, leading to 6month abstinence rates of between 10 and 25%. In highincome countries, NRT is among the most cost-effective of all known health-care interventions. The World Bank has estimated that the cost can be as low as \$749 per disability adjusted life-year (DALY) saved, representing one of the best investments for health gain by the healthcare sector currently available in high-income countries (Novotny *et al.* 2000).

In low- and middle-income countries, the World Bank estimates that NRT could cost about \$276 per disability adjusted life-year (Novotny *et al.* 2000). Although this is currently more expensive than other tobacco policy measures (\$4 per DALY saved for tobacco price increases of 10% and \$68 per DALY saved for non-price measures with an effectiveness of 5%) and other health-sector interventions (\$25 per DALY for child immunization and \$30–100 per DALY for the integrated management of the sick child), it is still cost-effective. The World Bank suggests that health interventions that can be delivered for less than the average per capita GDP of a country are cost-effective (low-income countries are defined by the World Bank as those with a per capita GDP of \$765 or less).

PUBLIC-PRIVATE PARTNERSHIPS AND PUBLIC HEALTH

Although public-private partnerships are receiving increased attention in public health, there remains confusion as to what such partnerships mean (Widdus 2001). One reason for this is that much of the discussion has focused on the differences between the two sectors. As defined by *The Oxford English Dictionary*, partnership implies a commitment to a common goal through the joint provision of resources and expertise, and the joint sharing of the risks involved. Although contractual arrangements need to be made, the concept of partnership means that the negotiations between the public and private sectors should be positively, not negatively, directed from the outset.

An inventory of over 70 collaborative public-privatesector projects has been established by the Geneva-based Initiative on Public-Private Partnerships for Health. These projects involve a diversity of arrangements with regard to participants, legal status, governance, management, policy-setting, contributions and operational roles (Widdus 2001).

Based on the inventory, Appendix I groups different types of partnerships. A number of legally independent not-for-profit partnerships have been established to deal with both product development and disease control. These partnerships provide not only treatment products but also support activities to ensure efficient distribution of treatments and their use. Partnerships that are located within a public-sector host organization are described as public-sector programmes with private-sector participation. A number of partnerships rely on the good will of pharmaceutical companies and the prospect of good public relations. Only a few partnerships have explicitly attempted to expand the sale of health products by opening up new markets.

Partnerships have sometimes focused on countries and activities that offer a reasonable chance of success and return on investment. Thus, they have tended to concentrate on high- rather than low- and middle-income countries and on drug donations and development, instead of capacity development for service delivery and research.

The Geneva-based initiative has suggested that partnerships are most justified where: traditional ways of working independently have a limited impact on a problem; the specific desired goals can be agreed by potential collaborators; there is relevant complementary expertise in both sectors; the long-term interests of each sector are fulfilled (i.e. there are benefits to all parties): and the contributions of expertise and resources are reasonably balanced (Widdus 2001). The initiative suggests that public sector agencies should continue to: fund

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fundamental research; set standards for product safety, efficacy and quality; establish systems whereby citizens have adequate access to health products and services; use public resources in an efficient manner; and create environments in which commercial enterprise is appropriately motivated to meet the needs of whole populations (Widdus 2001).

When setting up public-private partnerships, it seems that three key principles are important.

First, it is better if such types of partnerships are not over-managed. Developments often come from risktaking and from different points of initiative. The risks of failure should be accepted. Some activities will be found to achieve little and should be stopped.

Secondly, normative actions such as giving recommendations on the regulation of treatment products, and scientific actions such as developing evidencebased recommendations for treatment while using information and views from the pharmaceutical sector should remain independent of the pharmaceutical sector.

Thirdly, each partner should maintain autonomy in policy matters and in areas of work that are outside the focus of a partnership. Thus public health bodies and non-governmental organizations should speak out on matters of policy, even where their views may differ from those of their partners.

Partnerships with non-governmental organizations and institutions in the private sector are outlined in the WHO's corporate strategy as a core function that can help to bring about health for all (Buse & Waxman 2001). The WHO's approach to partnerships with the private sector is distinctive because of the explicit focus on health and the ethical principles that support its mission and values. The WHO has entered into partnerships that have usually sought to achieve well-defined and specific health outcomes, such as those that are linked to disease or risk factors.

Fears have been expressed that inadequately monitored relations with the pharmaceutical sector may subordinate the values and reorientate the mission of the WHO, detract from its abilities to establish norms and standards free of commercial considerations, weaken its capacity to promote and monitor international regulations, displace its organizational priorities and induce self-censorship (Buse & Waxman 2001). Interaction, it is argued, may result in these outcomes, not just because the private sector may pursue opposing underlying interests but, because it has limited financial resources, the WHO may face institutional capture by its more powerful partners. In particular, it has been argued that the WHO's emphasis on low-income countries will be displaced as resource-rich partnerships dictate organizational priorities and strategies.

PUBLIC-PRIVATE PARTNERSHIPS FOR THE TREATMENT OF TOBACCO DEPENDENCE IN LOW- AND MIDDLE-INCOME COUNTRIES

The European partnership project to reduce tobacco dependence was set up in 1999 as a public-private partnership with the objective of reducing tobacco-related harm among tobacco-dependent smokers (WHO 2001). When launching the project at the World Economic Forum in Davos, Switzerland, the Director-General of the World Health Organization stated:

'The WHO has the mandate and the opportunity to influence treatment policy processes and programmes, but cannot do so without the support of the private sector and other partners.'

