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Smoking and Health Promotion: Policies and Programs in Large Companies 1996

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Table of Contents

Introduction	1
Prevalence of Worksite Policies	2
How Does this Research Fill Gaps in Current Knowledge?	2
Methods	4
Study Instrument	4
Variables of Interest	4
Significant Findings	6
Background	6
I. Current Smoking Policy	11
II. Smoking Cessation Programs	14
III. Smoking Cessation Products	18
IV. Future Smoking Cessation Plans	21
V. Health Promotion/Disease Prevention Programs	24
Conclusions	27
The Sample	27
Smoking Policies	27
Smoking Cessation Programs	27
Smoking Cessation Products	28
Health Promotion/Disease Prevention Programs	28
References Cited	29
Appendix A. Study Limitations	A1

Introduction

Three decades of research have produced a staggering amount of evidence linking cigarette smoking to a vast array of negative health effects. Use of and exposure to tobacco cigarettes has been positively associated with a variety of diagnoses including respiratory ailments, cardiovascular complications, and, for pregnant women, fetal birth defects. To complement the increase in scientific evidence, community-based anti-smoking campaigns have been conducted in settings such as schools and places of worship by health advocacy organizations. Early efforts, often presented to the public as "Smoke-Outs," encouraged smokers to abstain from smoking during a designated period with the expectation that, at the close of the Smoke-Out, the abstinence would continue. Unfortunately, the relapse rates were high, as smokers had few ways to address their physiological dependence on nicotine. Moreover, with a high cultural emphasis on personal freedoms, smoking, however detrimental to the smoker's health, was viewed as a matter of individual choice more than as a public health issue.

As scientists began to examine the effects of exposure to secondhand smoke, however, evidence mounted that smoking was not simply a matter of personal choice. Increasingly, it became apparent that smokers could negatively affect the health of those around them by emitting secondhand smoke into the indoor environment. Two scenarios for exposure to secondhand smoke drew particularly sympathetic audiences: non-smoking children exposed to their parents' smoking, and non-smoking employees exposed to their co-workers' smoking. Shouldn't non-smokers have the right to limit smokers' behavior if that behavior negatively impacted the non-smokers' health? The perception of lack of control over these adverse health exposures helped catapult cigarette smoking into a major issue affecting public health.

As of June 1995, 47 states restricted smoking at some level in workplaces and/or public places, and 21 states regulated smoking in private worksites (USDHHS, 1995, pp. 3-6). The 1992 Survey of Worksite Health Promotion Activities indicated that 86% of worksites with 50 or more employees had a formal smoking policy that prohibits or severely restricts smoking. Of these, 34% had a policy that no smoking was allowed anywhere indoors, 25% permitted smoking only in separately ventilated smoking rooms, and 28% permitted smoking only in designated smoking areas (p. 71).

The two primary goals of developing and implementing restrictive smoking policies are to protect nonsmokers from exposure to environmental tobacco smoke and to encourage current smokers to consider quitting smoking. With proper implementation, the first goal is almost universally achieved, but the second appears to be more complicated and less straightforward. Studies have shown mixed results for increasing cessation rates via implementation of restrictive smoking policies. It is believed that while smokefree policies may cause smokers to reduce the number of cigarettes they smoke per day, there does not appear to be a consistent result demonstrating increased cessation. It is generally accepted within the corporate community that some measure of support for employees who smoke should accompany a transition from a less restrictive to a more restrictive smoking policy, primarily for human resources and employee relations purposes.

Following this principle usually leads employers to provide smoking cessation as a one-time or limited-time offering to support employees who smoke as the places where they can smoke become more restricted. A limited-time offer of cessation support does not mesh with the evidence that smokers often attempt to quit repeatedly before they are successful and therefore is not intended to maximize cessation but to demonstrate to employees who smoke that the company is willing to help them with the change.

Consequently, smoking policies and cessation programs are frequently intertwined, and cessation product and program marketers have significant interest in knowing the prevalence of certain types of smoking policies and the intentions of employers to change the policies.

Prevalence of Worksite Policies

Reduction of tobacco use within the worksite is a component of a targeted priority area of the U.S. Department of Health and Human Services' *Healthy People 2000* goals (*Healthy People 2000 Review, 1992*, pp. 260-264). For medium and large companies, the stated goal is to increase to at least 75% (from 54% at 1987 baseline) the proportion of worksites with a formal smoking policy that prohibits or severely restricts smoking in the workplace (Priority Area 3, Section 3.11). According to the *1992 Review*, this goal had been achieved by 1991, with 85% of medium and large worksites prohibiting or severely restricting smoking.

The 1992 Survey of Worksite Health Promotion Activities indicates that 88.5% of private worksites with 100-249 employees have a restrictive smoking policy (meaning no smoking within facilities except for separately-ventilated designated smoking areas); for companies with 250-749 employees, 93.4% have a restrictive policy, and 97.2% of companies with 750 or more employees have a restrictive policy (pp. 71-75).

How Does this Research Fill Gaps in Current Knowledge?

We have found research demonstrating the effectiveness of worksite smoking restrictions on employees' smoking cessation, and there is some information on how common smoking restrictions are within the worksites of U.S. companies, the relative restrictiveness of smoking policies, and the extent to which employers experience problems with their existing smoking policy. There is also little information on how highly employers prioritize smoking cessation programs in particular and health promotion/disease prevention issues in general. Related questions include the effects of company size and percent of employees covered through managed care on smoking policy and procedures. The published information does not probe in detail about the decision-making processes for smoking policies and smoking cessation programs. Our research, will not generalizable, does provide more specific information on the barriers and drivers influencing corporate decision-makers facing decisions on these issues. This information should prove most directly useful to marketers

with products and programs targeted to assist corporations, but can also assist other corporations to assess their current situations and develop strategies based on the experiences of others.

Our data are intended to be a first step in gathering more information about these issues. While collected at a single point in time, our data can provide a picture of current practices within our sample, thereby suggesting possible themes running through large corporations. This information provides useful guidance for program planners and product marketers in assessing this market in general, its potential, and its barriers. We hope that our data provide a basis for developing and testing future hypotheses about workplace characteristics and their relationship to implementing smoking cessation and other health promotion programs.

Also, large companies are frequently perceived as pioneers and trendsetters and their actions carry more significance than just influence over their employees. Even though our sample only employed about 2.4 million workers, these companies are followed as bellwethers by other large companies and smaller firms.

Methods

We used a study design examining groups -- in this case, corporations -- at a fixed point in time. The sample included the Fortune 100, as well as a randomly selected portion of the remaining 900 in the Fortune 1000 taken from the 1995 Fortune 1000 listing. During the calling period, 462 organizations were contacted by telephone. Appropriate contact persons at each company were identified, and written material providing more detail about the scope of survey questions was provided upon request. The sole incentive offered to prospective participants was a complimentary copy of the survey report. Those who agreed to participate were counted as respondents. The response rate was 141/462, or 31% of those contacted. Our final sample size (N) was 141.

Study Instrument

Our study instrument was a questionnaire administered via telephone interview. Trained interviewers began calling on December 6, 1995, with outgoing calls continuing through March 31, 1996. Potential respondents were contacted three times before being categorized as non-responsive. Organizations with whom we established first contact toward the end of the data collection period may have been contacted only once or twice. Surveys were administered and found to last approximately 20 minutes under normal conditions (that is, with a single respondent and with no interruptions).

Variables of Interest

The following is a listing of our significant dependent variables:

1. Company's current smoking policy
2. Applicability of policy to all sites
3. Main issues/problems associated with smoking policy
4. Plans to change current policy
5. How high a priority are smoking cessation programs
6. Ability to identify all smoking employees
7. To what kinds of programs for smoking cessation do employees have access
8. Does company keep utilization data for smoking cessation program use
9. Percentage of total cost of program the employee pays
10. Concerns/barriers to providing a smoking cessation program
11. Access to coverage for nicotine replacement therapy (transdermal or gum)
12. How is coverage provided
13. What portion of NRT does employee pay

14. Do employees get reimbursed for cost of NRT products as opposed to getting them covered as a standard benefit
15. Which is most important expectation of NRT product
16. Company's plans to change how employees receive smoking cessation products or services
17. What price would be acceptable for an ideal smoking cessation program
18. Reaction to FDA's potential approval of over-the-counter availability of nicotine replacement therapy
19. Awareness of upcoming U.S. Agency for Health Care Policy and Research guideline on smoking cessation
20. Expectations that a smoking cessation provider will follow the AHCPR guideline
21. Access to a formal health promotion/disease prevention program
22. Most important goal for this program

The following is a listing of our independent variables:

1. Number of company locations (less than 10, 11-100, 101-1000, 1001 or more)
2. Type of administration (centralized or decentralized)
3. Company's size category (less than 8,500 employees, more than 8,501 employees)
4. Percent of employees insured under managed care (less than 25%, 25.1-50%, 50.1-75%, over 75%)

The raw data were entered into the statistical package Epi Info Version 6, and verified for accuracy. We then used the Analysis portion of Epi Info to generate descriptive information about our sample. In particular, we calculated frequencies and generated tables on selected independent variable-dependent variable combinations to examine possible associations.

Significant Findings

This portion of the report presents a section-by-section review of the significant and meaningful responses. Percentages are based on the entire sample of 141 respondents except where noted, and percentages may not add up to 100 because of rounding or because of the possibility of multiple responses. Also, the N values (N=...) for questions may vary slightly because "did not know" responses were not included in the denominator for the percentages. When "did not know" was a significant category, it is mentioned and discussed. See the Tabulated Questionnaire (Appendix B) for details.

Background

Following are figures providing basic background information of our sample, displaying categories for numbers of locations (Figure 1), type of administration (Figure 2), and percentage of employees receiving their health benefit through some form of managed care (Figure 3). It is not surprising that a majority of our sample had over 10 locations in the U.S. (82.6%, N=138), and the average number of full-time employees is over 17,000. We used the median of 8,500 to split the sample by number of employees to perform cross tabulations. The sample also split fairly equally (46.4% v. 45%, N=140) regarding the centralization of administration of their various sites.

Our sample follows the trend toward increasing utilization of managed care for health benefits: Almost 70% of the sample (N=125) had over 50% of their employees enrolled in some form of managed care.

In only 15 cases were the interviewers required to contact a second individual to complete the interview. One of the following graphs (Figure 4), illustrates the departments of the primary contacts. The majority (61.5%, N=140) were from the Benefits and Human Resources departments of their corporations.

Figure 1

Number of Company Locations throughout the U.S.

N=138

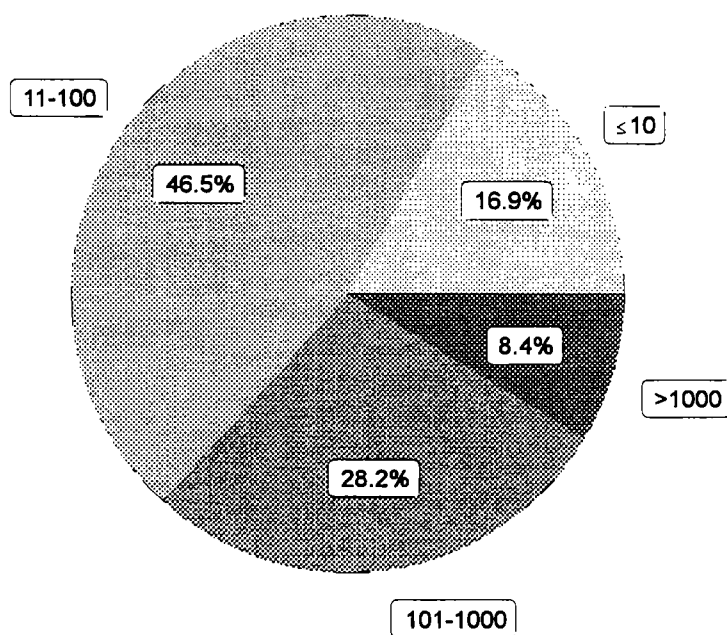


Figure 2

Company administration is...

N=140

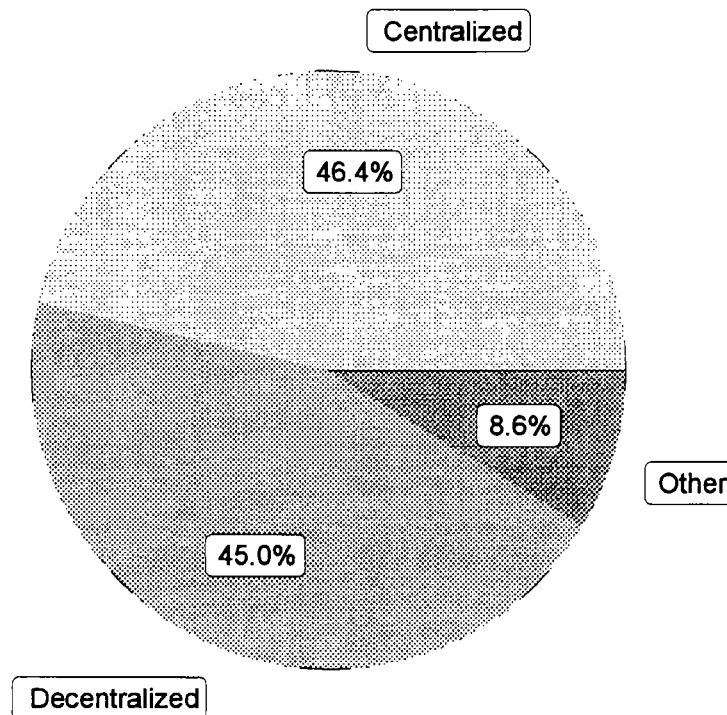
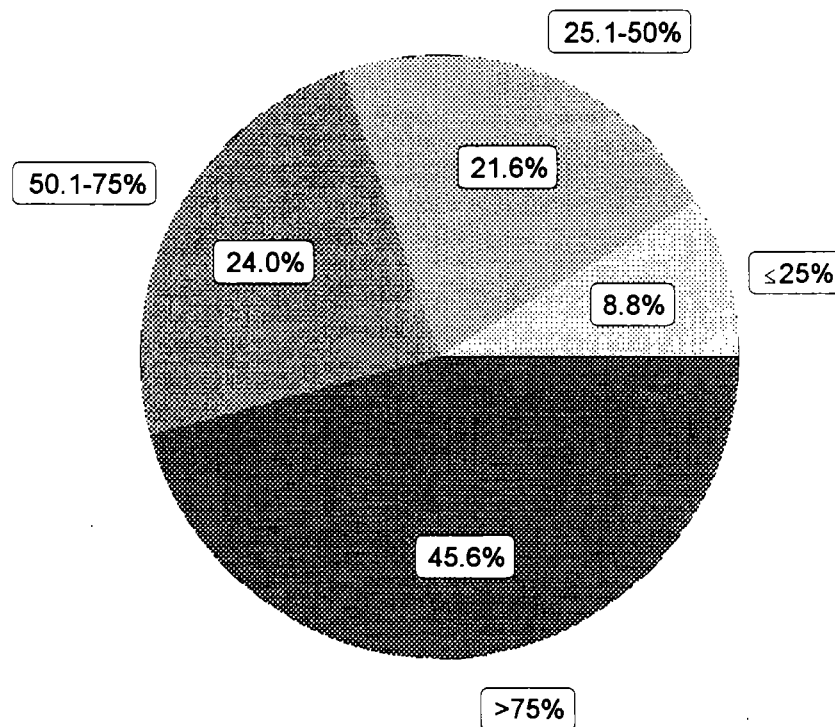


