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FUNDING FOR SMOKING CESSATION

An Interactive Qualifying Project Report

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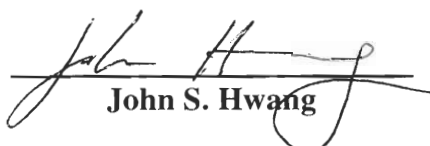
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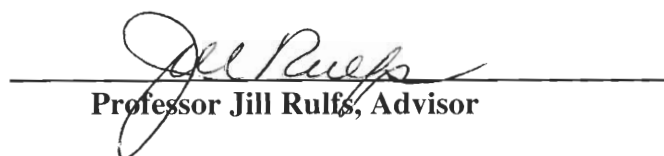
Degree of Bachelor of Science

by


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1. bupropion
2. smoking cessation
3. Medicaid

ABSTRACT

The initiative to have the Massachusetts Medicaid system include Zyban in their formulary for smoking cessation as a drug intervention therapy is a collaborative with the Worcester Healthcare Outreach and Worcester Polytechnic Institute. Research through relevant literature and contact with professionals in the medical discipline showed data that permitted a proposal for a study to directly link Zyban to cost savings. Access to drug cessation therapies can provide general improvement in health as well as save costs for the state.

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INTRODUCTION

Over the last two decades, smoking tobacco products has been linked to many health problems including lung cancer, heart disease, and respiratory dysfunction. A variety of studies have been conducted to assess the direct risks of smoking, some providing statistical analysis of relative risks (Lightwood et al. 1997) and others providing a more subtle inference of risk. (Chen et al. 1996) In addition to the increased risk of health related problems for smokers, studies have also indicated a relationship between increased asthma events in young children and smoking by the parent, and higher medical costs from low-birthweight infant incidences of pregnant smokers; however, the incidence of low-birthweight events is the same for pregnant smokers and non-smokers.

The medical expenditures attributed to cigarette smoking can be assessed by identifying medical care utilized for certain smoking attributed health problems and the associated collective cost. Using this approach, the annual direct health expenditures that are attributable to smoking, such as hospitalizations, physician care or prescriptions for health problems noted above, is estimated to be \$40-50 billion in 1993 nationally. (Adams et al. 1997) Not included in this estimate are the additional costs to third party payers for medical care resulting from second hand or environmental tobacco smoke (ETS) exposure as noted above.

Thus the identification and implementation of an intervention program to induce or increase smoking cessation should potentially increase the health of current smokers and those exposed to environmental tobacco smoke, and save medical insurance

programs as well as publicly funded institutions millions of dollars annually. (Adams et al. 1997)

Many smoking cessation programs have been scrutinized for their efficacy and cost effectiveness over the past several years. From brief counseling by a physician to available drug therapy, including nicotine replacement therapy, many of these techniques have been examined in a variety of studies with a variety of results. Recently, a smoking cessation program, which utilizes the drug bupropion hydrochloride produced by Glaxo-Wellcome as Zyban, has received significant attention in the medical community.

Zyban is the first non-nicotine drug approved by the FDA for use in smoking cessation. Bupropion hydrochloride is also prescribed for depression under the name Wellbutrin. Prepared in slow-release tablets, this amino-ketone antidepressant weakly inhibits the synaptic reuptake of norepinephrine and dopamine in neurons in the nucleus accumbens, a pleasure-reinforcing region of the brain. (Dale et al. 1998) Nicotine enhances neurotransmitter release in neurons which may account for the addictive properties of cigarette smoking. In the absence of nicotine, there is an attenuation of neurotransmitter production. The inhibitory properties of bupropion on neurotransmitter reuptake may act to make the resulting withdrawal symptoms of cessation less intense. The psychological effect of Zyban on nicotine addiction is what differentiates this drug from nicotine replacement therapies which primarily deal with the physical effects of the addiction. (Dale et al. 1998)

Interestingly, there is a higher percentage of smokers, about 37%, among the indigent population in the United States than in the population at large, around 26%. (Jaén et al. 1997) Many of these smokers also develop health problems due to smoking

and need extensive health care and services years later. Publicly funded programs such as Medicaid provide health services to a large part of this population, and smoking attributable care can be extrapolated to be a substantial proportion of the total costs, an estimated 14.4% of all Medicaid expenditures. (Miller et al. 1998) However, many such programs do not provide coverage of prescription drugs used in smoking cessation because this coverage is not required by federal standards. Not surprisingly, in addition to being more likely to smoke, Medicaid recipients are also less likely to feel they are able to afford to pay for pharmacologic interventions to stop smoking.

Currently, the Massachusetts Department of Health does not provide Zyban through Medicaid whose recipients are largely those under the federal poverty level. Worcester Healthcare Outreach, a Robert Wood Johnson funded collaborative of Worcester area health care providers whose mission is to improve health care access to the uninsured population, hopes to convince the Massachusetts Medicaid system to append Zyban to its state drug utilization specifications. The deputy commissioner of public health for Massachusetts has suggested that in order to convince the state legislature to implement this change, an analysis of costs spent on Zyban-based cessation programs and related cost savings accrued by decreased health expenditures on smoking-related diseases must be available. The initial purpose of this project, done in collaboration with the WHO organization, was to determine whether such an analysis existed either in the published literature or through any states that might provide Zyban to Medicaid recipients. If this data and subsequent analysis did not exist, a study which could directly demonstrate costs savings which resulted from the addition of Zyban to the Medicaid formulary was to be designed and proposed to the deputy commissioner for her

consideration and subsequent implementation. Results of such a study would be expected to provide incentive for the legislature to change the current policies by demonstrating that the pharmaceutical product is sufficiently effective in promoting successful smoking cessation and reducing smoking related medical problems that it would be cost effective to provide it under the state regulated Medicaid program.

METHODS AND MATERIALS

In order to determine whether such data was available in studies published in the medical or public health literature, a search was done on the Internet to relevant data. Medline (www.ncbi.nlm.nih.gov/PubMed/) was the primary search tool on the Internet used to find scientific and medical articles that dealt with topics from smoking cessation to Zyban to cost effectiveness studies. The articles were then found at the University of Massachusetts Medical Center library and photocopied for further analysis of data.

In an attempt to see if the data might be available from states which currently provide Zyban as part of their Medicaid formulary, the website for the Health Care Financing Administration (HCFA), at www.hcfa.gov, was visited for any information regarding Medicaid statistics. Information on state drug utilization was found for each state and contact information was given for the states' public health departments; unfortunately, most of them could not be contacted for any data.

Finally, using the information regarding study design and analysis from the available literature, two studies were proposed which would be of short enough duration and provide sufficient direct links between money spent on Zyban and money saved on smoking related medical care costs. The literature used in this study provided data on

smoking cessation programs, cost-effectiveness analysis of intervention programs, statistics on health risks of smoking and the effectiveness of Zyban. The studies proposed relate smoking cessation programs using Zyban to the costs saved on health expenditures for asthmatic children exposed to ETS and pregnant smokers and low-birth weight infants which will be detailed further in this analysis.

RESULTS

SHORT TERM EFFECTS OF SMOKING CESSATION

EFFECTS OF ENVIRONMENTAL TOBACCO SMOKE

While there are many long-term health consequences of smoking, including cancer, stroke and heart disease, it is also evident that smoking can exacerbate existing conditions and contribute to more immediate problems, either directly or indirectly. A study of ETS and its effects on allergic and non-allergic asthmatic children was done to examine the relationship between smoking by parents and the onset of asthma or changes in the severity of asthmatic events from exposure. (Chen et al. 1996) There is no conclusive evidence of ETS causing the onset of all asthmatic events in children in households where parents smoke. Interestingly, about 80% of asthmatic children are “allergic”, meaning that this population has a history of allergies, mostly to airborne particles. Several significant outcomes of this study rely on a differentiation between children with allergic and children with non-allergic asthma.