The project has aimed to influence policies and programmes that make the treatment of tobacco dependence more available, affordable and accessible. The project has been operational primarily in four highincome countries. It is funded largely by the pharmaceutical sector and is located within and managed by the European Office of the WHO.

The project has contributed to a considerable number of developments and achievements in promoting the treatment of tobacco dependence, including the production of tools, changes in the policy environment and expansion into other countries. The project has dealt with communicating health messages to smokers, providing recommendations and training to health-care providers and influencing the regulatory environment. An inevitable outcome of the project is an increased uptake in the use of evidence-based treatment, including pharmacological treatment products. Since for many smokers this represents a new approach, the project could be described as expanding the sale of tobacco dependence treatment products by tapping into new market segments.

If similar types of projects are to expand and serve the needs of low- and middle-income countries, attention must be paid to both the implementation of effective tobacco control polices to increase the motivation of smokers to quit and access to treatments for tobacco dependence. Partnerships need to be broad-based, involving the public sector, the commercial and pharmaceutical sectors and the not-for-profit non-governmental organizations.

Additional analysis in the treatment of tobacco dependence in low- and middle-income countries is needed so that partnership efforts can be guided. This could take the form of political and economic analyses of the treatment of tobacco dependence; studies of the effectiveness and cost-effectiveness of the treatment of

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tobacco dependence; an assessment of the fraction of the burden attributable to each disease that might be reduced by increased access to tobacco dependence treatment; studies of the barriers and incentives to implementing services for the treatment of tobacco dependence among health-care providers and their clients; and experience in developing, customizing and implementing services for the treatment of tobacco dependence based on primary health care.

The prospective market for tobacco dependence products in low- and middle-income countries might seem commercially unattractive in comparison with the markets in high-income countries, since there could be a low return on investment. However, there is no fundamental reason why tobacco dependence in lowincome countries should be of little commercial interest. A rational market would be large, characterized by high volumes and low margins. For the pharmaceutical sector to engage in the marketing of tobacco dependence treatment products in low- and middle-income countries the incentives must be aligned, and a self-sustaining market must be developed.

Liberalizing access is the key to increasing the cost effectiveness of treatments for tobacco dependence. In discussions on how to improve access to treatment products, drug affordability, interpreted as manufacturers' selling prices, is often singled out because it appears to be amenable to control. However, access is a multi-faceted problem and action is required on many fronts. Reducing trade and non-trade barriers to NRT, as well as reducing the regulation of the provider, seller and the conditions of sale would all increase access to NRT and thus increase its cost-effectiveness. There is also a crucial role for advocacy and the communication of health messages to both the public and health-care proiders to ensure widespread acceptance and utilization of tobacco dependence interventions.

More attractive markets could be created in middleincome countries where individuals themselves or their governments could afford to purchase products, and in low-income countries where some sort of marketguarantee funding could be provided from external sources. The creation of health-service infrastructures, allowing tobacco dependence treatment products and services to reach people in need, is necessary to achieve a return on investment. By raising the return to the seller, tax credits have been proposed as a mechanism to increase the incentive to market treatment products. Tax credits should also lead to lower prices for consumers.

Despite the competitive environments in which the pharmaceutical industry operates, there ought to be mechanisms whereby an increased amount of its resources and expertise can be targeted towards tackling the tobacco epidemic in low- and middle-income countries. Similarly, if the public sector is to take a lead, it has to commit resources that can provide realistic incentives for private-sector partnership and investment. Incentives for all partners must be aligned, and a self-sustaining market developed. One of the biggest incentives for the pharmaceutical sector is having the confidence that the public sector is serious about developing the appropriate infrastructure and capacities necessary to use partnership outputs for enhancing health.

The framework convention on tobacco control of the WHO provides a global infrastructure for taking public sector action to reduce the harm caused by tobacco (Framework Convention on Tobacco Control 2001). Implementation of the convention will need to be matched by the transfer of appropriate expertise and technology from high- to low-income countries. An ideal source of funding the implementation is through hypothecation of tobacco tax in all countries. A proportion of tobacco tax from high-income countries could also be used to fund tax credits and other incentives for increasing the access to tobacco dependence treatment in low-income countries.

CONCLUSION

In conclusion, public-private partnerships can be an appropriate and important response to increase the accessibility of the treatment of tobacco dependence in all countries. Public-private partnerships are social policy experiments that should continue to be analysed in terms of their governance, accountability, operations, risks and benefits. Although criticisms of such partnerships have been made it should be recognized that, without them, sometimes little new would be happening in reducing tobacco dependence.

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Appendix I Some examples of different categories of partnership projects (source: Widdus 2001).

Independent not-for-profit, public-private partnerships for product development:
Medicines for Malaria Venture;
International AIDS Vaccine Initiative;
Global Alliance for TB Drug development.
2 Independent not-for-profit, public-private partnerships for disease control:
Ivermectin for onchocerciasis;
Albendazole for lymphatic filariasis;
Eflomithine for sleeping sickness.
3 Public sector programs with private sector participation (secretariats in the World Health Organization):
Roll Back Malaria;
The Safe Injection Global Network;
The Stop TB initiatives.
4 Expanding the sale of health products, for example by opening up new markets:
Social marketing of contraceptives;
Social marketing of oral re-hydration salts;
The creation of an otherwise un-serviced market of the poorest countries for new vaccines.

CAN CAPITALISM ADVANCE THE GOALS OF TOBACCO CONTROL?