Figure 3

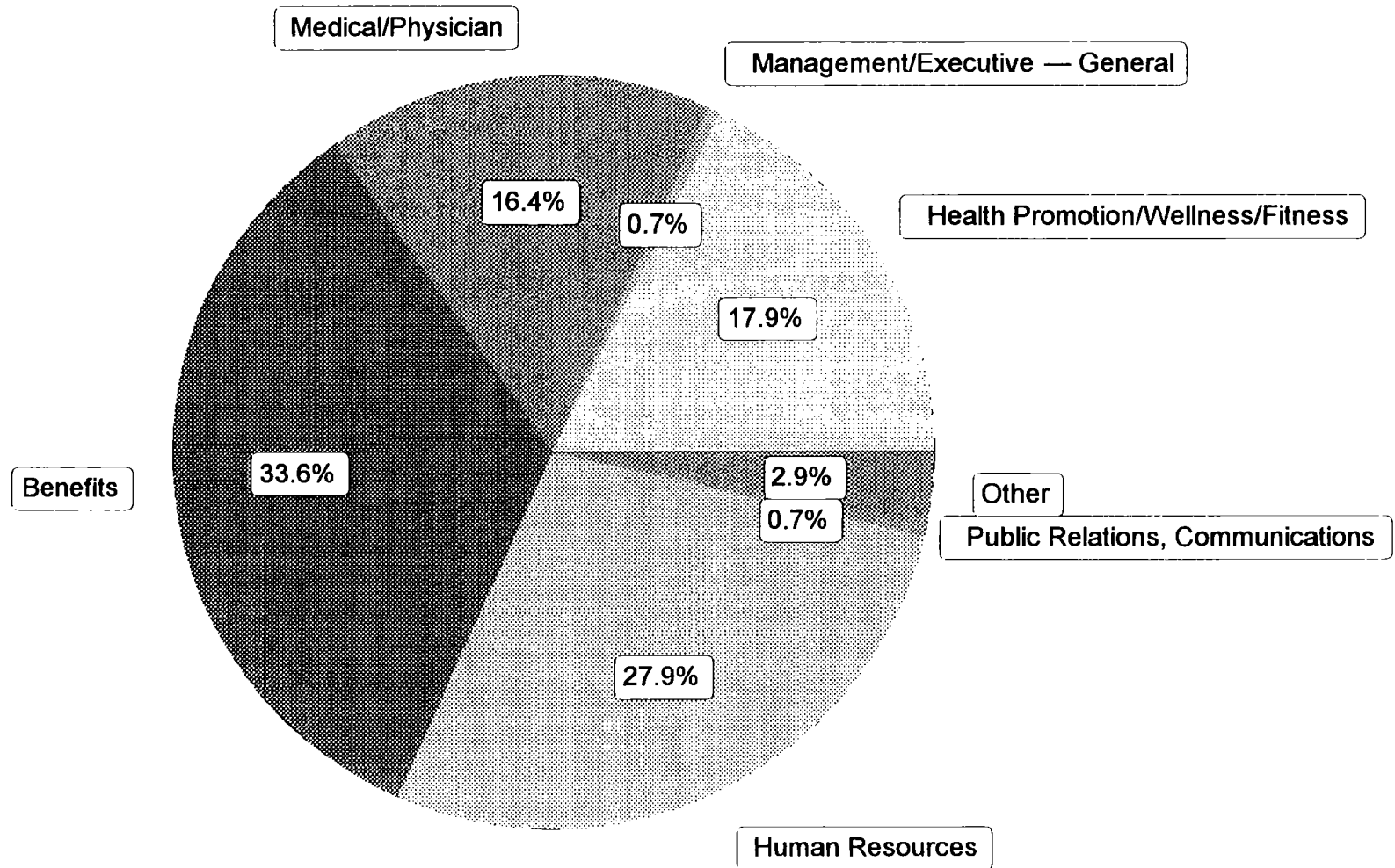
Percentage of Employees Covered through Managed Care (N=125)



Department of Primary Contact

N=140

Figure 4



I. Current Smoking Policy

Almost 60% of respondents reported that they allowed no smoking in company buildings, and an additional 12.8% extended their smokefree policy to include company property as well. Twelve percent permitted smoking only in separately-ventilated designated smoking areas. Less than 3% had no policy in place. The primary significance of these numbers is that almost 85% of respondents reported work environments where their employees are protected from environmental tobacco smoke. These numbers correspond reasonably well when compared with the 1992 National Survey of Worksite Health Promotion Activities results for companies with more than 750 employees (74.5% v. 85%). Figure 5 displays these results.

A concern arises from the result that these policies apply to *all* company sites in only 60% of our sample. In the other 40%, the policy either applied only to corporate headquarters (43.6%, N=55), or individual sites or operating units determined their smoking policies independently (40%). Based on unsolicited remarks from respondents, it is possible that the policies are more widespread. Because of the decentralized administration of the sites, however, there is no system to collect information from other sites. In fact, there is a strong association between the type of corporate administration and the universal application of a smoking policy. Forty-eight of 64 corporations with centralized administrations applied smoking policies to all company sites, while only 29 of 63 decentralized administrations did (See Figure 6).

Figure 5

Current Smoking Policy

N=141

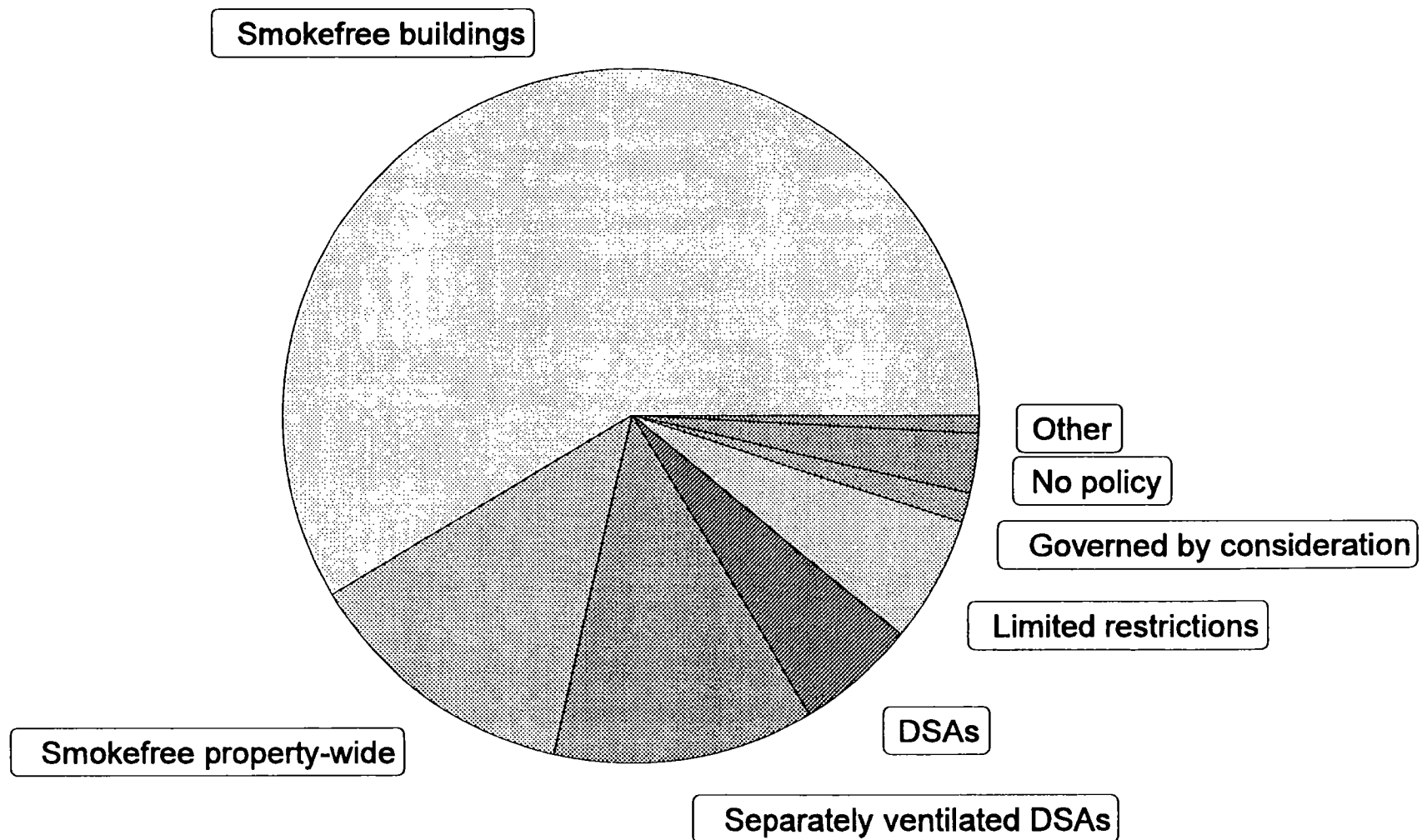
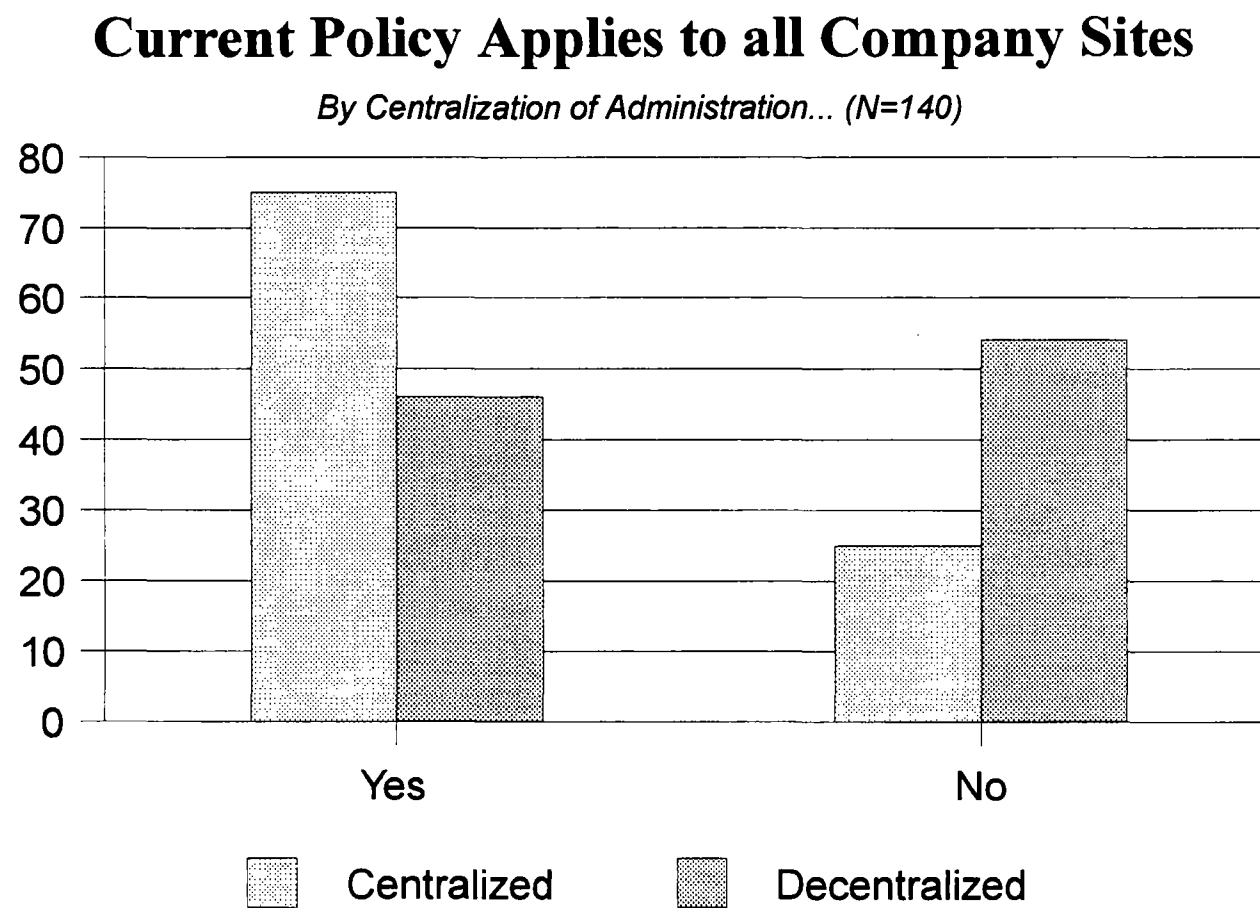


Figure 6



A majority (66.4%, N=140) of the sample reported no major problems with their smoking policy. When respondents did claim problems, the most common were employee complaints (13.6%), usually from smokers, abuse of break time (12.9%), and compliance with the policy (10.7%). Respondents also indicated a general satisfaction with their policies: less than 10% plan to change their current policy.

II. Smoking Cessation Programs

In comparison to the other issues the respondents face, providing smoking cessation to their employees is generally a fairly low priority: Less than a quarter (23.9%, N=138) asserted that it is a high priority, and over half (53.7%) stated that providing smoking cessation had either low or no priority. From this, it is not surprising that only 13.5% of respondents had a system in place to track all employees by smoking status, usually either through mandatory health risk assessments or through differential insurance premiums. Of the remaining 86.5%, the overwhelming majority (84.1%, N=113) do not expect to be able to track smokers in the future. These data parallel results from a study conducted by Pinney Associates (formerly Corporate Health Policies Group) last year on large HMOs where only about 17% of HMOs were able to identify the smokers within their enrolled populations (CHPG, 1992, p. 8)

Figure 7 displays the types of smoking cessation options our respondents make available to their employees. The most common offering, provided by almost a third of respondents (32.9%, N=140), is fairly comprehensive and includes written material, group behavior modification therapy, and some type of coverage for nicotine replacement therapy. However, the second most common response (28.6%) was no program or products.

Companies used various methods to provide access to smoking cessation to their employees who smoke, although the majority rely on external entities to deliver smoking cessation. Only 11.5% of the companies that provide some program or service (N=96) use their own staff exclusively, while just about 60% rely on their HMOs or wellness or smoking cessation vendors to deliver the programs. About one quarter draw on at least two of these resources. See Figure 8 for details.

The national health voluntaries, the American Lung Association, the American Cancer Society, and the American Heart Association, were the most commonly chosen vendors for smoking cessation materials and programs.