The significant results of this study can be seen in Tables 1 and 2. Table 1 shows the prevalence of asthma history by history of allergy and smoking variables. The study subjects are grouped into “no allergy” and “any allergy” categories, and the percentage of

children in each category who have had asthma events are reported for specific variables, including the parental smoking status, number of household smokers and number of cigarettes consumed in the household. Cases of “ever-asthma” represent events when the child has ever had an asthma attack and cases of recent-asthma signifies an asthma attack within the previous 12 months of this study. As can be seen, children with no allergies have higher cases of asthma events when the parents are smokers or increase the number of household smokers and/or cigarettes consumed in the home as compared with non-allergic asthmatics whose parental status is non/ex-smoking but not significantly. The case of events in the “any allergy” category vary inconsistently, indicating that ETS may not be the sole contributor of asthma attacks in these children. Other bronchial irritants may be responsible. Collectively, these data indicate that smoking does not increase or contribute to the onset of asthma in either allergic or non-allergic children.

Conversely, the results in Table 2 suggest that for non-allergic children there is an increased odds ratio (OR) for asthma relative to each of the smoking variables examined. An OR of 1 was assigned as the reference for non-smoking households. As the data show, in children with no recorded history of allergies, both the unadjusted and the adjusted OR increase when ETS is present or more prevalent in the home as compared to the control. Compared to the non-smoking odds ratio of 1, the OR for children in houses with paternal smoking is 2.47, maternal smoking is 2.93 and greater than two household smokers is 5.77. In allergic children these numbers are 1.44, 1.80 and 1.54 respectively. These data indicate that ETS has a more significant effect on children with no documented allergies than with children who have previously recognized allergies. This may be explained by the fact that in allergic children, asthma is exacerbated by other

airborne particles or possibly that the parents of allergic asthmatic children take care not to smoke or at least smoke around their children if a history of allergies is known.

However, for non-asthmatic children, smoking increases the odds ratio for asthma 2 to 6 fold for all of the smoking related variables examined. (Chen et al. 1996)

A study examining the reduction of ETS exposure in asthmatic children by counseling intervention was carried out with a 2-year follow-up to examine the effects of intervention programs on household ETS exposure. (Wahlgren et al. 1997) The study data documents a 79% decrease in ETS exposure, which is twice the decrease attained by the control group. Figure 1 shows the results of ETS reduction on the severity of asthma symptoms, using symptom ratings from 0=none to 4=severe. While the experimental counseling group had a higher average baseline symptom rating (1.6), it gradually decreased over the course of the study to about 1.2. The control groups (monitoring by physician or usual treatment) had a lower baseline rating (1.2-1.3), and both control groups showed a slight increase in severity of symptoms over the follow-up period. These data are consistent with a reduction in the severity of asthma symptoms with the reduction of exposure to ETS in children. If these trends related to intervention continued over time, it could translate into a reduction in the use of asthma related health care services and potential savings in cost. Conversely, the costs over time for the control groups might be predicted to rise with continued ETS exposure.

PREGNANT SMOKERS AND LOW BIRTHWEIGHT INFANTS

A report from the Centers for Disease Control and Prevention in 1993 attributed an estimated 32,000-61,000 cases of low-birthweight infants and 14,000-26,000

admissions to neonatal intensive care units to smoking during pregnancy, This translated to estimated direct medical care costs of approximately \$50 billion. (Adams et al. 1997) These estimates assume a smoking prevalence in pregnant women of between 19 and 27%. Interestingly, the probability of complicated births is about equal in both smoking and non-smoking pregnant populations; however, the estimated cost in 1987 dollars of a complicated birth was about \$10,894 for smokers vs. \$6544 for non-smokers. This difference is statistically significant with a p value less than 0.01. In 1987, the national medical-care expenditures for complicated births attributable to smoking during pregnancy were estimated to be \$791 million with a conservative estimate of a 19% prevalence of pregnant smokers. This constitutes 11% of the total costs for all complicated births. Assuming the same prevalence of smoking, in 1995 dollars, the estimate came to \$1.4 billion which was also 11% of the total costs for all complicated births in 1995.

Pregnant smokers show a greater intention of quitting in their first trimester than women in later stages of pregnancy. These intentions are based on concern for the health of the unborn child. (Hutchison et al. 1996) This may be the most critical time for cessation interventions for this particular population. A cost-benefit analysis of smoking cessation programs for pregnant women in their first trimester intended to prevent low birthweight occurrences was conducted. (Hueston et al. 1994) A decision model, illustrated in Figure 2, was used to analyze the effect of smoking cessation programs on low birthweight outcomes. In this model, women were assigned to two groups based on their decision about quitting smoking (quit or do not quit). Then the groups were followed, and the incidence of low birthweight as a percentage of total births in that

group was recorded. Among pregnant smokers, there was a 7.8% incidence of low birthweight infants in those who quit smoking compared to a 9.6% incidence in women who did not quit, which is not significant, as we mentioned earlier since smokers and non-smokers had about the same low birthweight incidences. It is estimated to cost an average of \$43,755 to treat a low birthweight infant and \$2738 to treat a normal birth infant. To calculate the efficacy of a smoking cessation program in saving costs, an 18% quit rate (midpoint between an estimate of cessation intervention effectiveness of 3-29%) was used. Using this figure, a program costing about \$84 per participant was calculated to be the break-even cost. Figure 3 is a graph of the break-even cost vs. baseline program effectiveness. Clearly, the higher the effectiveness of a program, the more a program can cost. The quit rate shown on the X axis in Figure 3 is the quit rate above baseline or the percentage increase in quit rate over that of the control group. However, pregnant women in their first trimester are more likely to quit than women in later stages of pregnancy and non-pregnant women; therefore, this population has a higher spontaneous quit rate. The data in Figure 3 is based on a relatively high spontaneous quit rate of a 37%. With lower spontaneous quit rates, the break-even cost of a program could be higher. The higher the effectiveness rate and the lower the spontaneous quit rate, the more a program can spend on intervention and still break even (see Table 3).

RELATIVE RISKS OF MYOCARDIAL INFARCTION AND STROKE

Although acute myocardial infarction (AMI) and stroke are somewhat longer term effects of cigarette smoking, the short-term economic and health benefits of smoking cessation can be detected by analysis of cost savings in the decrease of hospitalizations

for stroke and MI. (Lightwood et al. 1997) The impact of cessation increases rapidly when costs related to heart disease and stroke are considered, as opposed to those for cancer and emphysema. Lightwood et al. mentioned that within the first 2 years, the excess risk of AMI and stroke can go down to nearly 50%. The first year after cessation, it is estimated that nationally there may be 924 fewer hospitalizations for AMI and 528 fewer for stroke. The numbers will increase to reduce AMI related hospitalizations by 3234 and stroke related hospitalizations by 1669 in the 7th year. This estimated decline is graphically displayed in Figure 4 which shows the exponential decrease of relative risks of both AMI and stroke, over time, due to smoking cessation. Both graphs show an eventual stabilization after about 4 years, as relative risk almost equals that of non-smokers. There are two curves for the AMI graph because the relative risks for male and female differ. Estimated in 1995 dollars, using the estimates from Figure 4, approximately \$44 million could be saved in medical care costs in the first year and nearly \$933 million in cumulative costs over a 7-year period.