The paper by Anderson (2002) makes the point that public-private partnerships can be a powerful tool in combating the world-wide growth of tobacco. Ironically, in the developing world, cigarette manufacturers have perfected the use of public-private partnerships to fuel the sale of tobacco products while at the same time providing tangible and immediate economic benefits to the host country (World Bank 1999). The offer of a public health benefit in terms of extended life expectancies and reduced medical expenditures represents but a distant promise to those who must address the immediate concerns of a struggling country. In other words, in the developing world, profits will almost always trump public health. How can this situation be changed?

Anderson (2002) uses the example of how manufacturers of stop smoking medications might be engaged to help advance the cause of public health by increasing the accessibility of treatments for tobacco dependence. In this example, the pharmaceutical industry wins by making a profit selling their drugs, while the public health community wins by giving smokers greater access to treatments, which in theory aid smoking cessation. Ironically, the power of such a partnership has not escaped the thinking of the cigarette manufacturers who have, in the past, threatened economic hardship on those companies that might consider aggressively marketing nicotine replacement therapies as a cigarette substitute.^{1,2}

The real question for public health agencies interested in tobacco control is not whether public–private partnerships work, but how to make such partnerships strong enough so that they can compete for market share with cigarette manufacturers. As it stands today, the pharmaceutical industry is no match for the cigarette cartel,

nicotine medications are marketed to weak-willed, older smokers who have to quit. Cigarettes deliver what they advertise (i.e. pleasure and satisfaction), are cheap and largely unregulated. Nicotine medications do not work too well (i.e. most people fail to stop), are expensive and are regulated in ways that make people wonder how safe they really are to use. While Anderson (2002) was right when he advanced the concept of public-private partnerships to reduce tobacco dependence, his example of a partnership between public health agencies and the pharmaceutical industry is probably too narrow to make much of a dent in the emerging global epidemic of smoking-related diseases. Public health advocates should consider expanding their partnership list to include manufacturers of smokeless tobacco products and perhaps even companies that are willing replace their convention toxic cigarettes with lower-risk alternatives (Wilson 2001).

Cigarettes are marketed as pleasure products while

The dream of a tobacco-free society is not going to happen any time soon. Competition to produce a less toxic more consumer-acceptable delivery system for nicotine would benefit the goals of public health. At present there is no real competition, as the cigarette cartel is dominated by a small group of companies who have little incentive to change the status quo. Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in tobacco products really contribute to disease risk. Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as fairly minor compared to the difference in disease risk between smoked and smokeless products (Stratton et al. 2001). Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain. Capitalism, and not government regulation, has the greatest potential to alter the world-wide epidemic of tobacco-related disease. It is up to the public health community to harness the powers of capitalism to speed the development of less dangerous alternatives to the conventional cigarette.

¹Inter-office memorandum. From R. D. Latshaw to A. J. Kay Jr. Subject: Suspension of Dow Purchases, May 7 1984. Philip Morris Companies, Inc., Bates number 2023799800.

²Inter-office memorandum. From R. D. Latshaw to J. Bujold, A. J. Bulter, W. Campbell, T. Craig, A. J. Kay Jr, D. Sharrock. Subject: Dow–Nicorette Meeting, October 23 1984. Philip Morris Companies, Inc, Bates number. 2023799802.

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Declaration of interest

I have received fees for my work as an expert witness on behalf of plaintiffs' attorneys suing tobacco companies. In the past, I have received funding from manufacturers of smoking cessation medications for research activities and for professional speaking engagements.

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CONSIDER THE WHOLE BEFORE LOBBYING FOR PARTS

Partnerships with private industry can be important when they arise out of overlapping objectives, but they must be used as a complement to, not as a substitute for, countries acting in a coherent and organized way.

Anderson (2002) argues that use of cessation aids (read pharmacological aids supported by multi-national companies) should be subsidized by governments in low and middle-income countries because it is cost-effective. Cost-effectiveness estimates relate to specific forms of use in specific contexts. Generalizing beyond these contexts is fraught with danger, although that does not seem to stop most people doing it. But let us accept that the estimates Anderson provides are credible if NRT was available overthe-counter (OTC), so there are no professional consultation expenses to add to the costs. Would it be desirable to encourage it through government subsidy? The key questions we need to ask are: what is the most cost-effective and equitable range of strategies for a country? Only when this is answered do we ask the secondary question: where do pharmacological cessation aids fit?

At a time when the FCTC process is encouraging many governments to give serious consideration to tobacco control and where there is real impetus for integrated action, we need proposals that facilitate this balance, not proposals that favour one part at the expense of others.

In high-income countries pharmaceutical companies can take considerable credit for revitalizing interest in cessation. Pharmaceutical companies have come in and supported tobacco control efforts when other resources to do so have typically been pitifully small. For all of this, we should be grateful. However, as Anderson notes, a range of other tobacco control measures is far more costeffective. What he does not mention is that few if any of these measures are being adopted in many countries, especially those measures that involve up-front costs to government. In my view, efforts should be directed at supporting low-income countries to do more of the cheaper things before we turn our attention to more expensive (for them) parts of the overall solution.

What can we do for smokers? First we can encourage and motivate them to quit unaided; most smokers succeed that way even in countries where prevalence is low. Mass media campaigns can result in large numbers of smokers quitting at very low cost to society compared with what it would cost if all the reliance were on cessation aids. Effective use of mass media can be even more cost-effective, in countries where governments control the airwaves. Couple this with brief exhortations from health professionals, and with programmes that marginalize tobacco use socially, and you have an engine for change that has been shown to take tobacco control a long way.

Encouragement will not be enough for some smokers; they will need help if they are to quit successfully. Countries should encourage the establishment of cessation programmes and/or the availability of cessation aids. However, using precious government resources to subsidize them can only be justified when all more cost-effective options have already been adopted by governments. Anderson's proposal is putting the cart before the horse; resources need to be given to the horse first (the engine) or it will not be strong enough to pull the cart effectively.