Figure 7

Kinds of Programs to which Employees Have Access

N=140

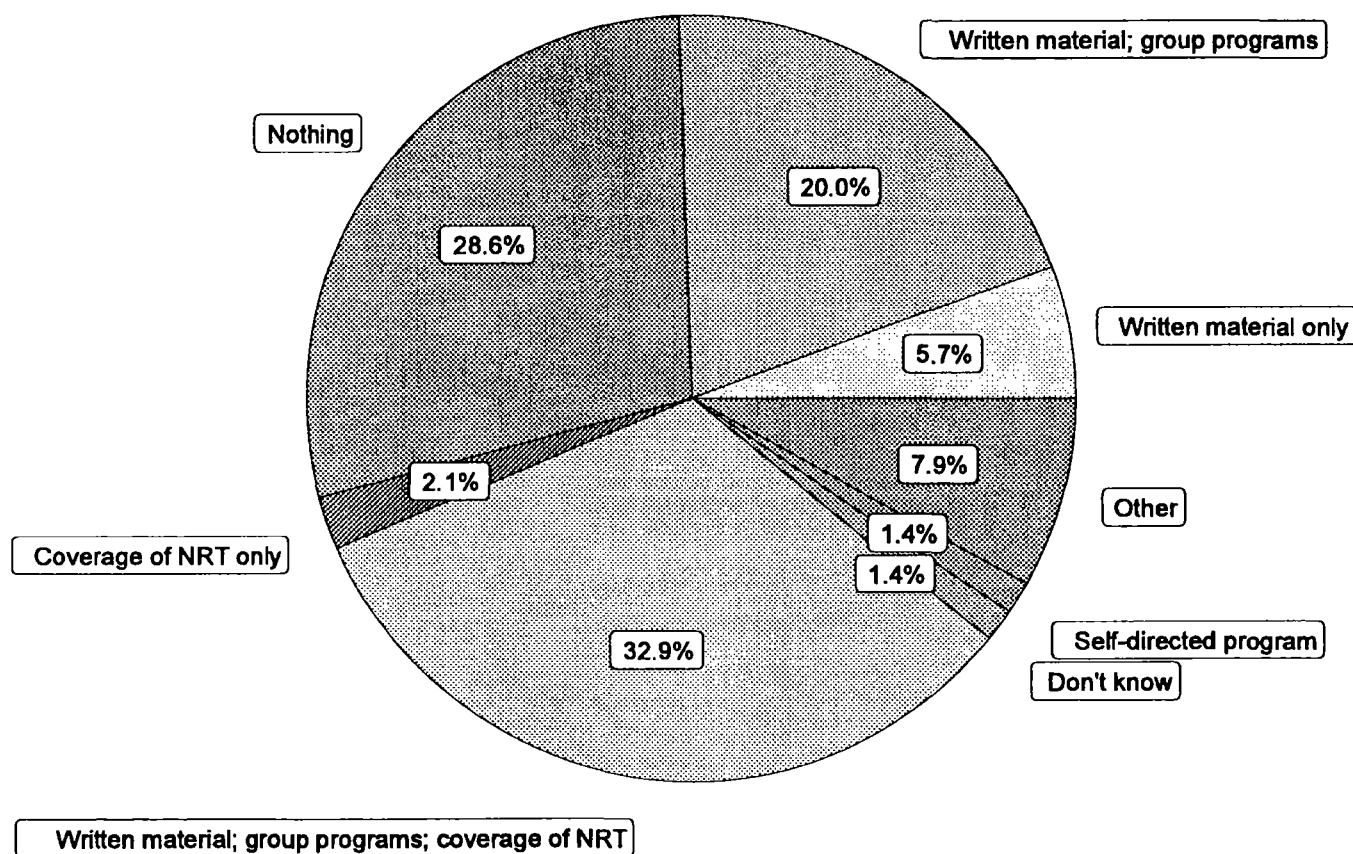


Figure 8

Programs provided by...

N=96

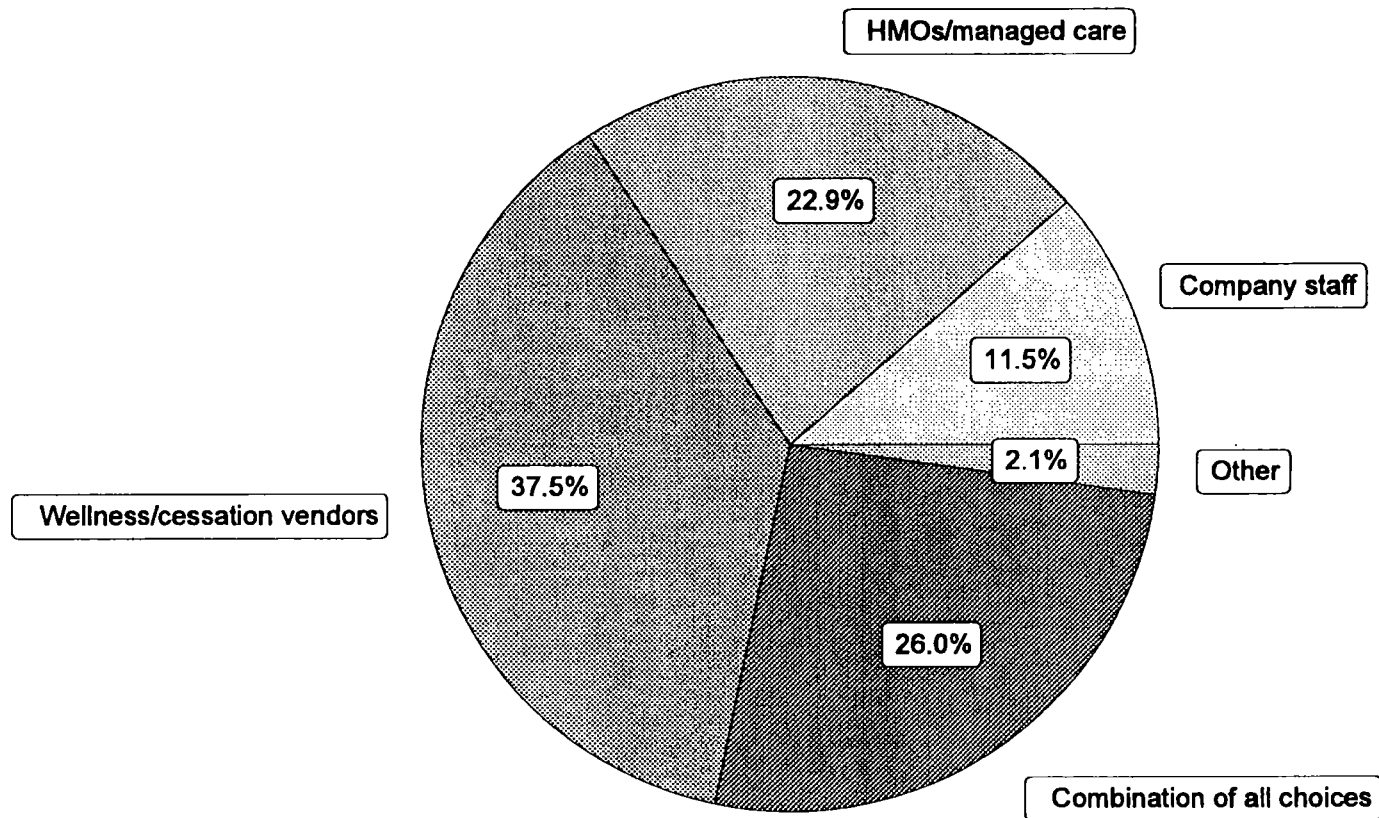
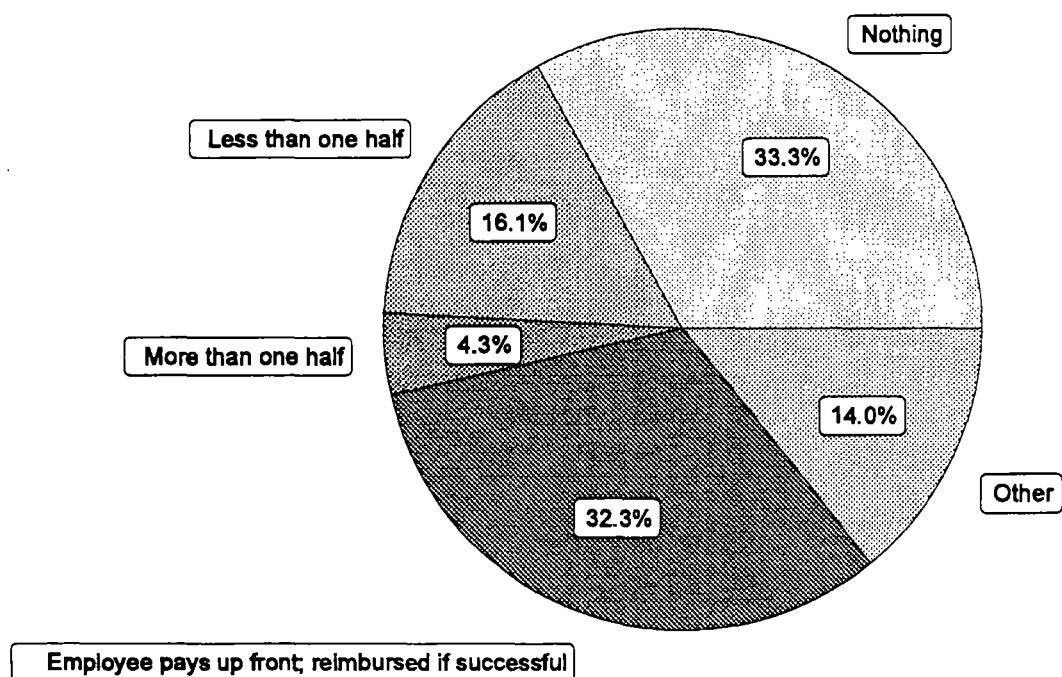


Figure 9

Employee's Percentage of Total Cost

N=93



Less than 40% (38.5%, N=96) of companies offering smoking cessation have any utilization data from the programs, and of those that do, the most common is merely the number of participants in the program (86.5%, N=37). Less than a third are able to report a quit rate at the completion of the program.

For the financing of the programs, the majority involve at least some contribution from the company. As Figure 9 shows, in a third of cases, the program is offered free of charge. In almost another third, the employee must pay the upfront cost but will be reimbursed at a later date. While this appears to be a covered benefit, having to finance the upfront cost can constitute a significant barrier to access.

Respondents were then asked, regardless of whether they provided access to smoking cessation programs to their employees, whether they had any significant barriers or concerns about providing smoking cessation. A few corporations did not have an answer to this question, but 44.7% pointed to low participation and a lack of employee interest and its consequences as major concerns. Unsolicited remarks from respondents suggested that they believe that their remaining smokers constitute the “hard-core,” truly addicted smokers who are not interested in quitting. Over 20% of respondents, however, proclaimed that they had no major concerns or barriers to providing smoking cessation. Another 17.4% suggested that cost was a problem with cessation programs.

III. Smoking Cessation Products

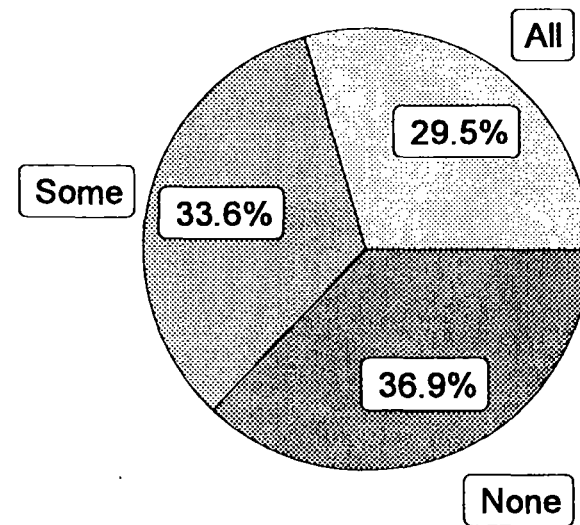
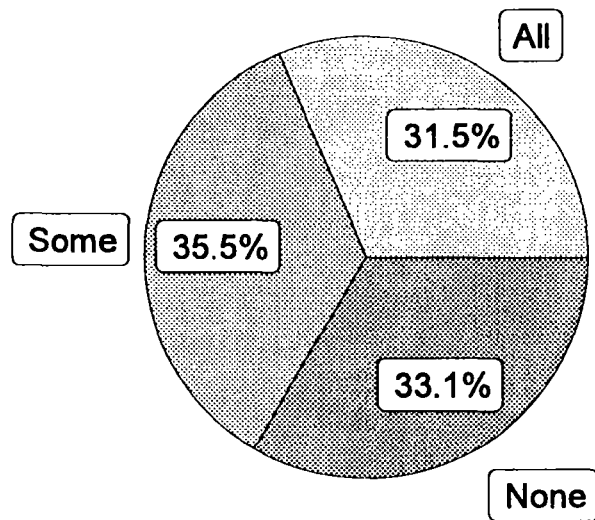
Respondents were then probed on the availability of some type of coverage for nicotine replacement products. As Figures 10 and 11 display, coverage for both the transdermal nicotine patches and the nicotine gum was split approximately into thirds, with about one third of respondents’ providing coverage for all of their employees, another third covering some of their employees, and another third not providing any coverage for these products. It is noteworthy that about 15% of the sample did not know what the coverage availability for nicotine replacement products was. For participants whose companies provided coverage to some of the employees, about a third did not know what percentage of their employees had access to some measure of coverage. It is important to keep in mind that, at the time of the interviews, both nicotine replacement therapies were available only by prescription.

Figure 10 and Figure 11

Number of Employees with Access to Coverage of...

nicotine patch (N=124)

nicotine gum (N=122)



In the overwhelming majority of cases where at least some of the employees had coverage (82.6%, N=86), the products were covered through the health plan(s) offered to the employees. In only 10.5% of the companies did the employer cover the product directly outside of the health plan. In 7% of the corporations there were different arrangements such as a cash wellness benefit that could be used to purchase these products. With the use of a prescription plan for providing coverage, it is not surprising that 72.3% (N=83) of respondents require a standard copayment to receive coverage for the product.

The following table provides results on the decision criteria that went into coverage decisions.

Table 1
Decision Criteria for Selecting Product(s)
N=69

Decision Criteria	%
Up to health providers/HMOs	59.4
Employee request/input	20.3
Cost	10.1
Efficacy	7.3
Other	18.8

Answers to this question suggest that our sample is not very engaged in decisions relating to smoking cessation.

Our sample reported that in the majority of cases where products are covered, (69%, N=87), employees received nicotine replacement products without having to pay for them upfront and then were reimbursed later on. However, the remaining 31% employed stern conditions for reimbursement. Fifty-four percent of these required the completion of a pre-approved smoking cessation behavioral program, and over 10% demanded maintenance of cessation from between three to 12 months (N=27).

The responses to questions on expectations of nicotine replacement products are very interesting. Respondents were first allowed to list their expectations; if they chose more than one, they were asked to choose the most important one. Half of the time (50.6%, N=77), the participants claimed that increasing the number of non-smokers or assisting current smokers to quit was the most important expectation. The next most commonly cited answer was no expectations by almost a third

of respondents. This is especially significant because only companies that provided at least some coverage for these products were asked this question, yet almost a third of them expected nothing from the availability of the products.

IV. Future Smoking Cessation Plans

Participants were queried on their plans to change how their employees received smoking cessation products or services. Over 80% (81.2%, N=138) stated they had no plans to change from the current situation. The few (N=26) that mentioned they might be implementing changes were probed on those changes. The most common response (46.2%) was to provide behavior modification support for their employees who smoke. Almost 20% desired more follow-up, and about 15% each wanted lower cost programs and fewer administrative responsibilities.

Next, participants were asked to consider the value, on a per participant basis, of an ideal but realistic smoking cessation program (meaning a program with a quit rate of 5-15% at one year). Many respondents (42) were unable to answer this question or “did not think about it in those terms.” The remaining 96 offered a fairly wide range of responses. Figure 12 reports these answers.

The next future issue explored was the over-the-counter availability of cessation products. It should be noted that the nicotine gum was approved for OTC marketing during the data collection phase of the survey but that data collection was closed before the gum was available on store shelves. Hence, respondents were asked about their reactions to the potential OTC availability of these products. Figure 13 provides these results.