The numbers and dollars change if a different model is used. The previous estimates assumed a one-time, 1% reduction in smoking prevalence in the general population. Another possibility is an annual 1% reduction in smoking prevalence, as is demonstrated by the decrease in smoking prevalence in California. Figure 5 shows the reduction in smoking prevalence in the United States as a whole and in California. After Prop 99, a program of anti-smoking media and community-based programs, was passed in California, an annual 1% in smoking prevalence was measured. This comes to a cumulative reduction in 18,356 AMI and 9729 stroke related hospitalizations in 7 years which would amount to a 7-year savings of \$3.2 billion dollars. Table 4 shows the cases

reduced and dollars saved using both types of models. In California, Prop 99, which cost about \$411 million dollars to implement would be paid for in 3 years. (Lightwood et al. 1997)

LOOKING AT THE LONG TERM EFFECTS OF CESSATION

LONG TERM MEDICAL EXPENDITURES

If we look at the more general picture and more in the long run, the effects of cessation are staggering in terms of health and cost savings. A report on Medicaid expenditures attributable to smoking was done in the 1993 fiscal year for each state. (Miller et al. 1998) The average smoking attributable fraction (SAF) of Medicaid expenditures is 14.4% for all states and Washington, D.C. Table 5 lists the SAFs for each state. Each state's SAF can be further divided by type of medical care such as ambulatory care, hospital care, and prescription drugs. For the state of Massachusetts, the SAF is 14.33% which is near the national average. In 1993 the estimated costs for these services was \$12.9 billion in 1993, with a relative error of 40.3%. Table 6 shows the smoking attributable expenditures (SAE) for each state in 1993. The expenditures for each type of medical service are also given. Massachusetts spent approximately \$405 million of Medicaid funding for smoking attributable health care costs.

Since many public health care officials are cautious about providing publicly funded smoking cessation programs to an indigent and migratory population such as Medicaid recipients, a study was done to discern the pattern of use of a free transdermal nicotine patch program among Medicaid and uninsured patients. (Jaén et al. 1997) Around 49% of the study subjects completed the program. Of these, 81% provided

follow-up data with 90% saying the program was helpful. There was no indication that such a population would not use a smoking cessation program effectively as a more affluent population; however, statistical data on a more affluent population was not provided. It is also noted that among those under the poverty level, 37% of American adults smoke as opposed to 26% in the general population, which indicates that this population is an important pool to whom cessation intervention should be available.

COSTS OF SMOKING TO SOCIETY

The impact of smoking on society should include considerations other than the cost of medical care for smoking related illness. Smoking can speed up the onset of other diseases such as cataracts and hip fractures. Recovery from illness and surgical procedures can be delayed due to overall poor health of the smoker. The effects of passive smoke, not only in asthmatic children and in pregnant women, can increase the passive smokers' chance of lung cancer by 26%, ischemic heart disease by 23%, and acute respiratory illness by 25%. Smoking related work absences and lower productivity can cost industry up to \$47 billion annually. Around \$552 million annually can be attributed to fires caused by cigarettes. These factors are worth considering even when we are thinking only in terms of dollars. (Cohen et al. 1998)

EFFECTIVENESS OF BUPROPION

Bupropion hydrochloride, also known as Zyban, is a non-nicotine alternative to other cessation therapies that works more on the psychological addiction to cigarettes. The program works by setting a target quit date at about 8 days after the start of the

treatment in a 7-12-week prescription program at 300-mg doses daily. Bupropion is different than other drug therapies such as nicotine replacement in that withdrawal symptoms seem to be less severe and weight gain after quitting is not as dramatic which can be a major incentive to be on such a therapy (Hurt et al. 1997) A study done using bupropion and placebo indicates that at 6 weeks, quit rates can be as high as 44.2% for the Zyban group, with a quit rate remaining as high as 23.1% at 1 year. These numbers compare to 19% at six weeks and 12.4% at 1 year for the placebo group (see Table 7). Abstinence was determined by self-reporting and carbon monoxide measurements in exhaled air. Figure 6 shows a graph of continuous abstinence from smoking in subjects with the Zyban (300-mg dose) group at 24.4% at month 6 as compared to the placebo group at 10.5% at month 6.

A study comparing the efficacy of bupropion and transdermal nicotine patches reveal that bupropion can be almost twice as effective in terms of continuous abstinence than the nicotine patch (18.4% compared with 9.8% at month 12, respectively). (Jorenby et al. 1999) A cost effectiveness study was done on the use of the nicotine patch in terms of quality-adjusted life years saved (QALYS). Table 8 compares the QALYS from the use of the nicotine patch to that for routine screening for asymptomatic hypertension, according to age and gender. In every category, the cost per QALY was for the cessation therapy than the screening procedure. The increase in the cost of screening versus cessation therapy ranged from 130% to 478% among the different groups. The cost of the nicotine patch therapy is around \$111.90/month (for a 2-month therapy) with physician time at approximately \$80 per hour. (Fiscella et al. 1996) Bupropion can cost up to \$186 for a 10-week, 150-mg/day supply, which comes to a 7-week, 300-mg/day

supply cost of \$260.85, plus physician time. (Medical Letter, August 15, 1997) Although slightly more expensive than the nicotine patch therapy (but not by much), if the efficacy of bupropion is almost twice that of the patch therapy which has been shown to be somewhat cost effective, it follows that bupropion use in smoking cessation can also be cost effective.

STUDY DESIGN

DESIGN CONSIDERATION

As can be seen in Figure 7, currently twenty-seven states and the District of Columbia include Zyban in their Medicaid formulary. (State drug utilization data, 1998, HCFA website at www.hcfa.com) The Massachusetts Division of Medical Assistance wants direct evidence to show the cost savings of providing Zyban to Medicaid recipients. In conversation with the director of MassHealth, it became clear that in order to change the current formulary, direct evidence of cost efficacy was needed. Essentially, the medical care costs saved had to pay for the cost of providing Zyban within a year or two. Since Zyban is relatively new and many states have just added it to their state drug utilization lists, cost-benefit analysis outcome data are not readily available. In designing a study to produce reliable outcome data that could be presented to the legislature, one clear consideration was the length of time it might take to demonstrate cost savings. Clearly, the shorter the duration of the study, the sooner the data would be available to begin the process of adding Zyban to the Medicaid formulary. If the program were to pay for itself in a year or two, the benefits of cessation measured would also need to be relatively short-term

According to the statistical data found on the Health Care Finance Administration (HCFA) website on the Internet in 1995, there were 18.7 million Medicaid recipients who were dependents less than 21 years of age. This is 51.5% of the total Medicaid population and is double the number in 1975. The female recipients of Medicaid total 21.2 million in 1995 and constitute 58.5% of the total population. These and other group data are presented in Table 9. What these numbers suggests is that these populations are important targets for studies which may affect any change in Medicaid policy.

Population availability was not regarded as problematic since the WHO and University of Massachusetts Medical Center physicians were certain that the network of providers involved collectively had sufficient numbers of patients to populate the study.

An initial contact was made with Roger Luckman, M.D. at the University of Massachusetts Medical Center in the Family and Community Medicine department to see if he had knowledge of outcome data from states providing Zyban. He did not, but suggested a study where one group of participants receive the Zyban program for free while patients in another group pay for their prescription and counseling, with the outcome data being the quit rates. This might be effective in showing that it is not necessarily the freely availability in terms of cost that might increase quit rates. Those who pay might be encouraged to finish the program and achieve abstinence since their own money is invested. This study would not, however, directly address costs saved versus costs accrued by providing Zyban. After reading the available literature and assessing the study parameters necessary to obtain the data over a relatively short time, two other studies were developed, one concerning the reduction of ETS in households

with asthmatic children by smoking cessation and the other, cessation in pregnant smokers to prevent low birthweight incidences and costs.

PROPOSALS FOR A STUDY OF THE COST-BENEFIT ANALYSIS OF ZYBAN IN SMOKING CESSATION

The officials in the Department of Medical Assistance, as with many parties associated with managed health care, want to be able to see short term outcomes of the efficacy of Zyban in saving health costs in order to take the measures to implement such a publicly funded cessation program. One scenario that can apply smoking cessation with short term cost savings is the influence of environmental tobacco smoke (ETS) on asthma in children.

ETS/ASTHMA STUDY

Target patients: Medicaid patients, specifically families with at least one child between 2 and 12 years old with no previously diagnosed allergies, who live in a household with at least one parent smoker.

Experimental group: The smokers receive counseling and Zyban therapy at no cost.

Three control groups: The same family description, but 1) the smokers have no desire to quit, 2) the smokers receive brief counseling by physician, and 3) the smokers receive counseling and nicotine patch therapy, all at no cost.