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Conflict of interest

Ron Borland is a member of a Smoking Cessation Consortium supported by GSK. He is in receipt of untied educational grants from that consortium and has undertaken small consutancies for both GSK and Pharmacia related to promotion of smoking cessation.

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PUBLIC-PRIVATE PARTNERSHIPS: A SUCCESSFUL MODEL IN TOBACCO CONTROL

In this issue of *Addiction*, Anderson argues in favor of using partnerships between public health groups and organizations in the private sector as an 'important vehicle' to advance a variety of tobacco control initiatives (Anderson 2002). He points out several ways in which such partnerships can contribute to the goal of reduced tobacco consumption, including health communications, training, assisting in smoking cessation services and policy issues. In the United States, these models have been used successfully for some time.

Beginning in 1991, the National Cancer Institute's American stop smoking intervention study (ASSIST) was implemented as a prevention and tobacco use reduction strategy, using policy-based initiatives to influence both individual tobacco use and public health activity at the state level (Manley et al. 1997). Interventions in 17 states across the United States included the development of both state-wide and local coalitions that included state/local public health departments, the American Cancer Society state divisions and local units, and a variety of other private sector groups involved in tobacco control. The comprehensive tobacco control programs in ASSIST were the basis for the highly successful state initiatives in California, Massachusetts and elsewhere in the United States. The Centers for Disease Control and Prevention includes development of coalitions to support tobacco control policy initiatives among the essential elements of state-wide comprehensive tobacco control programs (Centers for Disease Control and Prevention 1999).

Private-sector organizations should assume a leadership role in forming these collaborations, and take on several different sets of duties and responsibilities in the process. First, the private sector can provide political support and encouragement for production of scientific reports, policy White Papers, and related activity that government agency administrators may find uncomfortable, try to delay, or even attempt to scuttle. Even when such reports are not politically sensitive, public–private collaboration can be very important, as in the development of evidence-based documents such as the clinical practice guideline, *Treating Tobacco Use and Dependence* (Fiore et al. 2000) or The Guide to Community Preventive Services: Tobacco Use Prevention and Control (Task Force on Community Preventive Services 2001), both of which emphasize the role of policy interventions in tobacco control.

Private sector groups should also hold governmental agencies accountable for using resources wisely and fulfilling their obligations to taxpayers. Critics of the California tobacco control program were responsible for obtaining full funding for the program, after administrators reduced the revenues going into the highly successful media campaign that had helped to reduce tobacco consumption in that state (Balbach & Glantz 1998). Current efforts across the United States are focusing on using appropriate amounts of the funds from the Master Settlement Agreement (obtained from settlement of lawsuits against the tobacco industry by State Attorneys General) for tobacco use prevention and control activities (Centers for Disease Control and Prevention 1999), given that the lion's share of these revenues are being diverted to non-health uses by state legislatures.

The coalitions funded by The Robert Wood Johnson Foundation Smokeless States National Tobacco Policy Initiative are prime examples of public-private partnership in tobacco control. The initiative, administered by the American Medical Association, began in 1993 and has grown to become the third largest national initiative in tobacco control in the United States, exceeded in scope only by the federal government and the American Legacy Foundation. With coalitions in 42 states and the District of Columbia, SmokeLess States projects primarily address policy initiatives in three key areas: increasing the price of tobacco products, clean indoor air (environmental tobacco smoke) regulations and increasing access to and reimbursement for tobacco use cessation. Typically, a state coalition is led by a voluntary health agency (American Cancer Society, American Heart Association, American Lung Association), state medical society or a non-profit agency, and has representation from a wide variety of groups from the private health. business, education and youth sectors. These coalitions work actively with state and local health departments to promote comprehensive tobacco control plan development and implementation, funding levels compatible with their success and governmental accountability. Using tools such as media advocacy (Wallack et al. 1993). convening partners for training and policy development and developing activist strategies to advance policy goals. the SmokeLess States coalitions have made a significant impact on the landscape of tobacco control in the United States (American Medical Association 2002).

In summary, it is clear that public-private collaboration in tobacco control is an effective tool that

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can play a significant role in tobacco control policy (Fichtenberg & Glantz 2000; Robins & Krakow 2000; Emmons *et al.* 1997). Using strategic analysis to develop comprehensive, coordinated plans, a network of organizations with clear organizational and managerial accountability and sufficient staff and resources to accomplish common goals (Edwards *et al.* 1999), these partnerships can engage the health community, the public and policy makers to make a difference in combating the global tobacco pandemic (Houston & Kaufman 2000).

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ROLES OF THE PRIVATE SECTOR IN TOBACCO CESSATION PROGRAMMES

Most successful endeavours are attributed to smart partnerships. So it is in the business of health, where intersectoral collaboration is likely to strike a win–win situation between the participating parties. In recent years, tobacco companies have manoeuvered to exploit this universally accepted principle by teaming up with unwary organizations to carry out health promotions for youths, but these activities are proven to be detrimental to successful tobacco control (Cancer Research Campaign and Action on Smoking and Health 2000).

None the less, unlike the tobacco industry whose goals are completely opposite to public health, functional relations between the health sector and pharmaceutical companies are quite different. Smoking cessation serves as an essential requisite for medium-term health gains for governments. According to the World Bank, even if the most effective measures to prevent smoking uptake are in place, tobacco deaths will still rise dramatically in the next 50 years, unless significant numbers of current smokers quit (World Bank 1999) now.