Figure 12

Acceptable Price for Ideal, but Realistic,* Program

*Success rate between 5-15% at one year. (N=96)

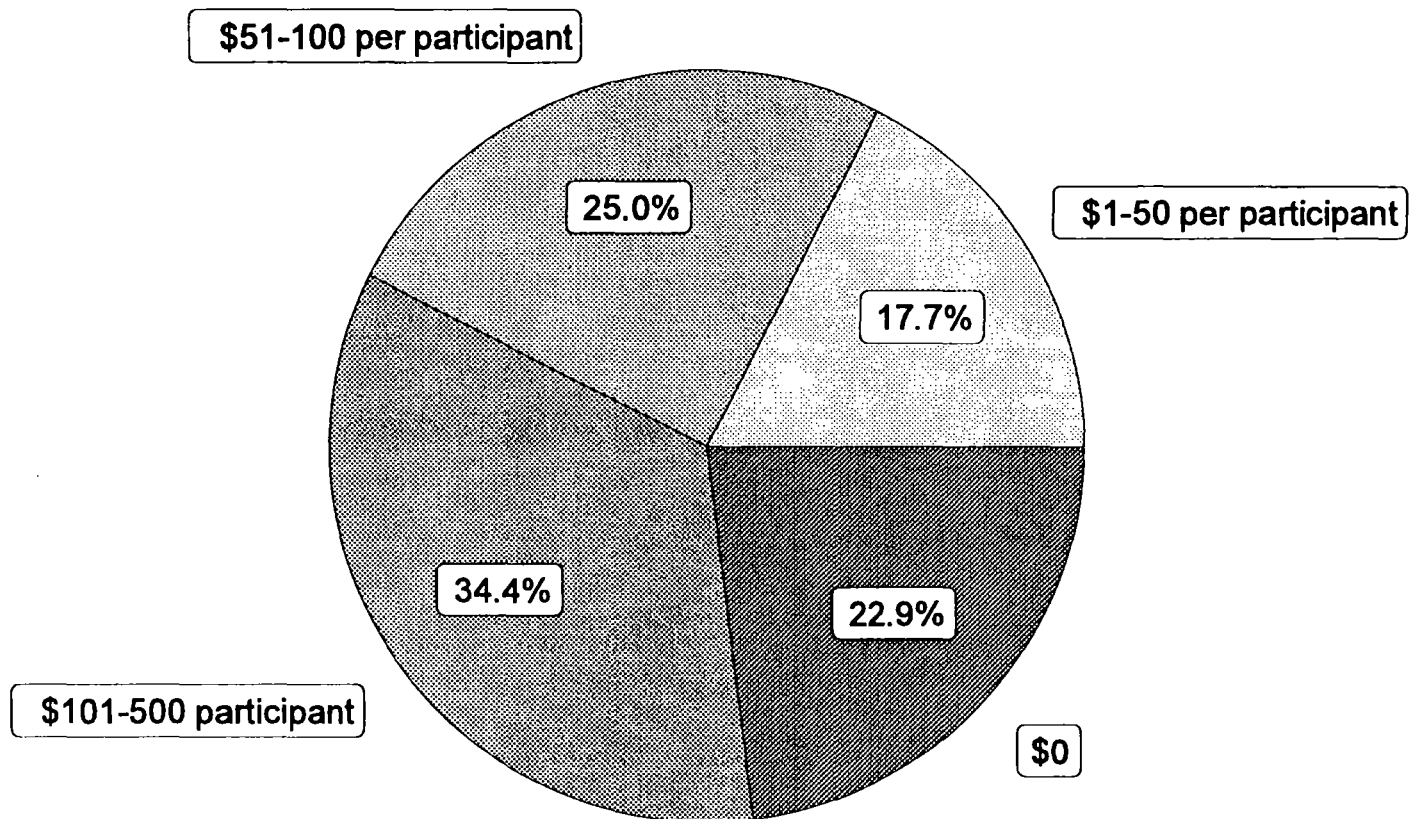
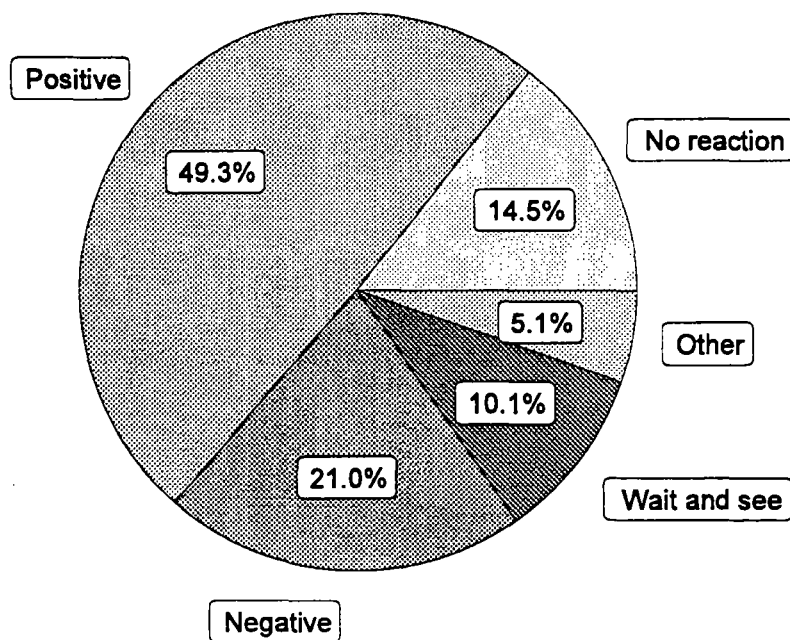


Figure 13

Reaction to Potential OTC Availability of Cessation Products (N=138)



Although respondents were fairly receptive to the concept of OTC nicotine replacement, it is significant that the majority of them (65.6%, N=128) would not change their approach to smoking cessation activities in light of OTC availability of the products. Of the 25.8% who said their activity in smoking cessation would increase or change, a majority (60.6%, N=33) said they would be willing to distribute educational materials about the products to their employees. It should be noted that 27.3% of this group made negative remarks about OTC availability, usually expressing concern that there should be behavioral programs to support the use of the products.

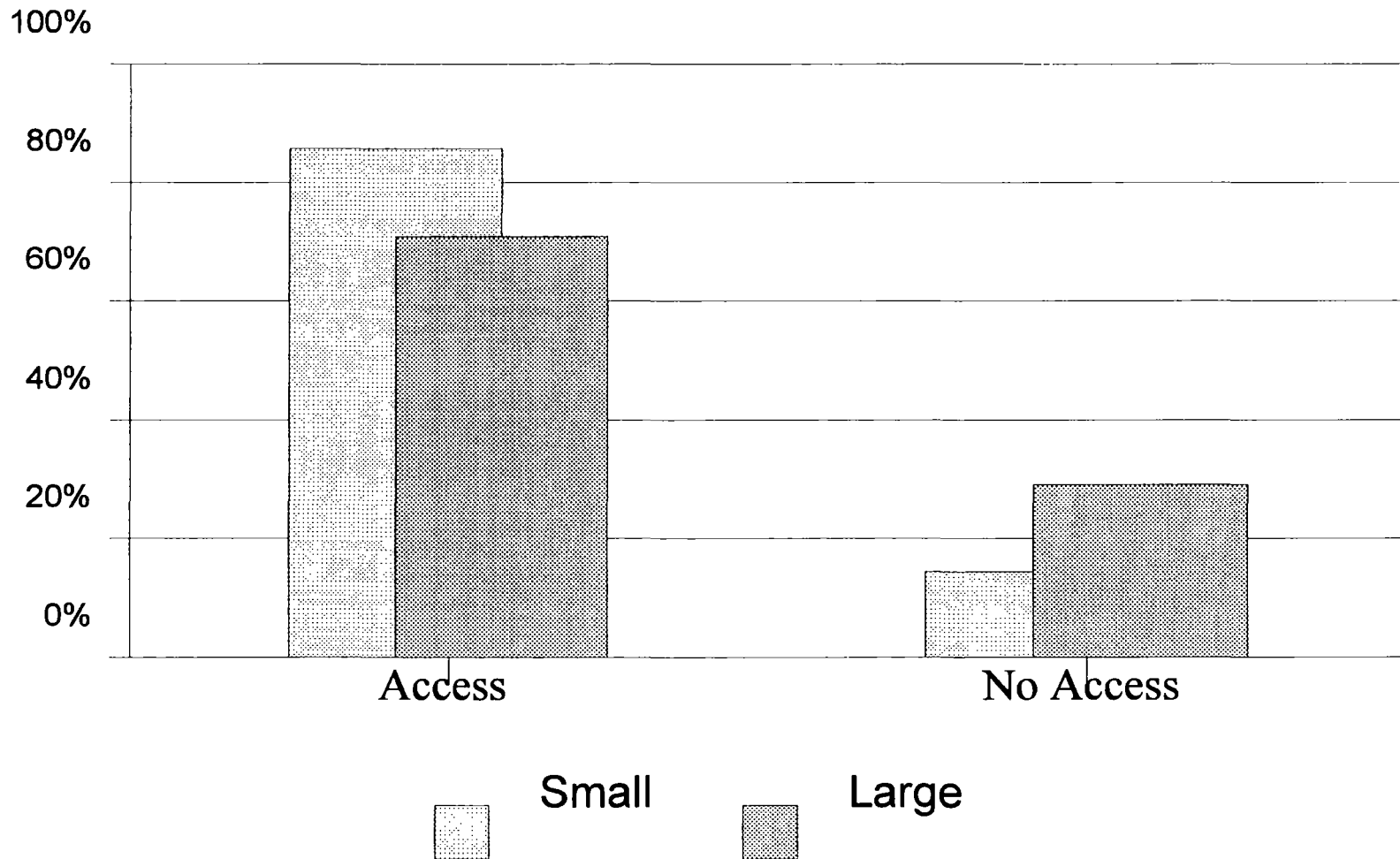
Finally, respondents' awareness of the upcoming smoking cessation guideline from the U.S. Agency for Health Care Policy and Research was measured. Only 15.6% (N=135) claimed to know that the guideline was in development. Even with this low recognition, over 90% (92.5%, N=106) affirmed that they would expect any smoking cessation provider they used to follow the guideline. Be aware that almost 30 respondents stated that they would need to see the guideline before making this decision.

V. Health Promotion/Disease Prevention Programs

This short section inquired on the provision of general health promotion and disease prevention programs to employees. Participants were asked if their employees had access to a formal health promotion/disease prevention program and were allowed to define "formal" themselves. Almost 80% (77.9%, N=140) of our sample said they provided access to a formal program. There was a fairly strong association between the number of full-time employees and access to a formal program. Surprisingly, however, our smaller companies were more likely than larger companies to offer these programs (60 out of 70 smaller companies compared to only 47 out of 68 larger companies). This is more likely a result of our sample's skew toward very large companies (the median number of employees was 8,500) than a generalizable result. Figure 14 shows this association.

Figure 14

Employee Access to Formal HP/DP Program By Company Size... (N=138)



Most commonly (48.6%, N=109), these programs were provided by a combination of company staff, HMOs, and/or wellness vendors. In less than 20% for each were they provided by company staff, HMOs, or wellness vendors alone. Among outside vendors, the national health voluntaries once again fared well, but there was a very large reliance on local sources such as hospitals and consultants (53.5%, N=71).

Participants were quite clear about their goals for these programs. Table 2 shows their responses for their most important goal.

Table 2

**Most Important Goal for Health Promotion/Disease Prevention Programs
N=103**

Goal	%
Improve employee health	45.6
Education/health awareness	19.4
Control costs	12.6
Improve employee relations	5.8
Save money	1.9
Other	14.6

Respondents seemed to agree that they get their money's worth from these programs. Almost 93% (92.8%, N=97) said that they do.

Conclusions

The Sample

- ▶ Our experience with this survey highlights the difficulty in gathering information from large corporations. We used experienced, well-trained callers over four months of calling and nevertheless were only able to complete 141 surveys. Our targets all claim they are very busy, get frequent requests for interviews, and often cite corporate policies that prevent them from participating. Also, as can be seen among those participants who deemed this a sufficiently engaging topic on which to participate in a survey, smoking policies and cessation programs are not a major priority.
- ▶ Another difficulty arises from the fact that in only 60% of cases could respondents provide information that was valid corporate-wide. Decisions on smoking policies and cessation programs appear to be made frequently at the unit- or operating-site level. This presents coordination challenges internally as well as hurdles to marketers with products intended for use by these corporations.

Smoking Policies

- ▶ This sample appears to have adopted smokefree environments almost completely -- approximately 85% of the sample follows a policy that is either smokefree or restricts smoking only to separately-ventilated designated smoking areas. Very few companies intend to change their current policy.
- ▶ In general, no major problems were reported with the implementation and enforcement of smoking policies.

Smoking Cessation Programs

- ▶ This survey somewhat validates the anecdotal belief that employers do not consider smoking as their problem. Very few companies plan on changing their smoking policies, and a similarly small number expect to change how their employees receive smoking cessation. Respondents did not rank providing smoking cessation to their employees who smoke as a high priority, and they were seldom able to track employees by smoking status or to cite outcomes from any smoking cessation programs that they provide or encourage.

Smoking Cessation Products

- ▶ Nicotine replacement products are offered to at least some of the employees of our respondents most of the time, usually through their standard prescription plan.
- ▶ A majority of respondents expect that the products will help people quit smoking, but it is significant that almost one third have no expectations of the products.

Future Smoking Cessation Plans

- ▶ As mentioned above, few companies have any plans to change how their employees receive smoking cessation activities or products.
- ▶ Of those respondents who could answer the question of the value (on a per participant basis) of a smoking cessation program that yielded a 5-15% quit rate at one year, almost 60% would pay between \$50 and \$500. About 20% of the respondents would not pay anything for this outcome.
- ▶ Respondents were generally positively disposed toward the over-the-counter availability of nicotine replacement products, but they did not indicate that it would change their approach to smoking cessation significantly.
- ▶ Participants were not aware of the forthcoming Agency for Health Care Policy and Research Smoking Cessation Guideline, but they did expect smoking cessation providers they use to employ the guideline.

Health Promotion/Disease Prevention Programs

- ▶ A majority of companies surveyed provide access to a formal health promotion/disease prevention program for their employees.
- ▶ The most common reason for providing these programs was to improve employee health.

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Appendix A. Study Limitations

This report attempts to break new ground in gathering information about the smoking cessation and health promotion/disease prevention practices and policies within companies. To the best of our knowledge, the information presented was correct during the time period in which data were collected. Because of the exploratory nature of this research, no inferential statistical analysis was conducted, and thus no inferences can be made. Instead, our primary goal in embarking upon this research was to take a first step to look for any patterns that might exist. As with any ecological study design, our report represents data collected at a fixed point in time. The descriptive data presented in this document are not meant to be representative of practices and policies within the entire Fortune 1000.

There are also confounding factors that invariably influence survey results. Most significantly, the current trend toward corporate downsizing, reengineering, and otherwise changing organizational structure may significantly affect survey responses. For example, it may appear to an employee respondent that smoking cessation is a "low priority" or "not a priority" because, compared to the past (for example, when a smoking policy is first implemented), a larger emphasis is being placed on issues of organizational structure.

Apart from the limitations listed above, there are other study biases which need to be elaborated upon in order to better understand and contextualize the results:

Selection Bias

From a strict, short-term productivity perspective, companies have a financial interest not to participate in unsolicited telephone surveys, given the drain on employees' time and the possibility of inadvertent divulgence of confidential company information. Some companies we contacted have an explicit, categorical policy of not participating in surveys. In qualifying potential respondents over the telephone, some companies were disqualified if they did not have someone who handled smoking cessation and health promotion issues. Other potential respondents were disqualified if they failed to respond to our solicitations after three contact attempts. It is at least possible, then, that those who agreed to participate were employed at companies where greater value is placed on smoking cessation and health promotion issues compared to the disqualified respondent companies. Therefore, it is possible that the subsequently collected data were biased toward more programs and a higher priority for smoking cessation. This possibility is particularly marked at companies that have full-time, paid wellness staff.