Study parameters:

- Each participant will be screened by physical examination (previous and recent events of asthma) and given a questionnaire at the 1st clinic visit inquiring about allergic status of children, health status of both parent and child, number of cigarettes

smoked daily and number smoked in the home, and use of health services by the parent for the child. The physician will also be able to obtain a history of the target child's respiratory illnesses through the Medicaid records.

- Those in the Zyban group will receive a week's supply of the drug and instructed to take a single 150 mg dose for the first three days and 2 doses of 150 mg each on subsequent days for a total period of 7 weeks.
- Target quit date will be set at 8 days after initiation of treatment

Follow-up

- Those receiving any form of therapy will be asked to return weekly for the 1st 7 weeks and at week 8, 12, 26, and 52.
- Those in Zyban group will receive a week's supply of Zyban at each weekly visit in the 7-week period
- Subjects in all groups will be asked about changes in amount or severity of asthma symptoms in child. Those in no-quit control group will be called about status of child's health.
- Cessation progress will be tested by self-reporting and carbon monoxide count in exhaled air with <10 ppm defined as an indication of abstinence.

Another potential study would be one which provides Zyban to pregnant smokers during their first trimester and follows the weight of the infant at birth. This study would be ideal because of the short and specifically defined term period between initiation of the study and collection of outcome data. Within a year, the health outcomes of infants and cost analysis could be carried out and calculated.

The Zyban Information sheet provided by its manufacturer, Glaxo-Wellcome, states that although there should be no apparent side effects in pregnant women and the fetus, there have not been sufficient data. It advises physicians to prescribe Zyban to pregnant women with caution, taking care to note the history of the patient (and other patients). Those who are on the anti-depressant Wellbutrin and who have a history of seizures should not be prescribed Zyban since it may cause seizures in these patients. Thus, it may be advisable to not provide Zyban to the pregnant smoker population; nonetheless, a study design for this population will be proposed in the event that it becomes absolutely safe for these women to take Zyban.

Low Birthweight Infants from Pregnant Smokers

Target patients: pregnant smokers in their 1st trimester

Experimental group: those receiving counseling and Zyban therapy

Two control groups: pregnant smokers with no desire to quit and pregnant smokers who receive brief counseling by physician. No NRT group is included because of the demonstrated negative effects of nicotine on fetuses.

Study parameters:

- Each participant will be screened by physical examination on the health of the pregnant subject and the fetus and given a questionnaire at the 1st clinic visit inquiring about health history, smoking status, number of cigarettes consumed daily, and the intention to quit; patient history can be obtained by the physician through Medicaid records.

- Those in the Zyban group will receive the drug and be instructed to take a single 150 mg dose for the first three days and take 2 doses of 150 mg each on each subsequent days daily for a total period of 7 weeks
- Target quit date will be set at 8 days after treatment

Follow-up

- Return weekly for the 1st 7 weeks and at week 8, 12, and 26.
- Those in Zyban group will receive a week's supply of Zyban at each weekly visit in the 7-week period while checking the status of the pregnancy; cessation progress can be monitored by self-reporting and carbon monoxide counts in exhaled air or cotinine levels in urine.

At the end of both of these studies, health costs of child hospitalizations or prescriptions or low birthweight costs can be obtained. The total medical costs of the target child in the ETS study or the costs of infant care at birth can be collected during the year long study and compared to the cost of providing Zyban, along with physician time, to the subjects. A questionnaire asking parents about incidences of asthma events and the severity of these events can be given to the parents. The incidence of events and the severity of symptoms can be compiled with the data obtained by Medicaid and the physician to total the costs of health services and the efficacy of the program. The pregnant subjects can be given a questionnaire after giving birth asking about any pregnancy complications and the incidence of a low birthweight along with its associated costs can be documented. Comparing the low birthweight weight costs from non-smoking women, it can be determined if the Zyban therapy was effective in saving costs.

DISCUSSION AND CONCLUSION

While both studies include follow up visits to determine quit rates and outcome effects on the children or infants involved, in fact none of these data need be collected to conduct a simple cost analysis which the MassHealth director seems to want. Quite simply, having defined the patient panels and protocols for cessation therapy, data for related health care costs can be extracted from the Medicaid database for the child or infant being followed. Using specific Medicaid codes for asthma related treatments or post-natal care, the costs per individual can be generated and the average calculated for each control or treatment group. Since the required outcome seems to be a cost savings equal to the cost of providing Zyban, the calculation should be very straightforward. Other outcomes (quit rates, severity of symptoms, etc.) may be collected for possible publication, but may be essentially irrelevant to achieving the goal of getting Zyban added to the Massachusetts Medicaid formulary.

The outcomes of the two previous studies can be collected and analyzed within a 1-2 year period, which is relatively short term. Many of the studies referenced here are not exact and certain in the direct effects of smoking on health and medical care costs and the effectiveness of smoking cessation on saving money. Ideally, the goal is to present an effective cessation program to increase overall quit rates, and thus the overall health of Massachusetts residents. Ultimately, however, if either one of the studies is carried out and proves effective in saving money, demonstration of increases in smoking cessation are not necessary. As cynical as this point of view is, if we can get the state Medicaid system to approve this drug for its recipients by pure numbers of dollars, then our mission

to provide a way for the uninsured and indigent population to potentially improve the quality of their health will have been accomplished.

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Table 1

Prevalence of Asthma History by History of Allergy and Smoking Variables

	No Allergy			Any Allergy		
	No.	Cases (%) of Ever-Asthma	Cases (%) of Recent Asthma	No.	Cases (%) of Ever-Asthma	Cases (%) of Recent Asthma
Paternal smoking status						
Nonsmoking	224	6 (2.7)	4 (1.8)	137	32 (23.4)	28 (20.4)
Ex-smoking	182	3 (1.6)	1 (0.5)	128	29 (22.7)	24 (18.8)
Smoking	142	8 (5.6)	5 (3.5)	79	15 (19.0)	12 (15.2)
Maternal smoking status						
Nonsmoking	283	5 (1.8)	4 (1.4)	180	37 (20.6)	33 (18.3)
Ex-smoking	144	6 (4.2)	3 (2.1)	96	23 (24.0)	19 (19.8)
Smoking	121	6 (5.0)	3 (2.5)	68	16 (23.5)	12 (17.6)
Number of household smokers						
0	369	6 (1.6)	3 (0.8)	239	55 (23.0)	47 (19.7)
1	112	5 (4.5)	3 (2.7)	70	12 (17.1)	10 (14.3)
≥2	67	6 (9.0)	4 (6.0)	35	9 (25.7)	7 (20.0)
Total daily cigarette consumption						
None	369	6 (1.6)	3 (0.8)	239	55 (23.0)	47 (19.7)
1-19	73	4 (5.5)	3 (4.1)	43	10 (23.3)	8 (18.6)
≥20	106	7 (6.6)	4 (3.8)	62	11 (17.7)	9 (14.5)
Cigarettes smoked daily at home						
None	370	6 (1.6)	3 (0.8)	239	55 (23.0)	47 (19.7)
1-9	66	3 (4.5)	2 (3.0)	31	5 (16.6)	5 (16.1)
≥10	112	8 (7.1)	5 (4.5)	74	16 (21.6)	12 (16.2)

This is a table two categories of target children in this study. A "non-allergic" and "allergic" column, each subdivided into cases of ever-asthma (any previous asthma events) and recent asthma (event in the past 12 months). Each result according to the different variables are listed as case numbers and the percentage of the total population in that specific population is in parentheses next to the case number.