As custodian to the wellbeing of citizens, governments are required to implement various strategic components of comprehensive tobacco control in order to achieve the desired outcomes. However, scarcity of resources means that not all these components can be carried out efficiently. Health promotions reach only a limited segment of the population, while the messages on the benefits of quitting would very often be omitted, hence resulting in a situation where most addicted smokers are abandoned with no follow-through. Although tobacco cessation using NRT is confirmed to be cost-effective (Smeeth & Fowler 1999), developing countries—usually burdened with high smoking prevalence—are not able to provide this for the majority of potential quitters.

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Sharing the same aim of encouraging smokers to quit, the pharmaceutical sector can supplement and complement health authorities in several areas, namely public health education providing general information on the hazards of smoking, benefits and methods of quitting as well as availability of smoking cessation services. There is evidence that many smokers are not fully aware of the high probability of disease and premature death that their choice entails and that new recruits to smoking may seriously underestimate the future cost associated with addiction to nicotine (Ayanian & Cleary 1999; Strecher, Kreuter & Kobrin 1995). In many countries, health promotions have to compete with the more sophisticated marketing techniques of the tobacco industry. Hence simply improved, standardized and repetitive health messages covering general and targeted populations will alert the masses about the truth of tobacco consumption.

A number of health-care providers in developing countries are not familiar with quit-smoking procedures and NRT; therefore, acquiring these skills through continuous medical education and training programmes conducted jointly by public and private health partners would be necessary. All members of the medical fraternity should recognize the smoking problem within their community and establish basic interventions to deal with it. This task would be too demanding if it were left solely to the government to deal with.

Addiction has resulted in chronic smokers having to face high costs if they want to reverse their decision to smoke. Rightfully, the tobacco industry must accept accountability and compensate smokers who wish to quit, but very few such mechanisms exist in most countries. Thus, under present circumstances, public health will certainly profit greatly from subsidies provided by the pharmaceutical companies in making NRT more widely accessible.

Undoubtedly, interested private companies can gain lucrative shares from this affiliation, while governments enjoy cost savings in national tobacco control efforts of structured communication and delivery of interventional services. The issue that arises is how this promising partnership can be carried out in the most transparent manner within the confines of highly regulated industry such as the pharmaceutical sector.

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MOBILIZING CAPITALISM FOR THE PUBLIC GOOD: A REPLY TO THE COMMENTARIES

I am very grateful to the commentators for their important and perceptive replies. Zarihah Zain (2002) points out the difficulty of low- and middle-income countries providing cessation advice with NRT for the majority of potential quitters. Michael Cummings (2002) argues the need for broader partnerships, including manufacturers of smokeless tobacco products to compete for market share with cigarette manufacturers. Ron Borland (2002) argues that efforts should be directed at supporting low income countries to do more of the cheaper things before we turn attention to more expensive parts of the overall solution; and Tom Houston (2002) describes some of the US experience in broader public private collaboration for tobacco control policy.

I will reply to each of these points in turn. My motive for writing the paper for debate was the special theme issue on public-private partnerships for drugs and vaccines of the *Bulletin of the World Health Organization* (see Feachem 2001) and my experience with the European partnership to reduce tobacco dependence of the World Health Organization (World Health Organization 2002). I believe that many of the principles for delivering drugs and vaccines for communicable diseases also apply for delivering treatments for tobacco dependence, the world's number one killer that is globally a disease of lowand middle-income countries.

To answer Zain's point, we need much more research on the cost-effectiveness of treatments for tobacco dependence in low- and middle-income countries, how these compare with treatments for other diseases, the burden of diseases that such treatments could prevent and how to transfer appropriately the technology of the treatment of tobacco dependence from high-income to low- and middle-income countries.

Cummings is right. Worldwide, the total NRT market is only 0.2% of the cigarette market (Novotny *et al.* 2000). So, there is a long way to go (and in Cummings' terms can capitalism advance the goals of tobacco control—the

1.1.1.1

opportunities for huge profits) to compete for market share for safer products. As Cummings argues, we need to broaden the opportunities for the development and consumption of safer products. The difficulty is that we still have a long way to go in reaching public health agreement on harm reduction, although good starts have been made (see Stratton et al. 2001), and public health is still reeling from the fiasco of the health impact of so-called light and ultra-light cigarettes (see Shopland 2001). Public health would need to find ways to break up the tobacco companies' oligopoly, where in any one country only two or three companies dominate sales. This would facilitate competition within the nicotine market to produce safer products. If agreement could ever be reached on what constitutes safer products, lower taxes could be introduced as defined by the content of specified constituents. A differential taxation for cigarettes, such as carbon taxes, could be used to promote safer products. A common regulatory authority that deals with all nicotine-containing products could classify all such products on the bases of their harm and dependence, and introduce price, advertising and availability policies that favour the least harmful nicotine deliverv systems.

Borland is right in that the focus should be on implementing the framework convention on tobacco control as an effective global tool. However, treatment of tobacco dependence is likely to be part of the convention and should not be neglected. Borland is also right in arguing for the implementation of the most cost-effective programmes for smoking cessation. However, we should also not discriminate against the smoker in low- and middle-income countries who should benefit from the best available treatment. It comes back to better understanding of the transfer of appropriate technology from high- to low- and middle-income countries and how to fund this. One way is through partnerships, with the private sector bearing some of the costs; another way is through hypothecation of taxes, with a proportion of tobacco tax from high-income countries being available to support cessation services (and other aspects of tobacco control) in low- and middle-income countries.