Measurement Bias

Our specific format for data collection, the telephone survey, using mostly categorical response measures, is particularly vulnerable to measurement bias, where responses may be given to insufficiently specific questions. The format of questions, and the subsequent coding and classification bias, often result in data that do not provide a real value of actual experience.

Recall Bias

Any survey of past behavior (or, in this case, previously enacted programs and policies) are subject to some recall bias. Individual respondents may not remember details of past events accurately, or may relate them to the interviewer within the context of present knowledge or present policy. (An example of this is the question "What were the decision criteria for choosing a [smoking cessation] program?" If the question was posed at the time the selection was originally made, the response might be a combination of cost and degree of administration required. Two years later, after observing that the non-smoking majority views the availability of a smoking cessation program favorably, and that a significant number of smokers have now quit, the respondent might give health benefits and employee relations as the "decision criteria" because now the respondent has more information about other criteria that may not have been considered originally.)

We attempted to counteract the latter two of these study biases by embedding differently worded versions of questions within our questionnaire. However, given the time pressure in speaking to corporate respondents, and the likelihood that the telephone call could be terminated if it ran over the agreed-upon length of time, corroborating responses in this manner was not frequently possible.

Review of the current status of smoking cessation in the USA: assumptions and realities

John M Pinney

This is going to be a whirlwind tour through the treatment system, describing the realities for people who are trying to quit smoking in today's treatment environment. First, I want to explore the basic assumptions that underlie, and in some cases inappropriately influence, how we look at the treatment of tobacco addiction. Next, I want to provide some of the characteristics of the system, recognising that there is really no comprehensive description of tobacco treatment available to us. And finally, I want to look at the factors that I think affect the system and will affect it in the future.

There are three basic assumptions. First, we often say "most smokers quit on their own", and that has some very significant implications. It permeates the thinking of many of the health care providers who are supposed to be addressing this problem. Second, we have communicated the idea that if you want help to quit smoking, it is available to you. And third, we have said, with some evidence, that tobacco control policies create incentives for cessation, and we also have said that the economic justification for smoking cessation is irresistible – the numbers are overwhelming.

Let me examine the assumptions briefly. The first assumption is that most smokers quit on their own.¹ I do not think we know whether that is a preference or whether that is by default. We do not often ask smokers about why they choose to do what they do. We also know that they often do not recall what it was they finally did to quit smoking, or they may recall what they finally did, but not what they did the first two or three times they tried and failed. The idea that they quit on their own suggests, I think, that we know very little about what that truly means in a treatment context.

The success of quitting smoking on one's own is not very high. Our calculations are usually based on the numbers of people who continue to abstain after the first 24 hours. Since there are millions of people who do not make it past 24 hours, we need to ask ourselves "What, then, is the true efficacy of quitting on your own?". I suggest it is somewhere between 4% and 5% at best.² What are the public health implications of this? As Dr Orleans has shown, we have built a public health model which implies that if we do certain things we will drive people either to quit on their own or into treatment. The next question is "If they seek treatment, how available is it; how

accessible is treatment?" I shall examine that in more detail.

The next assumption is that tobacco control policies create incentives for cessation. I have tried to characterise this with two thoughts: (1) "If you ban it, they will quit." From Dr Orleans' COMMIT data it seems that this is not necessarily the case. Certainly the results are mixed – and in the workplace, where we have probably had our most extensive impact in eliminating smoking – we may in many cases only have changed people's smoking patterns rather than inducing them to quit.³ (2) The second thought is "If you tax it high enough, they will quit". I suspect that this is probably one of our best hopes,⁴ but as we all know it is very hard to raise taxes.

The final assumption is that the economic justification for smoking cessation is irresistible. I quote from the late Rufus Miles, a great public servant, who said, "Where you stand depends on where you sit". Those of us who believe that the economic justification is overwhelming and irresistible do not run managed care plans. Those who do have found ways to resist the logic of this and continue to resist it.

I shall now examine the availability of products and services, beginning with group programmes. I think group programmes are what the US Food and Drug Administration (FDA) meant – although they said two years ago at our last conference they were not absolutely certain – when they coined the term "comprehensive behavioural smoking cessation programme." Group programme demand is hard to measure. All the reports we have are self reports from vendors, but it appears that demand is either flat or declining.⁵ We conducted a brief informal survey of group programmes in 10 cities in the United States and found that in four of them no group programmes were being offered by a major voluntary health agency because of a lack of demand.

Whether or not these programmes are "smoker-friendly," that is, whether or not they would attract smokers into treatment, is questionable. There are several anecdotes that suggest that the location, scheduling, duration, and format of group programmes are not necessarily smoker-friendly.

Table 1 presents self reported data from the three primary commercial smoking cessation group vendors.⁵ It suggests there was a substantial increase in sales between 1988 and

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Table 1 Cessation programme unit sales by commercial group vendors, 1988-1993

Programme	1988	1992	1993	% change 1988-93
SmokEnders	15000	10000	10000	-33
Smoke Stoppers	30000	56000	30000	0
SmokeLess	28000	45000	68000	+143
Total	73000	111000	108000	+48

Source: Marketdata, 1989; Marketdata/CHPG 1994.

Table 2 Estimated sales of non-prescription smoking cessation programmes and products, 1993

Programme	Volume (units)
Acupuncture	85000
Hypnosis	350000
American Cancer Society	150000
American Heart Association	19000
7th Day Adventists	85000
Addiction Management System	5000
SmokEnders	10000
Smoke Stoppers (group)	30000
Smoke Stoppers (self help)	10000
SmokeLess (group)	65000
SmokeLess (self help)	50000
Nonaffiliated Hospitals	175000
American Lung Association (group)	30000
American Lung Association (video)	1500
American Lung Association (self help)	50000
American Medical Association/GNC	5000
Total	1120500

Source: Marketdata, 1989; Marketdata/CHPG 1994.

Table 3 Survey data on physician advice and assistance

Question	Yes/No (%)	Source
Ever been advised to quit	61/39	Gallup 1993
Doctor explained and counselled how to quit	51/49	Gallup 1993
Been advised to quit in last 12 months	37/53	NHIS* 1991

* National Health Interview Survey.

1993 - overall, about a 48% increase. However, it is hard to know how much of that increase was driven by the short term effects of the introduction of the transdermal nicotine patch, as opposed to any major shift in consumer demand, and we do not have data later than 1993 to present. My informal survey, as I said, would suggest that demand may be flat or declining.

Most of these programmes, it is important to note, are presented by hospitals affiliated with these vendors, and much of the activity in 1992 and 1993 may be attributable to the increase in bans in smoking or increase in smoking restrictions in the workplace. Again we have no recent data, but I believe that this trend will now have levelled off because many workplaces have become smoke-free, and there is little interest in smoking cessation group programmes on the part of the employees.

Table 2 shows an overall estimate of the smoking cessation programmes and products, other than prescription products, in 1993 (Corporate Health Policies Group, unpublished data, 1994). It runs from acupuncture down to the American Medical Association/General Nutrition Centers programme, which was launched about 18 months ago. Some of these data are self reported, some are imputed

from other sources. It is as close as I have seen to an estimate of the total use of smoking cessation products and programmes in the United States. These are 1993 numbers, and the total is about 1.12 million units, products, or group programme participants. It is a little over 6% of the 16 or 17 million people who make an attempt to stop smoking lasting over 24 hours.

Physicians are clearly an important part of the treatment system. There are fewer individual practitioners in the system today, although much of what we say about physicians and cessation seems still to be focused on doctors as though they practise the way they practised 10 years ago. More group practices are being bought up by managed care and placed under the pressures that managed care exerts on physicians to deliver inexpensive health care. Managed care is growing substantially, and it places a reliance on guidelines, which physicians tend to ignore as some studies show.⁵ Finally, we have a guide for the behaviour of physicians: a strong recommendation from the US Preventive Services Task Force that behavioural counselling should be a requirement for all smokers.⁶ Clearly, physicians should deliver counselling, but we have evidence that they are not paying attention to the guidelines.⁵

Table 3 presents three different measures of counselling activity. First, a Gallup survey done in 1993 for SmithKline Beecham Consumer Healthcare, asked "Have you ever been advised to quit by your physician?" Sixty one percent answered in the affirmative. In response to the question "Did the doctor explain and counsel you how to quit?", the Gallup poll found that 51% of those who had been advised were actually counselled how to quit.⁷ The National Health Information Survey (NHIS) data show that 37% of smokers said they had been advised to quit in the last 12 months.⁸ I submit that the results of physicians following guidelines are not particularly encouraging so far.

Hospitals are another major element in the system. Hospitals have varied objectives in today's health care system, particularly when it comes to treating "behavioural problems" like smoking. They treat them for community relations purposes, perhaps their top priority. They also do it as a loss leader, to bring people into the hospital to deliver other services. Some do it for profit, although I heard an anecdote about a booming health promotion programme in a hospital that was purchased by a chain. The chain said "We are not in the business of doing this even though you are

making a profit," and cancelled the programme. Hospitals also offer treatment programmes as a contract service for employers in the community.⁵

We found in a survey of about 20 hospitals that several actually do provide smoking cessation treatment under contract to employers and to some managed care programmes, but the trends are unclear.⁵ It appears the demand may be flagging for group programmes, which are primarily what hospitals supply. Estimates of hospital cessation services not affiliated to a national vendor show that, if anything, there may be nil to modest growth in cessation activity; patient volume for these services has grown from 179 600 in 1988 to 188 600 in 1992, a 5% increase.⁵ However, these data are three years old and health systems integration is underway, which means that hospitals and doctors are teaming up to fight back against managed care, and they will be subject to many of the same pressures as managed care, meaning a reduction of costs. There are other indications that hospitals are not encouraging the demand for cessation services. Our survey of 20 hospitals in 1994 found that cessation fell into the "not hot" category of health promotion/disease prevention services.

The next, and probably the most important, element of the system is managed care. Managed care has always maintained that prevention is its middle name. When the federal government made it possible for health maintenance organisations to become federally chartered and get federal start-up money, the Congressional hearings were replete with justifications based on prevention. Second, while the economic justification is irresistible, it is also inescapable; sooner or later, a large group of people whose care is being managed by a single entity is going to incur smoking-related diseases.

Part of the problem with managed care and with the resistance to the economic imperative of smoking is that managed care believes short term competitive forces are far more powerful than long term health and economic considerations. However, I believe that the demographics and the customer demand factors in managed care are going to change that situation to some extent. Clearly, if we are going to be managing the care of the entire population, we can no longer expect managed care to have the benefit of only healthy young people who do not smoke or do other things which cost money.

The Group Health Association of American (GHAA) reported that in 1992, only 3% of all enrollees in health maintenance organisations were not covered for routine physical examinations, but 33% of all people enrolled in them were not covered for smoking cessation.⁹

I should like to present some data which were collected in 1993 in an extensive survey of health maintenance organisations.¹⁰ This survey was sponsored by Ciba-Geigy – which has graciously agreed to let the data be released – and was conducted by the Corporate Health Policies Group (CHPG). The data are two

years old, but they are from an extensive sample – not a generalisable one per se, but from 147 health maintenance organisations with 20 000 enrollees and higher, representing close to a 50% sample of all the organisations in that category. The first question asked in this survey was: "Is smoking cessation a covered service in your plan?" Sixty per cent said yes, and 40% no.

Another question asked was: "Do you have an in-house smoking cessation programme?" The response was: 46% yes, 54% no. There are two important aspects of these responses. First, if you were in a staff or group model health maintenance organisation, you were very likely to be covered and to have a programme available to you. Second, if you were an individual practice association or network member, you were much less likely to have that service available. And it is important to note that individual practice associations and network are the dominant forms of managed care and the ones that are growing the most rapidly in the United States.

Preferred providing organisations, which are somewhat in decline numerically, are another form of managed care, and there are data available on the percentage of these organisations offering health promotion and disease prevention services. That number is declining, and it was well under 25% in 1993.¹¹ Also interesting to note is that the predominant model of in-house smoking cessation programmes – for those health maintenance organisations that offered it – was a group programme based either on the American Lung Association or on the American Cancer Society model.

Let us look briefly at prescription products for smoking cessation. At present, demand for nicotine products and transdermal patches is fairly stable, somewhere in the range of \$50 to \$60 million a year in sales for nicotine gum, and \$150 to \$160 million in sales for transdermal patches (SmithKline Beecham, unpublished data, March, 1995). While data are not available publicly, there appears to be a major problem with the perceived efficacy of prescription products. Anecdotal evidence suggests that many physicians and consumers have heard from some source or other that these products do not work. This perception may have a lot to do with smokers' expectations of what pharmacological treatments can do, but I believe it also has to do with a failure of communication or of encouraging the proper use of the products, or indeed of linking smokers looking for treatment with those ever-elusive "comprehensive behavioural smoking cessation programmes". The approved indication for the transdermal patch is as an effective adjunct when used with a comprehensive behavioural smoking cessation programme,¹² and, as I indicated earlier, those are not widely available.

A major question is "If you are in managed care, can you get a patch?" The survey asked health maintenance organisations (n = 147) "Do you cover the transdermal nicotine patch?" The response was yes in 54%, no in

45%. There are some major restrictions that accompany coverage of the patch which I shall describe shortly.

In the case of over the counter (OTC) products, in June 1993, the FDA decided that none of the major smoking deterrent products, as the class was called, was shown to be effective and therefore ordered that they be removed from the market. The one that suffered the most was Cigarrest. I think this is a very instructive model, and I have often used it as an example. The 1988 sales of Cigarrest were approximately 1.75 million units.⁵ That equates with about \$33–\$35 million in sales. This was not an insignificant product in the minds of many consumers. What did it do better or different? The price was right, the package was right, and the promotion was right. It was aimed at a market segment that watched television and would respond to the opportunity to quit smoking by dialling a toll-free 800 number and charging \$14.95 on a credit card. How well did Cigarrest work? We may never know, but the fact is that the product itself was extremely popular to a significant segment of the smoking market. I think the most significant potential development in OTC products would be a shift from prescription to OTC status for nicotine gum (Nicorette[®]) and for transdermal patches. Both of these switches are under consideration or in various stages of consideration by the manufacturers or by the FDA.

Next, consider the cost of cessation products and services. The average price for smoking cessation programmes is, I think, an important indicator of what consumers are willing to pay to quit smoking. The prescription costs, based on Washington prices without the benefit of a drug card discount, are \$38.99 for 96 pieces of 2 mg nicotine gum, \$54.99 for 96 pieces of 4 mg gum, and \$54.59 for 14 patches. The total cost of treatment, using these products at those prices, is going to depend on how long the treatment lasts. One of the major problems with gum and patches is that smokers apparently do not use them properly, do not use them long enough, or do not use enough of the product, and therefore treatment may be quite inexpensive because they never finish a complete course of treatment.

Another problem with prescription products is that reimbursement is limited.¹³ Excluding managed care, indemnity plans usually copy the same drug riders. My company made an effort to change our own drug rider just to see what would happen in our plan, and we were told that it would require us to relicense with the state of Maryland, which was excessively complicated, and besides it was a generous rider and these products are not effective; therefore, they are not covered.

We have calculated the sales weighted average price of non-prescription smoking cessation products, including group programmes and all the products available in 1993 (CHPG, unpublished data, 1994). The sales weighted average price was \$76. At its peak volume of about 1.75 million units, Cigarrest would have brought that sales weighted average price down

to \$41. The calculation for commercially available self help programmes and those available through the voluntary health agencies was estimated to be \$35.

As indicated earlier, there are barriers to gaining access to products and services, particularly requirements on the prescription of transdermal nicotine and gum. Of those health maintenance organisations in the Ciba-Geigy survey that covered the patch, 67% had requirements of some kind, and 45% limited a prescription to once in a lifetime. If a smoker does not make it the first time around on the patch in those organisations, he does not get another chance.