Table 2

Unadjusted and Adjusted* Odds Ratios (OR) and 95% Confidence Intervals (CI) for Asthma in Relation to Smoking Variables among Nonallergic and Allergic Children

	No Allergy		Any Allergy	
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Paternal smoking status				
Nonsmoking†	1.00	1.00	1.00	1.00
Ex-smoking	0.61 (0.15–2.47)	0.58 (0.14–2.39)	0.96 (0.54–1.70)	0.80 (0.43–1.48)
Smoking	2.17 (0.74–6.39)	2.47 (0.74–7.86)	0.77 (0.39–1.53)	1.04 (0.49–2.21)
Maternal smoking status				
Nonsmoking†	1.00	1.00	1.00	1.00
Ex-smoking	2.42 (0.73–8.06)	2.57 (0.75–8.79)	1.22 (0.67–2.20)	1.28 (0.67–2.43)
Smoking	2.90 (0.87–9.69)	2.93 (0.80–10.66)	1.19 (0.61–2.32)	1.80 (0.85–3.78)
Number of household smokers				
0†	1.00	1.00	1.00	1.00
1	2.83 (0.85–9.44)	3.42 (0.95–12.33)	0.69 (0.35–1.38)	0.98 (0.46–2.10)
≥2	5.95 (1.86–19.05)	5.77 (1.59–20.99)	1.16 (0.51–2.62)	1.54 (0.62–3.83)
Total daily cigarette consumption				
None†	1.00	1.00	1.00	1.00
1–19	3.51 (0.96–12.75)	3.96 (1.01–15.42)	1.01 (0.47–2.19)	1.14 (0.49–2.66)
≥20	4.28 (1.41–13.02)	4.58 (1.34–15.68)	0.72 (0.35–1.48)	1.17 (0.53–2.62)
Cigarettes smoked daily at home				
None†	1.00	1.00	1.00	1.00
1–9	2.89 (0.70–11.85)	3.43 (0.77–15.27)	0.64 (0.24–1.76)	1.10 (0.38–3.21)
≥10	4.67 (1.58–13.75)	4.81 (1.47–15.69)	0.92 (0.49–1.73)	1.18 (0.58–2.42)

* Adjustment for gender (male, female), age (6–8, 9–11, 12–14, 15–17 years), parental history of asthma (yes, no), year that home was built (before 1980, during or after 1980, unknown), and number of household members (<5, ≥5).

† Referent category.

25 Table 2 shows the odds ratios for ever-asthma in relation to each measure of ETS exposure after adjustment for the effects of gender, age, parental history of asthma, number of household smokers, and year that home was built.

Table 3

Effect of the Spontaneous Smoking Cessation Rate
on Break-even Costs of Programs with Differing Smoking-
Cessation Effectiveness Rates

Baseline Quit Rate	Program Costs (\$) by Program Effectiveness Rate		
	3%	18%	29%
6%	21	124	201
15%	19	113	182
37%	14	84	135

** Maximum cost possible for program to be considered cost-effective. Note that the lower the baseline quit rate, the more a program can cost to achieve a given effectiveness rate.*

Table 4

		Effects of Reductions in Smoking Prevalence*						
		Year						
		1	2	3	4	5	6	7
		One-time 1% reduction in smoking prevalence						
Cases avoided annually**								
AMI		924 (679)	2098 (691)	2704 (674)	3011 (645)	3160 (640)	3226 (640)	3234 (623)
Stroke		538 (508)	1146 (599)	1457 (510)	1593 (439)	1655 (413)	1671 (415)	1669 (409)
Savings, millions of US dollars								
Annual		44 (26)	102 (28)	136 (27)	153 (25)	163 (25)	167 (25)	168 (25)
Cumulative		44 (26)	146 (48)	282 (69)	435 (90)	598 (111)	765 (133)	933 (155)
		Annual 1% reduction in smoking prevalence						
Cases avoided annually**								
AMI		924 (679)	3022 (1228)	5725 (1765)	8736 (2303)	11 896 (2862)	15 122 (3427)	18 356 (3986)
Stroke		538 (508)	1684 (905)	3141 (1211)	4734 (1497)	6389 (1792)	8060 (2097)	9729 (2403)
Savings, millions of US dollars								
Annual		44 (26)	146 (48)	282 (69)	435 (90)	598 (111)	765 (133)	933 (155)
Cumulative		44 (26)	191 (67)	474 (128)	909 (209)	1506 (313)	2272 (439)	3205 (587)

*Numbers in parentheses are SDs.

**Cases avoided does not include deaths before reaching the hospital.

Table 5

Smoking-attributable fractions (SAFs) of publicly funded medical expenditures, by state and type of expenditure, 1993

State	Ambulatory care	Prescription drugs	Hospital care	Home health services	Nursing home	Total
Alabama	7.15	9.56	15.62	7.16	7.52	9.01
Alaska	12.98	17.26	26.24	7.71	17.46	16.85
Arizona	8.47	12.76	18.65	7.43	14.87	14.25
Arkansas	11.74	11.77	21.20	12.13	12.81	13.61
California	12.73	14.67	20.27	4.73	14.72	16.22
Colorado	13.36	15.43	26.59	6.26	16.52	16.57
Connecticut	11.92	12.45	18.18	8.26	12.66	12.56
Delaware	12.94	12.83	21.48	10.49	15.43	15.59
District of Columbia	5.76	8.02	13.09	4.62	6.86	8.57
Florida	12.50	13.72	21.78	8.24	14.80	15.56
Georgia	11.06	12.10	18.94	8.98	10.03	12.84
Hawaii	11.08	14.25	21.05	7.47	13.46	14.33
Idaho	11.71	14.29	22.34	8.49	13.15	14.35
Illinois	11.01	15.36	24.29	7.45	16.24	18.13
Indiana	12.30	14.76	24.99	7.04	11.84	15.08
Iowa	11.01	12.86	21.26	6.59	13.56	14.17
Kansas	11.98	13.63	22.46	5.60	13.71	14.51
Kentucky	12.38	15.06	22.85	8.21	15.72	15.40
Louisiana	11.91	13.20	21.41	7.69	14.66	16.58
Maine	13.57	15.50	23.26	8.21	14.35	16.00
Maryland	11.67	12.82	20.10	9.49	13.14	14.79
Massachusetts	12.57	14.87	19.94	8.29	13.84	14.33
Michigan	13.37	15.52	25.79	7.47	14.53	16.43
Minnesota	13.60	13.56	26.20	6.34	10.06	12.52
Mississippi	10.85	11.85	18.16	6.85	13.91	13.62
Missouri	12.84	12.64	20.64	10.45	13.01	14.13
Montana	10.60	12.65	19.01	8.23	12.39	12.89
Nebraska	10.62	11.88	19.44	7.07	10.75	12.14
Nevada	12.16	18.31	25.57	8.65	22.60	19.24
New Hampshire	13.02	14.17	22.43	6.69	13.80	12.71
New Jersey	11.46	13.72	20.16	10.28	16.51	15.80
New Mexico	10.07	14.04	23.94	7.65	12.33	14.58
New York	11.95	14.34	23.14	13.67	13.74	15.83
North Carolina	10.44	12.68	21.69	9.95	10.86	13.27
North Dakota	10.52	11.74	19.90	6.32	9.82	10.93
Ohio	12.33	16.10	24.03	10.92	16.90	16.95
Oklahoma	11.12	11.15	23.31	6.07	10.14	12.72
Oregon	12.35	14.10	22.15	8.12	16.02	13.40
Pennsylvania	12.11	14.52	22.79	6.39	14.92	16.36
Rhode Island	13.50	13.72	22.58	8.59	12.96	14.52
South Carolina	11.18	12.07	19.87	8.48	10.89	13.63
South Dakota	10.16	11.92	21.76	5.02	12.60	12.57
Tennessee	11.20	15.12	22.69	7.21	14.26	14.81
Texas	10.37	12.69	22.04	13.55	13.69	15.05
Utah	9.05	10.83	20.09	3.61	9.30	11.92
Vermont	12.07	16.27	25.12	6.41	15.22	14.43
Virginia	11.57	13.49	19.15	10.65	13.85	14.18
Washington	12.85	14.30	21.66	7.27	16.92	16.29
West Virginia	10.89	13.84	23.38	7.13	13.62	14.07
Wisconsin	11.34	12.80	20.92	9.67	13.40	13.93
Wyoming ^a	11.80	12.54	22.70	4.59	12.84	14.33
Mean	11.51	13.52	21.69	7.92	13.51	14.36

NOTE: SAFs are expressed as percentages of Medicaid expenditures, reduced by amounts spent for people under 19 years old and for family planning, mental hospitals, mental retardation services, and dental services. State SAFs are evaluated for the poor and low-income population with weights equal to BRFSS individual weights.