Finally, Houston's commentary brings forward the idea that we need to share and pool the world-wide experience of public sector/private sector initiatives in tobacco control to learn what works and what does not and, as Cummings points out, how best to mobilize capitalism for the public good in reducing the global burden of disease caused by tobacco.

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Attachment B

Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products

K. Michael Cummings, PhD, MPH, Gary A. Giovino, PhD, Maansi A. Bansal, Andrew Hyland, PhD, Jan Hastrup, PhD, Berwood Yost

National Conference on Tobacco or Health New Orleans, Louisiana November 2001

Address correspondence to: K. Michael Cummings Roswell Park Cancer Institute Department of Cancer Prevention, Epidemiology, and Biostatistics Elm and Carlton Streets Buffalo, NY 14263 michael.cummings@roswellpark.org

Methods – Beliefs About Nicotine Delivery Devices (BAND)

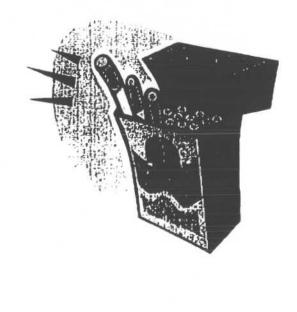
- Nationally representative sample of 1,046 current adult smokers (≥18 years of age)
- 25-minute telephone survey
- Random digit dial



- Time period: May—September, 2001
- Response Rate: 77%
 - Calculated using Advertising Research Foundation guidelines, through Council for Marketing and Opinion Research

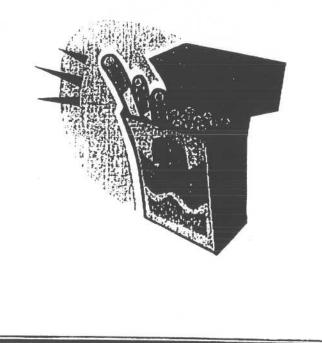
Misinformation of Smokers

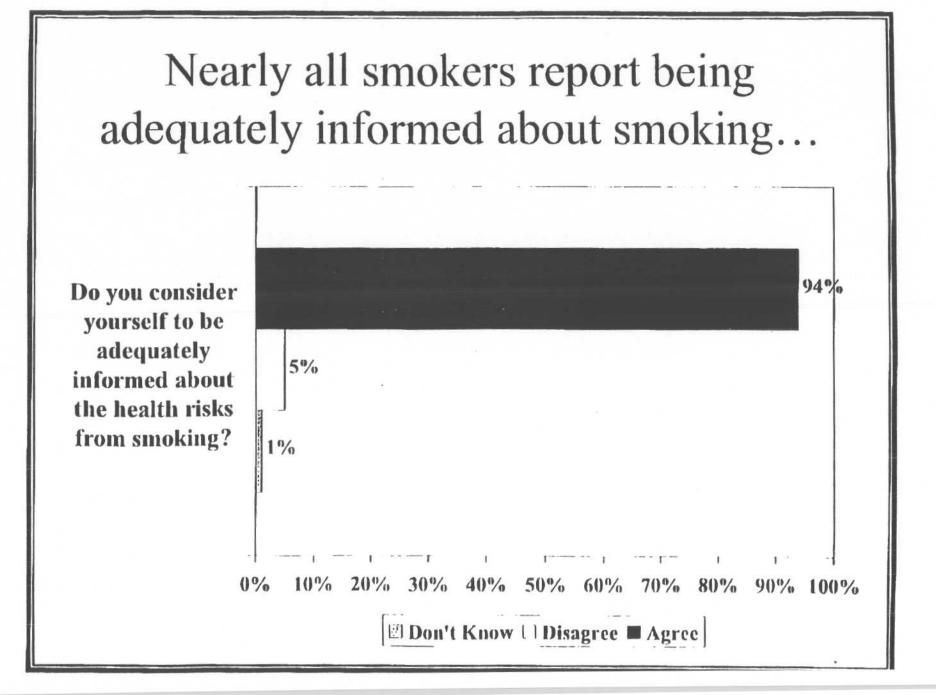
- Survey questions included items on...
 - Health risks
 - Ingredients
 - Cessation
 - Desire for additional information