There are other barriers to consider, including time to gain access to a programme: "How long do I have to wait before I can get help?" As I indicated earlier, in our informal survey of 10 cities in the United States we found that in four, the voluntary health agency offered no programme; two offered programmes requiring prompt action by the smoker; if the window of opportunity was missed, the smoker would have to wait another three months. In the remaining four, smokers would have to wait five to 10 weeks for the next group to start.

Knowledge and attitudes are also noteworthy barriers. In this case, researchers, clinicians, providers, and regulators seem to have a single set of attitudes about cessation products and services, often negative. I am not sure that we know what smokers' attitudes are about quitting smoking, particularly in terms of what types of assistance they would prefer to use. Yet I believe we are still dealing with a "one size fits all" mentality, which is driven by the concept of a comprehensive behavioural treatment programme which I have yet to see defined.

We also tend to deal in terms of treatment failure, and tell people in one way or another that "If you cannot quit on your own, you are a failure; if you cannot quit in six or eight weeks, you are a failure; and if you use nicotine replacement products for more than three months, you are a failure." Again, we have the problem of perceptions of efficacy. How effective does a programme have to be to be acceptable? What is acceptable efficacy? If you ask physicians and other health care practitioners what they consider to be an effective smoking cessation programme, they might not have an answer, but my guess is it would be significantly higher than the rates most of our programmes achieve.

Clearly, there are sociodemographic factors that affect the use of cessation support. How does the effectiveness of products and programmes vary among different minority groups, particularly different racial and ethnic groups, and are there significant differences in how the system treats these groups and how they respond to the system?

Finally, I want to consider factors that affect the system, to see what we can expect in the future. First is the switch of prescription cessation products to OTC availability. If this happens, it will make a major difference

because it is likely to generate more demand for cessation through advertising and promotion of cessation itself. Second, I think we shall see efforts to define and develop new prescription products. However, they will face some of the same problems that nicotine replacement has in that the clinical response to them will be similar: "How do I use this properly, what kind of efficacy is acceptable, and how do I connect my patient with a comprehensive behavioural smoking cessation programme, or do I even bother?"

It is also important to consider how receptive the health care system is to new products. It is not likely to be receptive unless the price is right. Is there a continued need for behavioural support components? There is no question that we need them, but can we create better programmes that work quicker and easier, and are more accessible?

What will be the impact of demand generated by new products, and what about increased access? We have cessation guidelines under development by the Agency for Health Care Policy and Research (AHCPR), and I hope these are close to release. Will they be broad enough to encompass the new treatment concepts, and is there a plan to institutionalise the guidelines? Will they fare better, for example, than the US Preventive Services Task Force recommendations for counselling by clinicians?

We also have disease management, an emerging concept launched by the pharmaceutical industry. Disease management offers interventions on a public health model, focused primarily on chronic diseases. There is some evidence that the smoking models of disease management are likely to prove effective. But there is a tension between the tendency of the health care system to standardise and "medicalise" those treatments that are foreign to it and the perceived need to offer more flexible treatment. How do we deal with this?

With managed care and health care reform, the basic question is: "When does the economic justification become irresistible?" Do the changing demographics and developments, such as Medicaid managed care, drive the economic issue to the point where managed care will be more forthcoming in offering cessation programmes and products?

What about consumer and payer demand? Are employers more likely to demand intensive interventions for their employees, and are they willing to pay additional premium dollars for

coverage? I cite the lesson of health care reform. Many of my colleagues said that health care reform would institutionalise prevention. It is significant, however, that "smoking cessation classes and other health education classes" were the only optional benefit in the Clinton plan.¹⁴

These are my questions for the future. First, will the continuing costs of tobacco addiction and all substance abuse (despite declining prevalence) drive treatment investment? Second, is there a need and an opportunity to develop a tobacco addiction treatment policy that provides treatments as accessible and affordable as cigarettes? Third, can we both create and satisfy demand for treatment, tailored to individual smoker profiles and needs, with culturally appropriate treatment and marketing strategies? And finally, can we have a national strategy that balances prevention, policy, and treatment?

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Sales Volume and Total Sales of Smoking Cessation Programs and Products - 1993

Program	Volume	Price	Total
Acupuncture	85,000	250	21,250,000
Hypnosis	350,000	50	17,500,000
Am Cancer Soc	150,000	5	750,000
Am Heart Assoc	19,000	50	950,000
7th Day Advent	85,000	50	4,250,000
AddMgtSys	5,000	150	750,000
SmokEnd	10,000	200	2,000,000
Smok Stop Grp	30,000	125	3,750,000
Smok Stop SH	10,000	45	450,000
SmokLess Grp	65,000	125	8,125,000
SmokLess SH	50,000	45	2,250,000
Nonaffil Hosp	175,000	120	21,000,000
Am Lung Grp	30,000	65	1,950,000
Am Lung Vid	1,500	66	99,000
Am Lung SH	50,000	10	500,000
AMA/GenNutritn	5,000	70	350,000
Total	1,120,500		\$85,924,000

Source: Marketdata, 1989; Marketdata/CHPG 1994

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A few other ideas beyond those presented by Jack -

Ken Warner PhD - phone 313-936-0934 - interested in a regulation strategy that combines nicotine reduction with making pharmaceutical nicotine more available.

Ken Perkins PhD - phone 412-624-1716 - psychologist interested in nicotine as a reinforcer - relevant to the threshold for addiction issue

William Farrone PhD - former tobacco scientist - has been testifying for the states AG's - knows a lot about technology for safer cigarette.

Neal

June 24, 1997

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Office of Science and Technology Policy
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17th Street and Pennsylvania Avenue, NW
Washington, DC 20502

Dear Jerry:

It was a pleasure to talk to you last week, in the days before the Tobacco Settlement Proposal. The Proposal is historic, but it will require much work to guarantee that it becomes a turning point for improved public health and not license for barely mitigated tobacco industry growth at the expense of public health. In this case, the devil is in the details; factors not ostensibly tied to the final settlement may greatly influence the nature of its impact. During my two decades of involvement in tobacco research, I was most privileged to serve Drs. William Pollin, C. Everett Koop and David Kessler in their efforts to reduce the devastation tobacco use caused to our national health and productivity. These public servants and others have forged important in-roads on tobacco control. Though I now work in the private sector, I would be happy to serve in any way possible in continuing the work they undertook.

Despite media attention given to the labyrinthine negotiations of the Settlement, I remain much more concerned with its overall impact on public health. How much the industry pays, who gets paid, and whether or not Americans have unfettered opportunities to sue tobacco companies—these things do matter, of course. But they seem to have gained prominence in their own right, when they are not necessarily the determining public health factors. For example, although mass litigation efforts have been important in getting us to the bargaining table with the tobacco industry, we could spend additional decades in litigation, losing further generations of young people and doing relatively little to help those already addicted in the process. Let me share with you two key projections that guide my thinking:

- (1) On our current course, between 10 and 20 million current cigarette smokers will prematurely develop debilitating diseases, suffer and die, because of their unmitigated tobacco use.
- (2) Under the most wildly optimistic impact of the Settlement in reducing youth tobacco use, more than 500,000 kids will continue to develop nicotine addiction every year.

The Proposed Settlement does very little to address these issues in either the long- or short-term.

We need to consider certain elements of the Settlement in their relation to the 1996 FDA Tobacco Rule, which is really the foundation of everything that has followed it. Elements of this Settlement could lose gains won for us by FDA. Though some compromises may seem reasonable when evaluated by the metric of how to most expeditiously negotiate a deal between the States Attorneys General and the tobacco industry, if we accept the premise of the FDA Tobacco Rule—that the main purpose of our efforts is to reduce the death and disease caused by tobacco use nationwide—other compromises might seem too costly. There are a variety of concerns we should strive to keep at the forefront of our discussions and to position as priorities.

FDA must retain full authority to regulate tobacco products, including the nicotine contained therein: FDA acts in accord with the best available scientific information to foster improved public health. The agency has already explained its opposition to any course of nicotine reduction in the near future. It based this decision on the state of the science, and all such future decisions should be similarly science-based. Science is not static; it evolves. We should not limit our possible response to public health concerns through bargaining accords. Instead, we should follow the scientific directives. FDA jurisprudence allows everyone effected by its proposed and final rules legal recourse whenever an agency action appears capricious or scientifically indefensible. Finally, it is important to remember that even under the FDA Tobacco Rule, nicotine-delivering tobacco products are treated much more liberally than nicotine-delivering medications such as the gum and patch. The Proposed Settlement could foster still greater disparity in regulation, making tobacco products even more palatable and more readily available, while pharmaceutical manufacturers will typically face years of effort in making the most minor modifications of their products (e.g., improving the flavor of nicotine gum). Public health loses once again in this scenario.

Our national tobacco and nicotine research agenda must be substantially expanded to complement and support any settlement processes: The Proposed Settlement might lead some to conclude that to achieve an “acceptable” level of tobacco use, we need only harden restrictions on tobacco-marketing or increase the availability of existing tobacco-dependence treatments. While those are important steps, substantial public health strides will require our possessing knowledge that we do not have. Research on the nicotine-dependence process, its treatment and prevention is not yet adequately funded and directed. It was not until the Robert Wood Johnson Foundation recently established a youth tobacco dependence etiology network that we even had a national forum for planning and possibly facilitating research on the transition from tobacco use to addiction, much less any systematic research agenda. There is a keen need and significant demand for treatment of nicotine-addicted youth, but not a single proven treatment modality. Even with this new network, progress will depend on the extent of NIH funding for such research. In addition, the ability of the FDA to draw valid scientific conclusions on tobacco-related issues, including whether the nicotine levels of cigarettes should be altered, also hinges on the

extent and nature of NIH research. (In December 1995, at the suggestion of Drs. Varmus and Kessler, NCI convened a working group to discuss research needs for exploring the removal of nicotine from cigarettes, but its suggestions were never implemented.) Many basic research questions need to be addressed, but they can not be addressed without funding or oversight. NIH seems to bear a considerable burden in this regard.

Reduction of tobacco toxin exposure might be an important component of our national efforts to reduce the death and disease caused by unmitigated tobacco use: Then again, it might not; this depends on how an exposure reduction scheme is implemented and on the rules of its implementation. Ameliorating smoking-related death and disease by reducing smokers' exposure to tobacco toxins is consistent with the finding of many major studies, Surgeon General's Reports, and a 1997 NCI monograph. David Burns (the editor of several Surgeon General's Reports) developed a model predicting that depending on his or her age, baseline cigarette smoking, and magnitude of smoking reduction, a smoker might enjoy an increase in life expectancy ranging from approximately one month to 5 years. On the other hand, the aggressive marketing of theoretically low-tar cigarette brands by tobacco companies led to an apparently increased risk of lung cancer. The CDC has suggested that the marketing of these cigarette brands may have lowered the motivation to quit smoking in approximately two-thirds of American smokers who have switched to such brands in their misguided exposure reduction efforts. Any accord which encourages tobacco companies to embark on even more creative schemes to sell cigarettes, without premarketing research and post marketing surveillance comparable to that expected of pharmaceutical companies, is contrary to the consensus reached in a number of recent conferences, among them the American Society of Addiction Medicine meeting held in Toronto last March. We should discourage tobacco companies from selling cigarettes made more toxic than necessary, and we should encourage pharmaceutical companies to develop products and indications that serve the many smokers who are currently unwilling or unable to completely abstain from tobacco use. Attached is a set principles for exposure reduction approaches; I have been working on for more than two years, initially as part of my efforts to help FDA evaluate novel tobacco products and more recently with my colleagues at Pinney Associates.

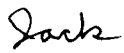
We need new treatments, developed and implemented on a more rapid timetable, with FDA in the role of partner and facilitator: One of the barriers to FDA's reducing nicotine from tobacco (if the agency even believed that was appropriate) is the relative lack of acceptable alternatives for people who are currently unable or unwilling to submit to absolute cessation therapies. Pharmaceutical companies have the resources to develop and implement new strategies that could reach many more of these people within two years. The current approval process runs on a much slower timetable, but I believe that it could be expedited without significantly increasing the risk of approving unsafe or ineffective approaches. But within the Drug Divisions (i.e., OTC and Anesthetics, Critical Care and Addiction Medicine) that actually deal with these issues on a daily basis, there needs to be a strong executive mandate for FDA staff to be pro-active. Such a mandate could reduce the reaction time between sponsor and agency from many months to a few weeks. It could also give Division staff greater flexibility and encourage sponsors to be creative. Minor

Jerold Mande, Page 4
June 24, 1997

modifications in the review and approval process, the addition of a few staff members (perhaps paid for by sponsors of applications), and other seemingly picayune administrative details could allow new approaches to launch in 1998 or 1999, as opposed to several years later, in the next millennium.

These issues are significant to discussions on the public health, and I hope that some of my say in it has been useful to you. Also attached is a paper I presented at the 1994 World Congress on Smoking and Health in Paris; I included because I received several comments that it provided some key perspectives on tobacco control. Please do not hesitate to let me know if there is anything further I can do to help in your present work.

Sincerely yours,



Jack E. Henningfield, Ph.D.
Vice President, Research and Health Policy
Pinney Associates
Associate Professor, Behavioral Biology
Johns Hopkins University School of Medicine
President Elect,
Society for Research on Nicotine and Tobacco

cc: David Kessler, M.D., J.D.
C. Everett Koop, M.D.
John Seffrin, Ph.D.
Harold Varmus, M.D.
The Honorable Henry Waxman

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For Discussion at the Conference on " Alternative Nicotine Delivery Systems: Harm Reduction and Public Health"

March 21-23, 1997
Toronto, Canada

Jack E Henningfield
Pinney Associates and
Johns Hopkins University School of Medicine
(301) 718-8440

**Exposure Reduction by Partially or Fully Substituting
Safer Forms of Nicotine Delivery for Cigarettes**

The observation that the toxicity and addictiveness of nicotine varies widely as a function of the dosing characteristics and other constituents of nicotine delivery system raises the possibility that alternate forms of nicotine delivery could be fully or partially substituted for cigarettes. In principle, both tobacco and pharmaceutical companies could market such products and/or applications of nicotine delivery products to achieve this end. However, the degree to which individuals and society as a whole benefit from such nicotine product use might depend as much on the actual patterns of product usage as on the products themselves.

The following draft principles and questions to ask of tobacco exposure reduction efforts is an attempt to develop strategies that might lead to genuine tobacco exposure reduction and reduction of both individual and overall tobacco exposure. These principles have been under development by Jack Henningfield, John Pinney and Saul Shiffman as part of a research and development effort supported by SmithKline Beecham Consumer Healthcare and Pharmacia & Upjohn AB.

I. Basic Principles for Exposure Reduction Products and Strategies

1. The purpose of the indication or product must be to reduce the death and disease caused by tobacco.
2. The long range goal for the indication or product should be to leave smokers both tobacco- and nicotine-free.
3. It should pose no added safety risk and safety data should be extensive, including data on extended use.
4. The indication or product should not worsen the individual's level of nicotine dependence.
5. It should not reduce the likelihood of eventual cessation of tobacco use.

6. The indication or product should not lead to increased population prevalence of nicotine dependence.
7. It should not appeal to adolescents or increase the risk of adolescent misuse or abuse.
8. Marketing for the indication or product should provide consistent smoking cessation messages and offer help in quitting as well as help in terminating use.

It is important to note that these principles do not embrace the premise that nicotine dependence itself is inherently benign and that the only goal is to lessen the risk incurred, regardless of whether the prevalence of dependence is increased. The ultimate goal is for individuals to be tobacco- and nicotine-free to the greatest possible extent.