^aWyoming has no BRFSS dataset. The Wyoming SAFs were computed as the mean of the SAFs of its contiguous states: Montana, Idaho, Utah, Colorado, South Dakota, and Nebraska.

Table 6

Smoking-attributable Medicaid expenditures by state and type of expenditure, fiscal year 1993
(in thousands)

State	Ambulatory care	Prescription drugs	Hospital care	Home health services	Nursing home	Total
Alabama.....	\$17,273	\$10,083	\$56,404	\$1,172	\$22,372	\$107,304
Alaska.....	7,823	1,782	8,195	29	5,789	23,617
Arizona.....	31,516	779	79,931	254	9,366	121,846
Arkansas.....	21,294	6,051	22,924	687	27,500	78,456
California.....	272,240	139,845	1,078,348	716	241,600	1,732,749
Colorado.....	29,001	7,981	75,849	764	37,904	151,500
Connecticut.....	32,539	8,840	61,231	4,099	75,046	181,755
Delaware.....	5,888	1,262	7,176	816	7,703	22,845
District of Columbia.....	3,490	1,433	22,587	472	7,848	35,830
Florida.....	118,297	42,579	204,648	5,356	146,101	516,980
Georgia.....	59,712	18,508	125,056	2,600	46,060	251,936
Hawaii.....	8,037	2,782	20,409	103	12,728	44,059
Idaho.....	6,943	2,344	7,983	109	7,965	25,343
Illinois.....	60,083	38,420	317,997	721	143,408	560,629
Indiana.....	50,101	25,333	96,600	1,876	80,982	254,892
Iowa.....	14,954	7,778	27,743	1,027	27,882	79,384
Kansas.....	13,292	7,231	27,424	379	23,975	72,300
Kentucky.....	53,354	21,252	77,126	4,145	44,863	200,740
Louisiana.....	55,817	24,732	259,635	1,297	75,544	417,026
Maine.....	18,082	6,621	41,820	717	28,623	95,862
Maryland.....	44,766	11,240	102,440	3,196	50,662	212,304
Massachusetts.....	71,662	23,350	163,184	5,267	142,481	405,943
Michigan.....	111,036	29,652	257,278	1,890	132,723	532,580
Minnesota.....	49,473	10,667	52,176	1,327	73,203	186,846
Mississippi.....	19,540	10,828	53,620	437	26,704	111,130
Missouri.....	33,777	18,995	101,701	565	51,884	206,923
Montana.....	8,844	2,221	6,335	145	10,519	28,065
Nebraska.....	9,810	4,142	12,142	616	16,724	43,434
Nevada.....	7,222	1,852	27,748	367	12,947	50,137
New Hampshire.....	11,507	2,760	61,795	145	18,325	94,531
New Jersey.....	70,594	31,090	284,444	9,174	149,405	544,708
New Mexico.....	12,965	3,395	21,772	304	9,877	48,314
New York.....	309,407	75,606	961,369	60,260	444,050	1,850,692
North Carolina.....	48,558	16,580	80,511	4,209	55,742	205,600
North Dakota.....	4,445	1,282	5,292	128	7,910	19,056
Ohio.....	73,167	45,673	243,456	2,566	232,356	597,217
Oklahoma.....	19,948	6,833	32,675	28	20,621	80,105
Oregon.....	37,608	7,719	20,091	123	23,690	89,231
Pennsylvania.....	77,016	53,056	210,607	1,717	263,119	605,516
Rhode Island.....	18,955	3,572	49,188	242	24,927	96,884
South Carolina.....	24,023	8,889	88,870	523	19,740	142,044
South Dakota.....	4,398	1,272	5,959	73	9,038	20,740
Tennessee.....	47,326	25,079	159,051	965	67,459	299,880
Texas.....	122,706	32,608	370,230	2,242	126,216	654,003
Utah.....	7,516	2,583	18,287	89	5,737	34,211
Vermont.....	8,112	2,854	8,572	213	9,274	29,025
Virginia.....	39,539	17,787	59,422	954	44,862	162,564
Washington.....	58,490	14,936	95,810	619	67,304	237,159
West Virginia.....	31,164	9,089	52,185	982	25,815	119,235
Wisconsin.....	45,166	17,058	44,992	3,875	86,836	197,927
Wyoming ^a	3,634	744	4,031	44	2,995	11,449
Total.....	\$2,312,108	\$869,047	\$6,274,322	\$130,624	\$3,306,405	\$12,892,507

NOTE: Smoking-attributable Medicaid expenditures (SAEs) include the Federal share of Medicaid expenditures. State SAEs are evaluated with state SAFs for the poor and low-income population with weights equal to BRFSS individual weights.

^aWyoming has no BRFSS dataset. The Wyoming SAFs were computed as the mean of the SAFs of its contiguous states: Montana, Idaho, Utah, Colorado, South Dakota, and Nebraska.

Table 7

POINT-PREVALENCE SMOKING-CESSATION RATES CONFIRMED BY CARBON MONOXIDE MEASUREMENT.*								
TIME AFTER TARGET QUITTING DATE	PERCENTAGE OF SUBJECTS NOT SMOKING				OVERALL	P VALUE†		
	PLACEBO (N=153)	100 mg OF BUPROPION (N=153)	150 mg OF BUPROPION (N=153)	300 mg OF BUPROPION (N=156)		PLACEBO VS. 100-mg DOSE	PLACEBO VS. 150-mg DOSE	PLACEBO VS. 300-mg DOSE
6 wk‡	19.0	28.8	38.6	44.2	<0.001	0.04	<0.001	<0.001
3 mo	14.4	24.2	26.1	29.5	0.01	0.03	0.01	<0.001
6 mo	15.7	24.2	27.5	26.9	0.06	0.06	0.01	0.02
12 mo	12.4	19.6	22.9	23.1	0.06	0.09	0.02	0.01

*Point prevalence was estimated weekly.

†The P values given are from analyses that did not include site as a covariate; therefore, they can be obtained directly from the given cessation rates. In logistic-regression analyses that included site as a covariate the same differences were found to be statistically significant. The overall P value is for the simultaneous comparison of all four groups treated categorically. When dose was treated as a continuous variable, a significant dose effect was detected at all times ($P < 0.001$ at week 6, $P = 0.003$ at 3 months, $P = 0.03$ at 6 months, and $P = 0.02$ at 12 months). The pairwise dose comparisons presented were identified a priori, and the corresponding P values are unadjusted.

‡Week 6 was the final week of study medication.