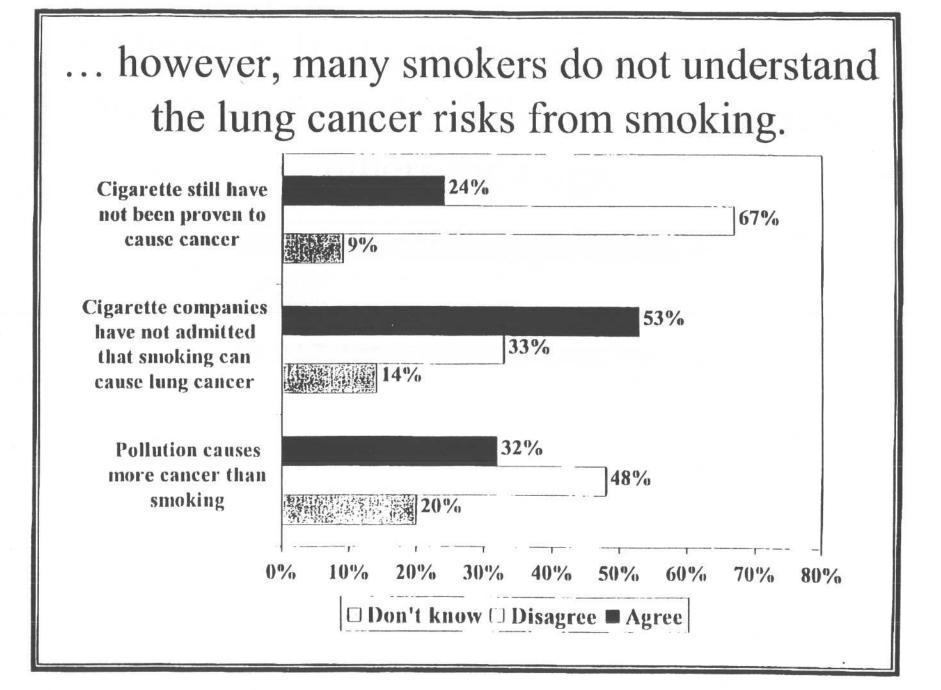


Misinformation of Smokers

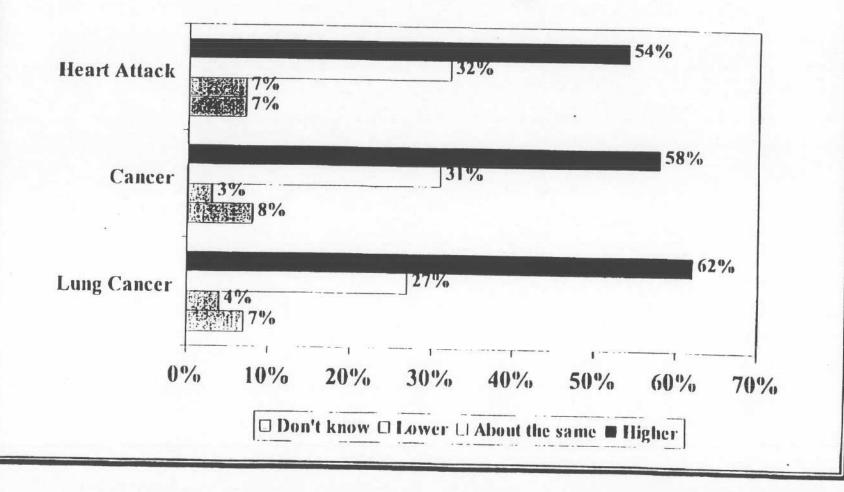
• Health risks







Almost half of smokers believe they are not at greater risk of disease compared to others their age.



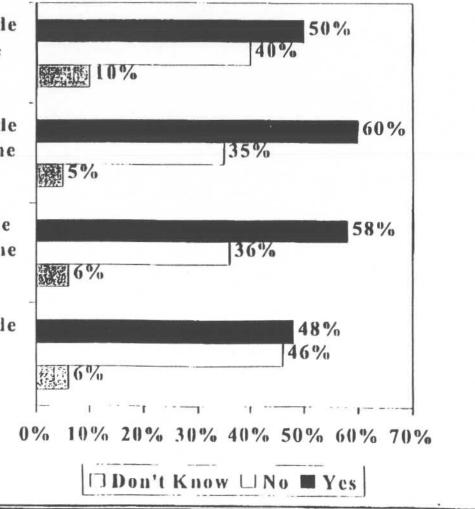
Over half of smokers believe past technologic changes to cigarettes have made them safer.

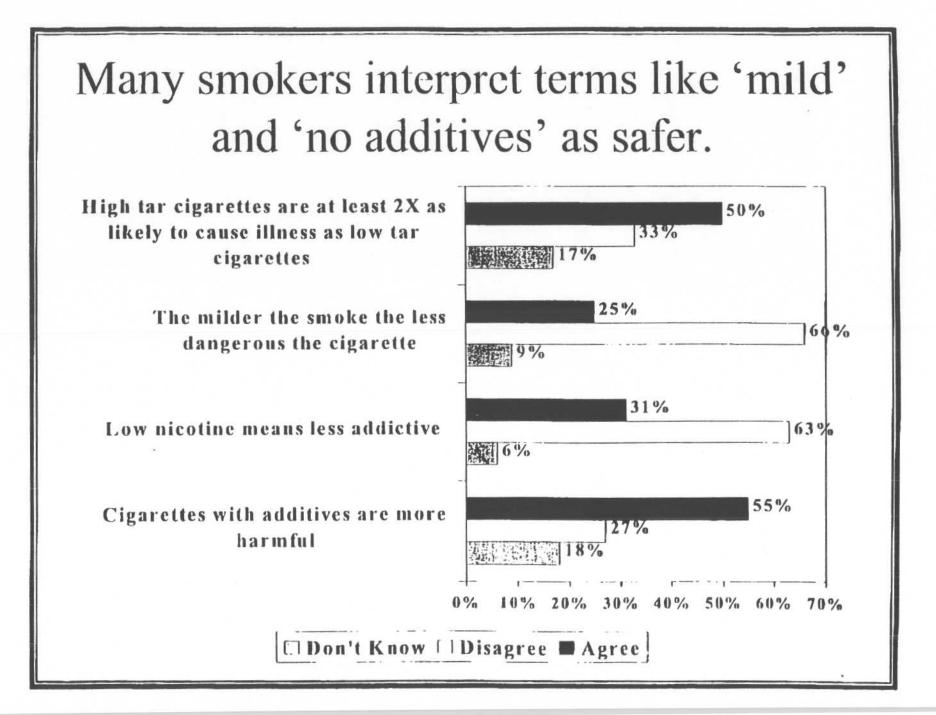
Has the removal of additives made cigarettes less dangerous to the smoker?