Questions to be Asked of All Indications or Products

In addition to the principles above, there are questions which could be applied to any product/indication, whether developed by a pharmaceutical company or the tobacco industry, to help insure the principles are upheld. These might include:

1. What is the intended or predicted patterns of consumer use?
2. What are the short term and long term safety/toxicity data?
3. What are the nicotine delivery characteristics?
4. What are the abuse liability and dependence potential characteristics?
5. What are the potential immediate and long term health effects for individuals?
6. What are the potential immediate and long term health effects at the population level?
7. What constituents other than nicotine are delivered to the user?
8. What are the standards for evaluation of health effects?
9. What are the regulatory issues posed by the product/indication?
10. What level of post marketing surveillance is required?
11. What is the likely effect of this indication/product on the prevalence of nicotine dependence?

These principles and questions provide a framework for careful consideration of the intent, design, and impact of an indication or product. They should be validated by scientific and regulatory experts and consistently applied to all potential uses.

NICOTINE REPLACEMENT TREATMENT AND PUBLIC HEALTH INTERVENTIONS

Toward a Marriage of Two Approaches

Leslie M. Schuh and Jack E. Henningfield

Clinical Pharmacology Branch
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INTRODUCTION

The extant goal of nicotine dependence treatment is generally to produce absolute and lasting tobacco abstinence. When this does not occur, the medication is generally considered to have been a failure. Overemphasis on this goal may lead us to ignore other medically important objectives as well as to lose sight of the more important long range goal of treatment. The long range goal of nicotine dependence treatment in individuals and public health efforts to reduce smoking prevalence in populations is the same: to reduce the morbidity and mortality associated with tobacco use. High rates of tobacco-caused morbidity and mortality and associated costs are the reason for treatment and public health efforts. From this perspective, it follows that public health objectives might be furthered by incorporating nicotine replacement medications. Similarly, nicotine replacement medications might be used to greater public health benefit by substantially broadening our views of what is considered appropriate medical use.

Let us briefly comment on the applications and consequences of public health and treatment efforts. Historically, it has been public health efforts that have had the greatest impact in increasing the numbers of nonsmokers. For example, in the U.S., public health efforts have functioned primarily to increase cessation efforts across populations and within individuals. Public health efforts may also contribute to successful, long term tobacco abstinence by providing supportive environments, such as smoke-free areas, and social reinforcement for not smoking.

The availability of treatment has not been the major direct determinant of the numbers of smokers who become nonsmokers. For example, in the United States where smoking cessation treatment and medications are more widely available than in many parts of the world, it has been estimated that, at least through the 1980's, less than 10% of people who

successfully quit smoking did so within the context of a formal treatment program, although many of these people may have been exposed to self-guided smoking cessation materials or quit in the context of a powerful variable with a treatment-like contingency, such as the encouragement of a spouse or development of a major smoking-associated illness (US DHHS, 1988). It is possible that, during 1991 and 1992 when several million smokers used a nicotine replacement product, there was an increase in overall quitting attempts, successful efforts, and the prevalence of smokers whose quitting was aided by treatment intervention, but an evaluation of the epidemiologic data is not yet available. In the future, public health and treatment efforts may mutually benefit by working more closely in coordination.

A critical factor to address is the current paradoxical state of affairs in which it is much easier to get the disease than to get treatment. Highly toxic tobacco-based nicotine delivery systems (i.e., cigarettes) are as readily available as candy in most parts of the world, but nicotine replacement medications are not available at all in many areas and, in the U.S., they are available only with a prescription from a physician.

Public health and regulatory efforts need to make it more difficult to obtain tobacco and easier to obtain replacement medications and other effective treatments, if substantial reduction in morbidity and mortality are to be achieved. Thus, both prevention and treatment should be part of a coordinated public health effort. An example of this two-pronged approach is in public health efforts to reduce malaria. Not only must one treat the disease but also reduce the likelihood of being bitten by a mosquito carrying the parasite. Treating tobacco dependence in societies that permit unrestricted access to tobacco and smoking is similar to trying to eradicate malaria in the middle of a swamp. Likewise, one would caution an alcoholic person in treatment against taking a job in a nightclub. Simply stated, if one's goal is to reduce prevalence in populations, it is beneficial to pay attention to all vectors of disease spread (including current carriers). In turn, treatment of individuals may be more effective in supportive and prophylactic environments.

Our public health efforts should strive to increase quitting efforts and to sustain abstinence among those who attempt to quit. However, these goals are just the means to a broader end: reducing death and disease. If tobacco users and others exposed to environmental tobacco smoke did not become sick and die by the millions each year, this conference would be unnecessary. It is not nicotine dependence per se that is the issue. Consider that, worldwide, many more people may be dependent to some degree on caffeine, but its toxicity is so low that there is little public health concern relative to that for tobacco and other debilitating addictive substances such as heroin and cocaine.

If one accepts the premise that the primary problem is not that people are nicotine dependent but that the resulting, repeated exposure to a highly toxic tobacco vehicle puts them at greater risk of illness and death, then perhaps we should reexamine our definitions of treatment success.

SUCCESS AND LIMITATIONS TO REPLACEMENT MEDICATIONS

When used therapeutically, nicotine replacement medications can be effective, but there are important limitations. The two usual clinical indications for nicotine replacement products are smoking itself and the withdrawal syndrome. The core problem is that, unlike the way most people drink alcohol, people who smoke rarely smoke occasionally. If their use were limited to a few cigarettes per day, the excess mortality would probably not be so great that this conference would be occurring. However, most smokers smoke 20 or more cigarettes per day and, even with minimal intervention, more than 90% of people who quit quickly relapse (Fiore et al, 1990). Hughes et al (1992) has demonstrated that relapse among self-quitters is even faster than among those in a treatment setting.

Moreover, people suffer withdrawal symptoms. It is sometimes said that no one dies from nicotine withdrawal, but this misses the point. In the long run, most efforts to quit smoking never succeed beyond the withdrawal phase. Instead, most will relapse to smoking while in the withdrawal phase (Hughes et al, 1992), and nearly 1/2 of continuing smokers will die prematurely (Doll et al, 1994).

THE GOLDEN WISH FOR SMOKING CESSATION TREATMENT

What has been looked on as the gold standard for smoking cessation treatment, a drug to use in short term treatment (i.e., 2 to 3 months) to control symptoms and produce absolute long term cessation, is in reality what we would call a golden wish. There are few if any clear examples of such drugs in all of medicine. For example, antibiotics may be used to treat bacterial infections, but reexposure to the bacterium typically leads to disease recurrence. This is not considered a medication failure. The golden wish not only imposes a unique efficacy standard to nicotine, but it runs contrary to our understanding of nicotine dependence as a chronic, relapsing disorder. Furthermore, this efficacy standard for nicotine replacement medications places the focus on the means (smoking cessation) instead of the end (reduction of death and disease).

EFFICACY TESTS

The standard indications and applications for nicotine replacement products include validated abstinence and withdrawal relief. Potential additional indications may include: 1) reduction of smoking, 2) relapse prevention, 3) sustaining mood and performance during temporary abstinence, and 4) long term control of abstinence and treatment of emergent symptoms, including weight gain and cognitive and mood declines. It is unlikely that one medication type will be equally effective on all of these potential targets for intervention. This brings us to the need for greater diversity among medications.

WHY WE NEED DIVERSE NICOTINE AND NON NICOTINE MEDICATIONS

As each smoker may present with different needs and preferences in a smoking cessation plan, there is a need to develop a diverse arsenal of treatments which may better enable us to match patient to treatment. Some factors which may be taken into account include:

- Physical reactions to medications (e.g., skin reactions to nicotine patch or poor teeth that may preclude nicotine gum use),
- Dependence related dosing needs (e.g., high dose, intermittent dosing during peak craving, or low dose maintenance preparations),
- Symptom specific preparations (e.g., withdrawal relief, relapse prevention, or abstinence specific weight control), or
- Individual preferences (e.g., some people may hate or love gum or want to use anything but a nicotine containing medication).

Of course, with diversity comes not only diversity in advantage but also diversity in risk. For example, both toxicity and abuse liability may vary across nicotine delivery systems. The cigarette appears to be the worst on both counts. It is the most abused and toxic nicotine

delivering formulation, requiring and reinforcing frequent deep pulmonary exposure to nicotine, tar and many other toxins (US DHHS, 1988). The presently developed nicotine replacement medications differ in pharmacokinetics (Henningfield & Keenan, 1993); those which act most rapidly to provide high nicotine doses likely have greater physical dependence potential and abuse liability. This may also lead to differences in how medications are regulated by regulatory agencies such as the U.S. Food and Drug Administration.

EFFICACY VS. COST EFFECTIVENESS

Many of us are frustrated that government and other third party payers will pay tens of thousands of dollars to treat a case of heart disease that could have been prevented by a few hundred dollars worth of tobacco dependence treatment. As data accumulate on short and long term benefit and cost recovery, perhaps this will become less of an issue. A basic barrier, however, is that even wealthy nations do not appear likely to make available the many billions of dollars required for the kinds of treatments many are currently promoting to be available on a massive scale.

Treatment costs primarily consist of materials cost (generally high for medications and fairly low for counseling) and professional costs (variable for medications and counseling depending on the intensity of the regimen). We may see overall cost savings if we target the more costly, intensive therapies to high risk patients (e.g., pregnant women or those with immediate, life-threatening, tobacco-associated disease such as heart disease) (Henningfield et al, 1994). In the end, an appropriate marriage between medication and counseling which considers the individual patient may be the key to cost concerns (Henningfield & Singleton, 1994).

If we accept that our ultimate goal is to reduce death and disease, not nicotine dependence treatment, we may consider additional means to this end, such as nicotine maintenance preparations or even smoking reduction. If the best we can do with some patients is reduce their smoking from 50 to 5 cigarettes per day, should we deny them therapy and medication and call them failures? When heart attack patients are given medication, told to exercise and lower dietary saturated fat, do we lock them out of the cardiology clinic and refuse medication if they don't exercise and continue eating eggs? Surely, these two sets of patients should not be measured against such different yardsticks.

RECOMMENDATIONS TO MEDICATION DEVELOPERS

Our recommendations to medication developers are twofold. Current product development, clinical testing, marketing, labeling, and pricing are based on a short term application approach. Yet, we know that there are some people with long term needs, and we suspect that there is diversity in patient need. Therefore, our first recommendation is to gather solid data on the diversity of patient medication needs and, second, to develop products and evaluate them over the range of potential applications that are indicated. Clinical trials, product design, and subsequent pricing should also be appropriate to the application. For example, maintenance products must cost less than products intended for short term use and they must be of minimal risk.

RECOMMENDATIONS TO HEALTH CARE ORGANIZATIONS

To health care organizations, first, we recommend that they work towards developing cost effective integrations of medication and non medication based approaches. It is no

longer helpful to pose these as mutually exclusive approaches as the best cessation rates have occurred in programs combining medication and counseling or behavior management (Henningfield & Singleton, 1994; US DHHS, 1988).

Second, work is urgently needed to reverse the current paradox whereby tobacco products are cheap, easily obtained, and of such strength that dependence development is likely, and medications are expensive and difficult to obtain.

Third, it is necessary to plan for the possibility that some tobacco users may be unable to function well without nicotine. Nicotine dependence usually begins in childhood or adolescence before physiological development is complete (Slade, 1991). The smoker may have used tobacco for decades. To suggest that two to three months of treatment should be sufficient for all users is shortsighted; to assume that all nicotine dependent persons may live comfortably and function effectively without continued nicotine intake may be wrong.

Fourth, realize that nicotine delivering medications may vary in toxicity and abuse liability, and there is a probable need for multiple types just as there is a need for multiple types of analgesics. Some appear appropriate for over-the-counter availability. Other medications with higher risks of side effects (including dependence and abuse) may be lifesaving for people with seemingly intractable tobacco dependence or who are at immediate substantial risk if they continue smoking (e.g., people with active heart disease), but the medications should be under greater marketing restrictions. These factors should be a consideration in matching patient to treatment and in making decisions about appropriate regulatory status of the various medications.

CONCLUSION

We have made rapid progress in the last few years in understanding the uses and limitations of nicotine replacement medications. Yet, we clearly have a long way to go, not only in developing new medications and getting the existing ones to patients, but also in increasing the flexibility with which we use medications to reach our main goal, to reduce the death and disease caused by tobacco use. We have an equally long way to go in developing an appropriate marriage of population-targeted public health efforts and individual-targeted treatment efforts. However, if the predictions of Doll and Peto are right, tens of millions will undoubtedly die in the next few decades without substantially more effective approaches.

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424

L. M. Schuh and J. E. Henningfield

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- (1) On our current course, between 10 and 20 million current cigarette smokers will prematurely develop debilitating diseases, suffer and die, because of their unmitigated tobacco use.
- (2) Under the most wildly optimistic impact of the Settlement in reducing youth tobacco use, more than 500,000 kids will continue to develop nicotine addiction every year.

Jerold Mande, Page 2
June 24, 1997

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Jerold Maile, Page 3
June 24, 1997

extent and nature of NIH research. (In December 1995, at the suggestion of Drs. Varmus and Kessler, NCI convened a working group to discuss research needs for exploring the removal of nicotine from cigarettes, but its suggestions were never implemented.) Many basic research questions need to be addressed, but they can not be addressed without funding or oversight. NIH seems to bear a considerable burden in this regard.

Reduction of tobacco toxin exposure might be an important component of our national efforts to reduce the death and disease caused by unmitigated tobacco use: Then again, it might not; this depends on how an exposure reduction scheme is implemented and on the rules of its implementation. Ameliorating smoking-related death and disease by reducing smokers' exposure to tobacco toxins is consistent with the finding of many major studies, Surgeon General's Reports, and a 1997 NCI monograph. David Burns (the editor of several Surgeon General's Reports) developed a model predicting that depending on his or her age, baseline cigarette smoking, and magnitude of smoking reduction, a smoker might enjoy an increase in life expectancy ranging from approximately one month to 5 years. On the other hand, the aggressive marketing of theoretically low-tar cigarette brands by tobacco companies led to an apparently increased risk of lung cancer. The CDC has suggested that the marketing of three cigarette brands may have lowered the motivation to quit smoking in approximately two-thirds of American smokers who have switched to such brands in their misguided exposure reduction efforts. Any accord which encourages tobacco companies to embark on even more creative schemes to sell cigarettes, without premarketing research and post marketing surveillance comparable to that expected of pharmaceutical companies, is contrary to the consensus reached in a number of recent conferences, among them the American Society of Addiction Medicine meeting held in Toronto last March. We should discourage tobacco companies from selling cigarettes made more toxic than necessary, and we should encourage pharmaceutical companies to develop products and indications that serve the many smokers who are currently unwilling or unable to completely abstain from tobacco use. Attached is a set principles for exposure reduction approaches; I have been working on for more than two years, initially as part of my efforts to help FDA evaluate novel tobacco products and more recently with my colleagues at Pinney Associates.