Table 8

The Cost-effectiveness of the Nicotine Patch Compared With Screening for Asymptomatic Hypertension*

Sex, Age (y)	Nicotine Patch, \$/QALY	Screening for Asymptomatic Hypertension, \$/QALY
Men, 40 y	6852	27 576
Women, 40 y	8332	39 867
Men, 60 y	10 626	14 185
Women, 60 y	8729	21 011

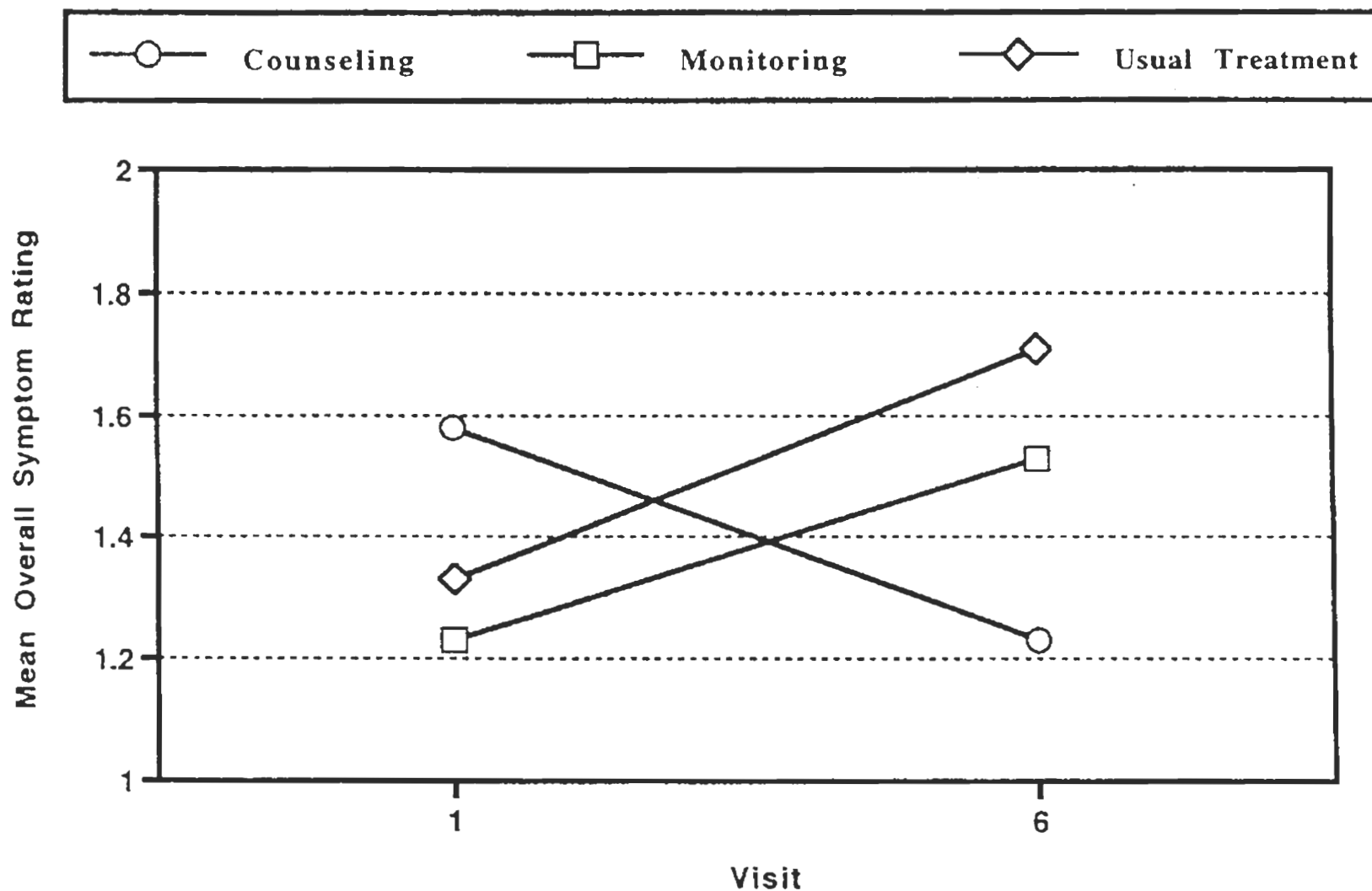
*Ratios based on 1995 US dollars and quality-adjusted life years (QALYs); a discount rate of 5% was used for purposes of comparison; data on hypertension was derived from Littenberg et al.⁴⁷

Table 9

Medicaid Recipients/Demographics

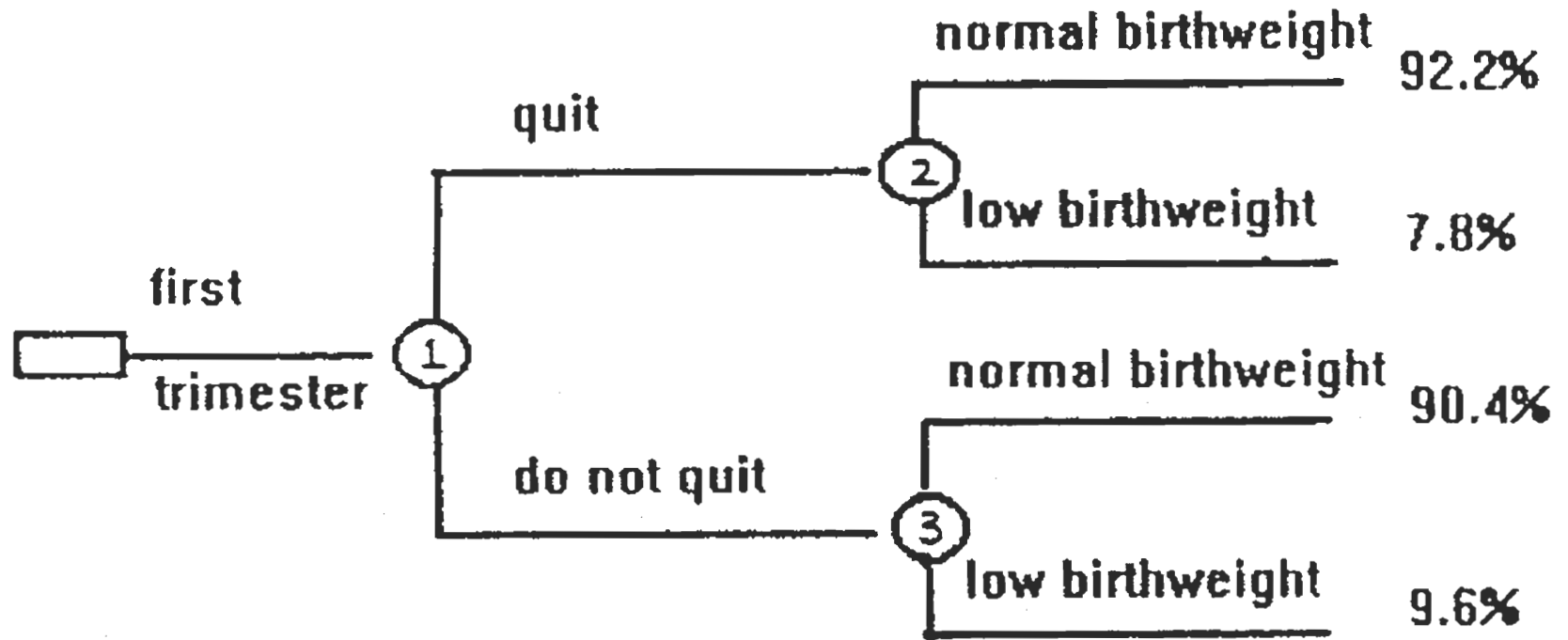
Fiscal Year 1995 Medicaid Recipients (In millions)		Percent Distribution
Total Recipients	36.3	100.0
Age	36.3	100.0
Under 21	18.7	51.5
21-64 years	11.4	31.5
65 years and over	4.4	12.2
Unknown	1.7	4.8
Sex	36.3	100.0
Male	13.2	36.5
Female	21.2	58.5
Unknown	1.8	5.0
Race	36.3	100.0
White	16.5	45.5
Black	9.0	24.7
Am. Indian/Alaskan Native	0.3	0.8
Asian/Pacific Islander	0.8	2.2
Hispanic	6.2	17.2
Unknown	3.5	9.7