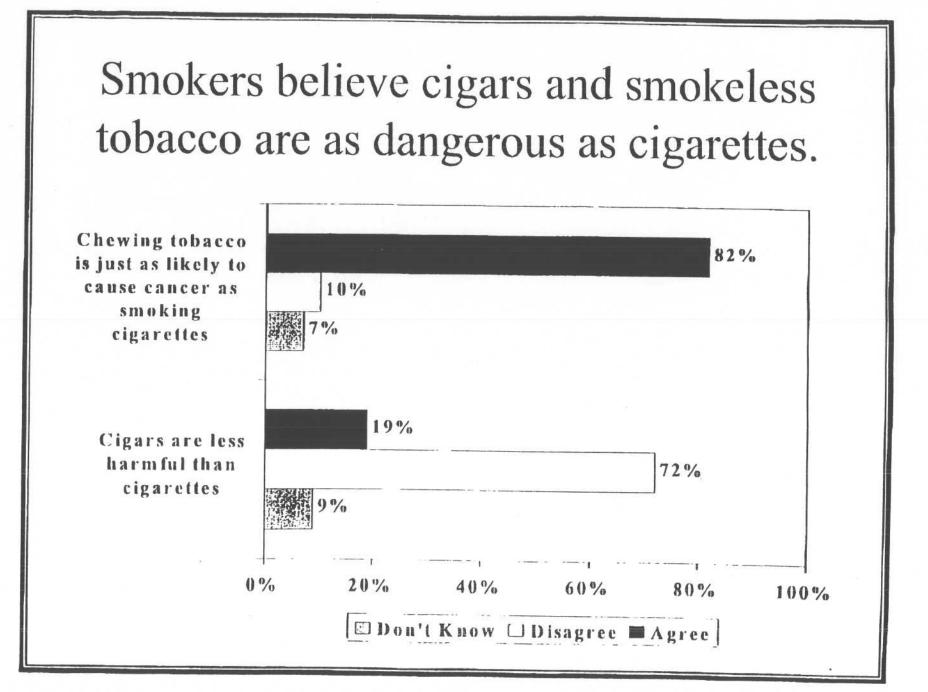
Has the addition of filters made cigarettes less dangerous to the smoker?

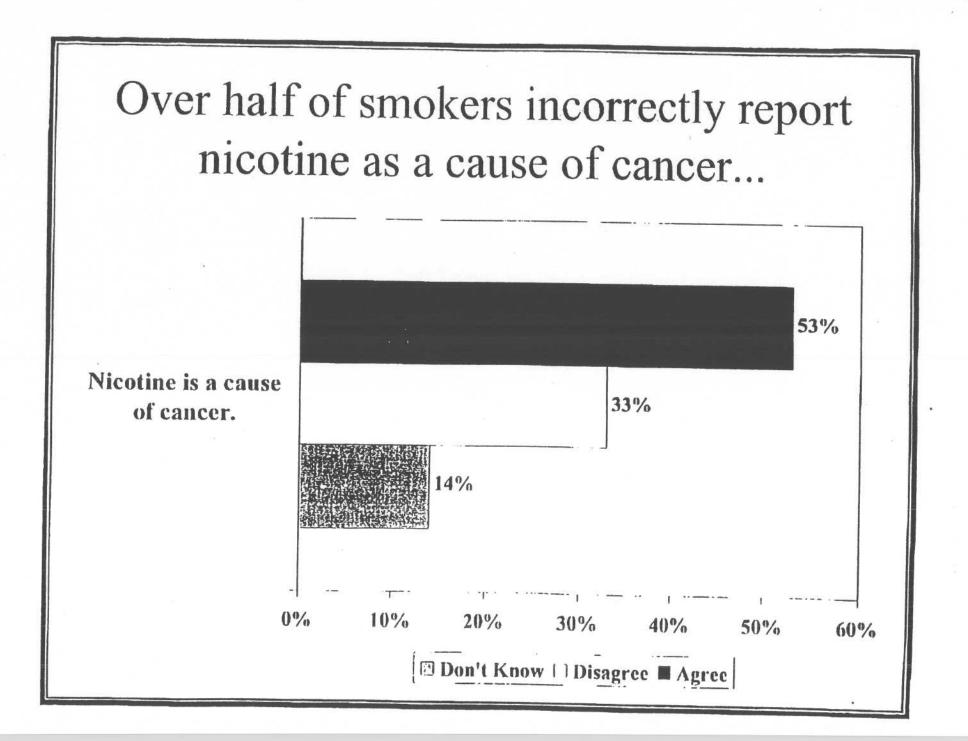
Il as the reduction of tar made cigarettes less dangerous to the smoker?

Uas the reduction of nicotine made cigarettes less dangerous to the smoker?





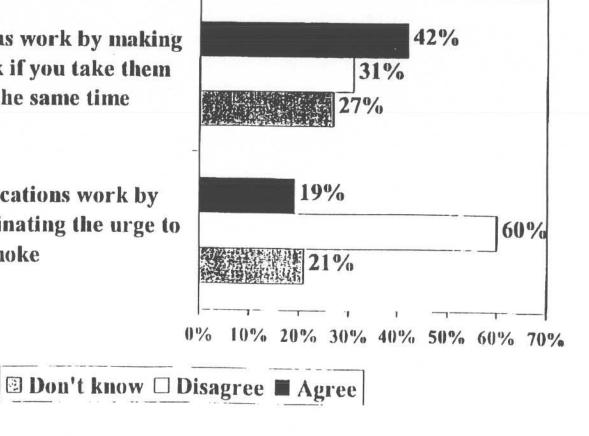




... and many smokers don't understand how NRT works.

Nicotine medications work by making you physically sick if you take them and smoke at the same time

Nicotine medications work by completely eliminating the urge to smoke



Few had heard of new products like Accord and Eclipse, but half were interested in trying them.