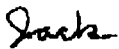
We need new treatments, developed and implemented on a more rapid timetable, with FDA in the role of partner and facilitator: One of the barriers to FDA's reducing nicotine from tobacco (if the agency even believed that was appropriate) is the relative lack of acceptable alternatives for people who are currently unable or unwilling to submit to absolute cessation therapies. Pharmaceutical companies have the resources to develop and implement new strategies that could reach many more of these people within two years. The current approval process runs on a much slower timetable, but I believe that it could be expedited without significantly increasing the risk of approving unsafe or ineffective approaches. But within the Drug Divisions (i.e., OTC and Anesthetics, Critical Care and Addiction Medicine) that actually deal with these issues on a daily basis, there needs to be a strong executive mandate for FDA staff to be pro-active. Such a mandate could reduce the reaction time between sponsor and agency from many months to a few weeks. It could also give Division staff greater flexibility and encourage sponsors to be creative. Minor

Jerold Mande, Page 4
June 24, 1997

modifications in the review and approval process, the addition of a few staff members (perhaps paid for by sponsors of applications), and other seemingly picayune administrative details could allow new approaches to launch in 1998 or 1999, as opposed to several years later, in the next millennium.

These issues are significant to discussions on the public health, and I hope that some of my say in it has been useful to you. Also attached is a paper I presented at the 1994 World Congress on Smoking and Health in Paris; I included because I received several comments that it provided some key perspectives on tobacco control. Please do not hesitate to let me know if there is anything further I can do to help in your present work.

Sincerely yours,



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cc: David Kessler, M.D., J.D.
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Harold Varmus, M.D.
The Honorable Henry Waxman

For Discussion at the Conference on " Alternative Nicotine Delivery Systems: Harm Reduction and Public Health"

March 21-23, 1997
Toronto, Canada

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**Exposure Reduction by Partially or Fully Substituting
Safer Forms of Nicotine Delivery for Cigarettes**

The observation that the toxicity and addictiveness of nicotine varies widely as a function of the dosing characteristics and other constituents of nicotine delivery system raises the possibility that alternate forms of nicotine delivery could be fully or partially substituted for cigarettes. In principle, both tobacco and pharmaceutical companies could market such products and/or applications of nicotine delivery products to achieve this end. However, the degree to which individuals and society as a whole benefit from such nicotine product use might depend as much on the actual patterns of product usage as on the products themselves.

The following draft principles and questions to ask of tobacco exposure reduction efforts is an attempt to develop strategies that might lead to genuine tobacco exposure reduction and reduction of both individual and overall tobacco exposure. These principles have been under development by Jack Henningfield, John Pinney and Saul Shiffman as part of a research and development effort supported by SmithKline Beecham Consumer Healthcare and Pharmacia & Upjohn AB.

I. Basic Principles for Exposure Reduction Products and Strategies

1. The purpose of the indication or product must be to reduce the death and disease caused by tobacco.
2. The long range goal for the indication or product should be to leave smokers both tobacco- and nicotine-free.
3. It should pose no added safety risk and safety data should be extensive, including data on extended use.
4. The indication or product should not worsen the individual's level of nicotine dependence.
5. It should not reduce the likelihood of eventual cessation of tobacco use.

6. The indication or product should not lead to increased population prevalence of nicotine dependence.
7. It should not appeal to adolescents or increase the risk of adolescent misuse or abuse.
8. Marketing for the indication or product should provide consistent smoking cessation messages and offer help in quitting as well as help in terminating use.

It is important to note that these principles do not embrace the premise that nicotine dependence itself is inherently benign and that the only goal is to lessen the risk incurred, regardless of whether the prevalence of dependence is increased. The ultimate goal is for individuals to be tobacco- and nicotine-free to the greatest possible extent.

Questions to be Asked of All Indications or Products

In addition to the principles above, there are questions which could be applied to any product/indication, whether developed by a pharmaceutical company or the tobacco industry, to help insure the principles are upheld. These might include:

1. What is the intended or predicted patterns of consumer use?
2. What are the short term and long term safety/toxicity data?
3. What are the nicotine delivery characteristics?
4. What are the abuse liability and dependence potential characteristics?
5. What are the potential immediate and long term health effects for individuals?
6. What are the potential immediate and long term health effects at the population level?
7. What constituents other than nicotine are delivered to the user?
8. What are the standards for evaluation of health effects?
9. What are the regulatory issues posed by the product/indication?
10. What level of post marketing surveillance is required?
11. What is the likely effect of this indication/product on the prevalence of nicotine dependence?

These principles and questions provide a framework for careful consideration of the intent, design, and impact of an indication or product. They should be validated by scientific and regulatory experts and consistently applied to all potential uses.

NICOTINE REPLACEMENT TREATMENT AND PUBLIC HEALTH INTERVENTIONS

Toward a Marriage of Two Approaches

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INTRODUCTION

The extant goal of nicotine dependence treatment is generally to produce absolute and lasting tobacco abstinence. When this does not occur, the medication is generally considered to have been a failure. Overemphasis on this goal may lead us to ignore other medically important objectives as well as to lose sight of the more important long range goal of treatment. The long range goal of nicotine dependence treatment in individuals and public health efforts to reduce smoking prevalence in populations is the same: to reduce the morbidity and mortality associated with tobacco use. High rates of tobacco-caused morbidity and mortality and associated costs are the reason for treatment and public health efforts. From this perspective, it follows that public health objectives might be furthered by incorporating nicotine replacement medications. Similarly, nicotine replacement medications might be used to greater public health benefit by substantially broadening our views of what is considered appropriate medical use.

Let us briefly comment on the applications and consequences of public health and treatment efforts. Historically, it has been public health efforts that have had the greatest impact in increasing the numbers of nonsmokers. For example, in the U.S., public health efforts have functioned primarily to increase cessation efforts across populations and within individuals. Public health efforts may also contribute to successful, long term tobacco abstinence by providing supportive environments, such as smoke-free areas, and social reinforcement for not smoking.

The availability of treatment has not been the major direct determinant of the numbers of smokers who become nonsmokers. For example, in the United States where smoking cessation treatment and medications are more widely available than in many parts of the world, it has been estimated that, at least through the 1980's, less than 10% of people who

successfully quit smoking did so within the context of a formal treatment program, although many of these people may have been exposed to self-guided smoking cessation materials or quit in the context of a powerful variable with a treatment-like contingency, such as the encouragement of a spouse or development of a major smoking-associated illness (US DHHS, 1988). It is possible that, during 1991 and 1992 when several million smokers used a nicotine replacement product, there was an increase in overall quitting attempts, successful efforts, and the prevalence of smokers whose quitting was aided by treatment intervention, but an evaluation of the epidemiologic data is not yet available. In the future, public health and treatment efforts may mutually benefit by working more closely in coordination.

A critical factor to address is the current paradoxical state of affairs in which it is much easier to get the disease than to get treatment. Highly toxic tobacco-based nicotine delivery systems (i.e., cigarettes) are as readily available as candy in most parts of the world, but nicotine replacement medications are not available at all in many areas and, in the U.S., they are available only with a prescription from a physician.

Public health and regulatory efforts need to make it more difficult to obtain tobacco and easier to obtain replacement medications and other effective treatments, if substantial reduction in morbidity and mortality are to be achieved. Thus, both prevention and treatment should be part of a coordinated public health effort. An example of this two-pronged approach is in public health efforts to reduce malaria. Not only must one treat the disease but also reduce the likelihood of being bitten by a mosquito carrying the parasite. Treating tobacco dependence in societies that permit unrestricted access to tobacco and smoking is similar to trying to eradicate malaria in the middle of a swamp. Likewise, one would caution an alcoholic person in treatment against taking a job in a nightclub. Simply stated, if one's goal is to reduce prevalence in populations, it is beneficial to pay attention to all vectors of disease spread (including current carriers). In turn, treatment of individuals may be more effective in supportive and prophylactic environments.

Our public health efforts should strive to increase quitting efforts and to sustain abstinence among those who attempt to quit. However, these goals are just the means to a broader end: reducing death and disease. If tobacco users and others exposed to environmental tobacco smoke did not become sick and die by the millions each year, this conference would be unnecessary. It is not nicotine dependence per se that is the issue. Consider that, worldwide, many more people may be dependent to some degree on caffeine, but its toxicity is so low that there is little public health concern relative to that for tobacco and other debilitating addictive substances such as heroin and cocaine.

If one accepts the premise that the primary problem is not that people are nicotine dependent but that the resulting, repeated exposure to a highly toxic tobacco vehicle puts them at greater risk of illness and death, then perhaps we should reexamine our definitions of treatment success.

SUCCESS AND LIMITATIONS TO REPLACEMENT MEDICATIONS

When used therapeutically, nicotine replacement medications can be effective, but there are important limitations. The two usual clinical indications for nicotine replacement products are smoking itself and the withdrawal syndrome. The core problem is that, unlike the way most people drink alcohol, people who smoke rarely smoke occasionally. If their use were limited to a few cigarettes per day, the excess mortality would probably not be so great that this conference would be occurring. However, most smokers smoke 20 or more cigarettes per day and, even with minimal intervention, more than 90% of people who quit quickly relapse (Fiore et al, 1990). Hughes et al (1992) has demonstrated that relapse among self-quitters is even faster than among those in a treatment setting.

Moreover, people suffer withdrawal symptoms. It is sometimes said that no one dies from nicotine withdrawal, but this misses the point. In the long run, most efforts to quit smoking never succeed beyond the withdrawal phase. Instead, most will relapse to smoking while in the withdrawal phase (Hughes et al, 1992), and nearly 1/2 of continuing smokers will die prematurely (Doll et al, 1994).

THE GOLDEN WISH FOR SMOKING CESSATION TREATMENT

What has been looked on as the gold standard for smoking cessation treatment, a drug to use in short term treatment (i.e., 2 to 3 months) to control symptoms and produce absolute long term cessation, is in reality what we would call a golden wish. There are few if any clear examples of such drugs in all of medicine. For example, antibiotics may be used to treat bacterial infections, but reexposure to the bacterium typically leads to disease reoccurrence. This is not considered a medication failure. The golden wish not only imposes a unique efficacy standard to nicotine, but it runs contrary to our understanding of nicotine dependence as a chronic, relapsing disorder. Furthermore, this efficacy standard for nicotine replacement medications places the focus on the means (smoking cessation) instead of the end (reduction of death and disease).

EFFICACY TESTS

The standard indications and applications for nicotine replacement products include validated abstinence and withdrawal relief. Potential additional indications may include: 1) reduction of smoking, 2) relapse prevention, 3) sustaining mood and performance during temporary abstinence, and 4) long term control of abstinence and treatment of emergent symptoms, including weight gain and cognitive and mood declines. It is unlikely that one medication type will be equally effective on all of these potential targets for intervention. This brings us to the need for greater diversity among medications.

WHY WE NEED DIVERSE NICOTINE AND NON NICOTINE MEDICATIONS

As each smoker may present with different needs and preferences in a smoking cessation plan, there is a need to develop a diverse arsenal of treatments which may better enable us to match patient to treatment. Some factors which may be taken into account include:

- Physical reactions to medications (e.g., skin reactions to nicotine patch or poor teeth that may preclude nicotine gum use),
- Dependence related dosing needs (e.g., high dose, intermittent dosing during peak craving, or low dose maintenance preparations),
- Symptom specific preparations (e.g., withdrawal relief, relapse prevention, or abstinence specific weight control), or
- Individual preferences (e.g., some people may hate or love gum or want to use anything but a nicotine containing medication).

Of course, with diversity comes not only diversity in advantage but also diversity in risk. For example, both toxicity and abuse liability may vary across nicotine delivery systems. The cigarette appears to be the worst on both counts. It is the most abused and toxic nicotine

delivering formulation, requiring and reinforcing frequent deep pulmonary exposure to nicotine, tar and many other toxins (US DHHS, 1988). The presently developed nicotine replacement medications differ in pharmacokinetics (Henningfield & Keenan, 1993); those which act most rapidly to provide high nicotine doses likely have greater physical dependence potential and abuse liability. This may also lead to differences in how medications are regulated by regulatory agencies such as the U.S. Food and Drug Administration.

EFFICACY VS. COST EFFECTIVENESS

Many of us are frustrated that government and other third party payers will pay tens of thousands of dollars to treat a case of heart disease that could have been prevented by a few hundred dollars worth of tobacco dependence treatment. As data accumulate on short and long term benefit and cost recovery, perhaps this will become less of an issue. A basic barrier, however, is that even wealthy nations do not appear likely to make available the many billions of dollars required for the kinds of treatments many are currently promoting to be available on a massive scale.

Treatment costs primarily consist of materials cost (generally high for medications and fairly low for counseling) and professional costs (variable for medications and counseling depending on the intensity of the regimen). We may see overall cost savings if we target the more costly, intensive therapies to high risk patients (e.g., pregnant women or those with immediate, life-threatening, tobacco-associated disease such as heart disease) (Henningfield et al, 1994). In the end, an appropriate marriage between medication and counseling which considers the individual patient may be the key to cost concerns (Henningfield & Singleton, 1994).

If we accept that our ultimate goal is to reduce death and disease, not nicotine dependence treatment, we may consider additional means to this end, such as nicotine maintenance preparations or even smoking reduction. If the best we can do with some patients is reduce their smoking from 50 to 5 cigarettes per day, should we deny them therapy and medication and call them failures? When heart attack patients are given medication, told to exercise and lower dietary saturated fat, do we lock them out of the cardiology clinic and refuse medication if they don't exercise and continue eating eggs? Surely, these two sets of patients should not be measured against such different yardsticks.

RECOMMENDATIONS TO MEDICATION DEVELOPERS

Our recommendations to medication developers are twofold. Current product development, clinical testing, marketing, labeling, and pricing are based on a short term application approach. Yet, we know that there are some people with long term needs, and we suspect that there is diversity in patient need. Therefore, our first recommendation is to gather solid data on the diversity of patient medication needs and, second, to develop products and evaluate them over the range of potential applications that are indicated. Clinical trials, product design, and subsequent pricing should also be appropriate to the application. For example, maintenance products must cost less than products intended for short term use and they must be of minimal risk.

RECOMMENDATIONS TO HEALTH CARE ORGANIZATIONS

To health care organizations, first, we recommend that they work towards developing cost effective integrations of medication and non medication based approaches. It is no

longer helpful to pose these as mutually exclusive approaches as the best cessation rates have occurred in programs combining medication and counseling or behavior management (Henningfield & Singleton, 1994; US DHHS, 1988).

Second, work is urgently needed to reverse the current paradox whereby tobacco products are cheap, easily obtained, and of such strength that dependence development is likely, and medications are expensive and difficult to obtain.

Third, it is necessary to plan for the possibility that some tobacco users may be unable to function well without nicotine. Nicotine dependence usually begins in childhood or adolescence before physiological development is complete (Slade, 1991). The smoker may have used tobacco for decades. To suggest that two to three months of treatment should be sufficient for all users is shortsighted; to assume that all nicotine dependent persons may live comfortably and function effectively without continued nicotine intake may be wrong.

Fourth, realize that nicotine delivering medications may vary in toxicity and abuse liability, and there is a probable need for multiple types just as there is a need for multiple types of analgesics. Some appear appropriate for over-the-counter availability. Other medications with higher risks of side effects (including dependence and abuse) may be lifesaving for people with seemingly intractable tobacco dependence or who are at immediate substantial risk if they continue smoking (e.g., people with active heart disease), but the medications should be under greater marketing restrictions. These factors should be a consideration in matching patient to treatment and in making decisions about appropriate regulatory status of the various medications.

CONCLUSION

We have made rapid progress in the last few years in understanding the uses and limitations of nicotine replacement medications. Yet, we clearly have a long way to go, not only in developing new medications and getting the existing ones to patients, but also in increasing the flexibility with which we use medications to reach our main goal, to reduce the death and disease caused by tobacco use. We have an equally long way to go in developing an appropriate marriage of population-targeted public health efforts and individual-targeted treatment efforts. However, if the predictions of Doll and Peto are right, tens of millions will undoubtedly die in the next few decades without substantially more effective approaches.

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424

L. M. Schuh and J. E. Henningfield

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