Figure 1 Mean Overall Symptoms Rating of Asthma Events



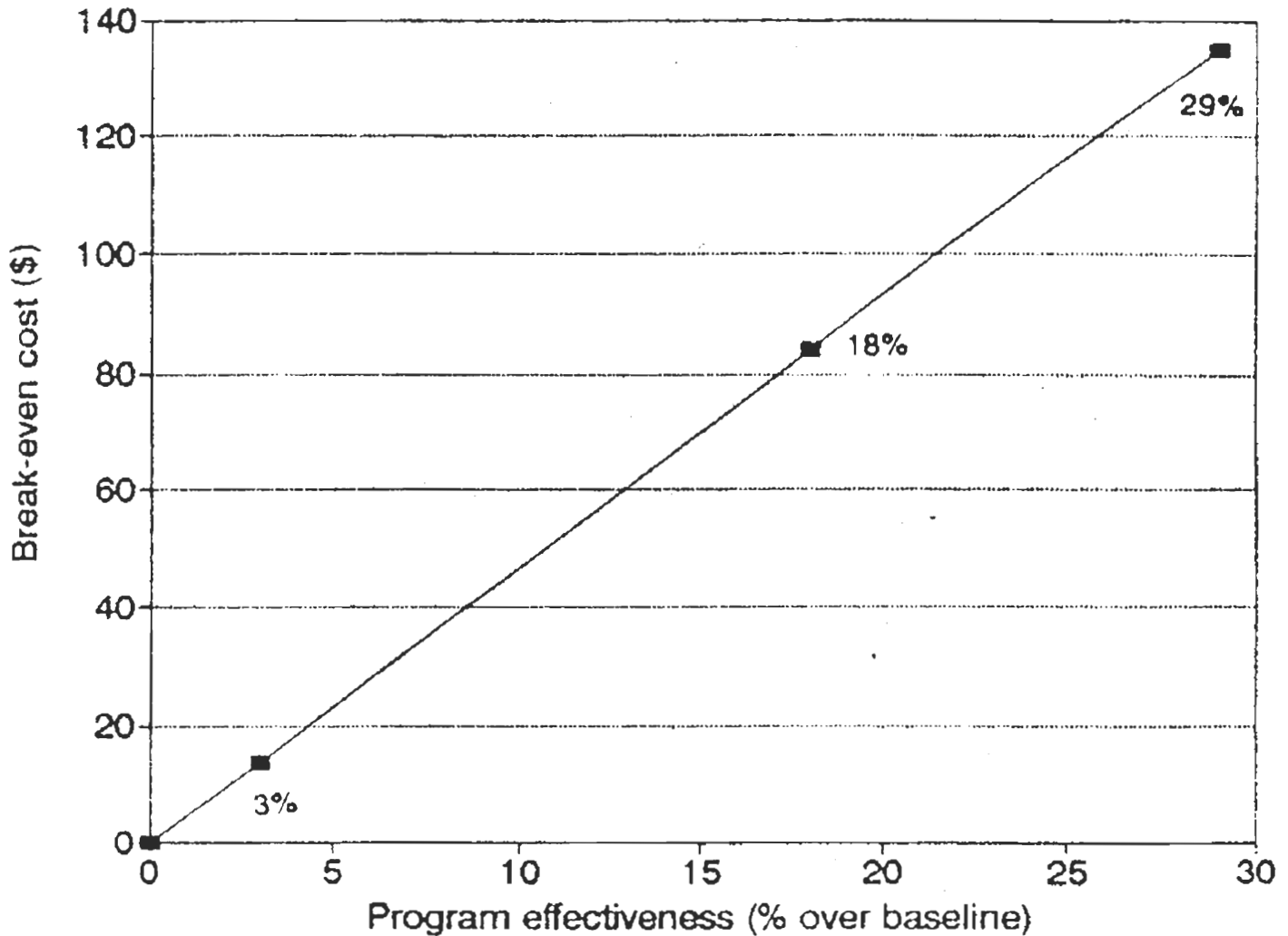
Mean 2-week overall symptom ratings by group for the first and last (sixth) clinic visits (0=none, 1=mild, 2=modest, 3=moderate, 4=severe).

Figure 2



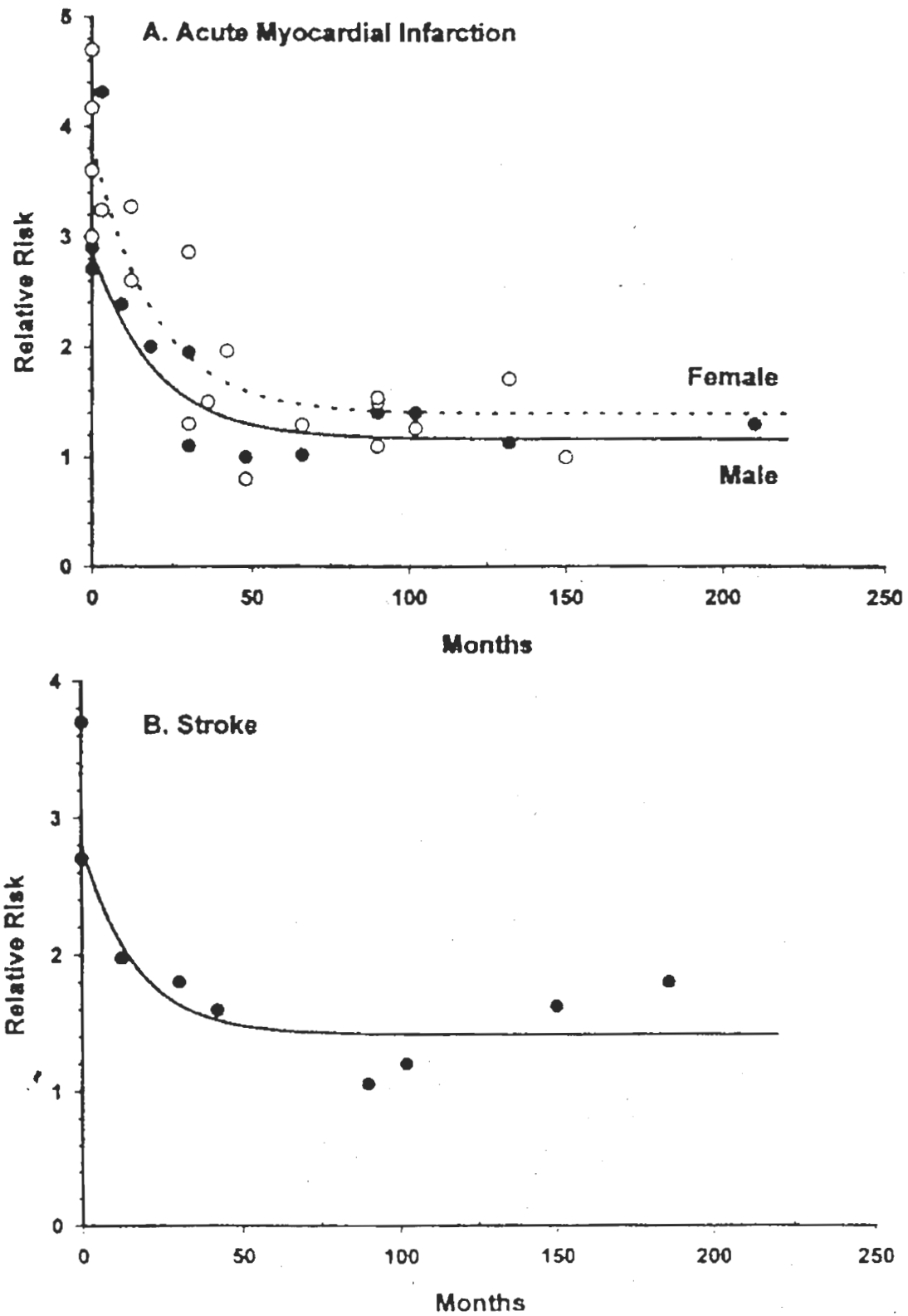
Decision model used in an analysis of the effect of smoking cessation programs on the outcome of low birthweight. Chance nodes mark the point at which the patients decided whether to quit smoking (1), and the effect of their decisions on the rate of low birthweight deliveries (2 and 3).

Figure 3



The impact of smoking cessation program effectiveness on the calculated break-even costs for programs. Costs for programs of a given effectiveness rate would have to fall below the solid line to be considered cost-effective.

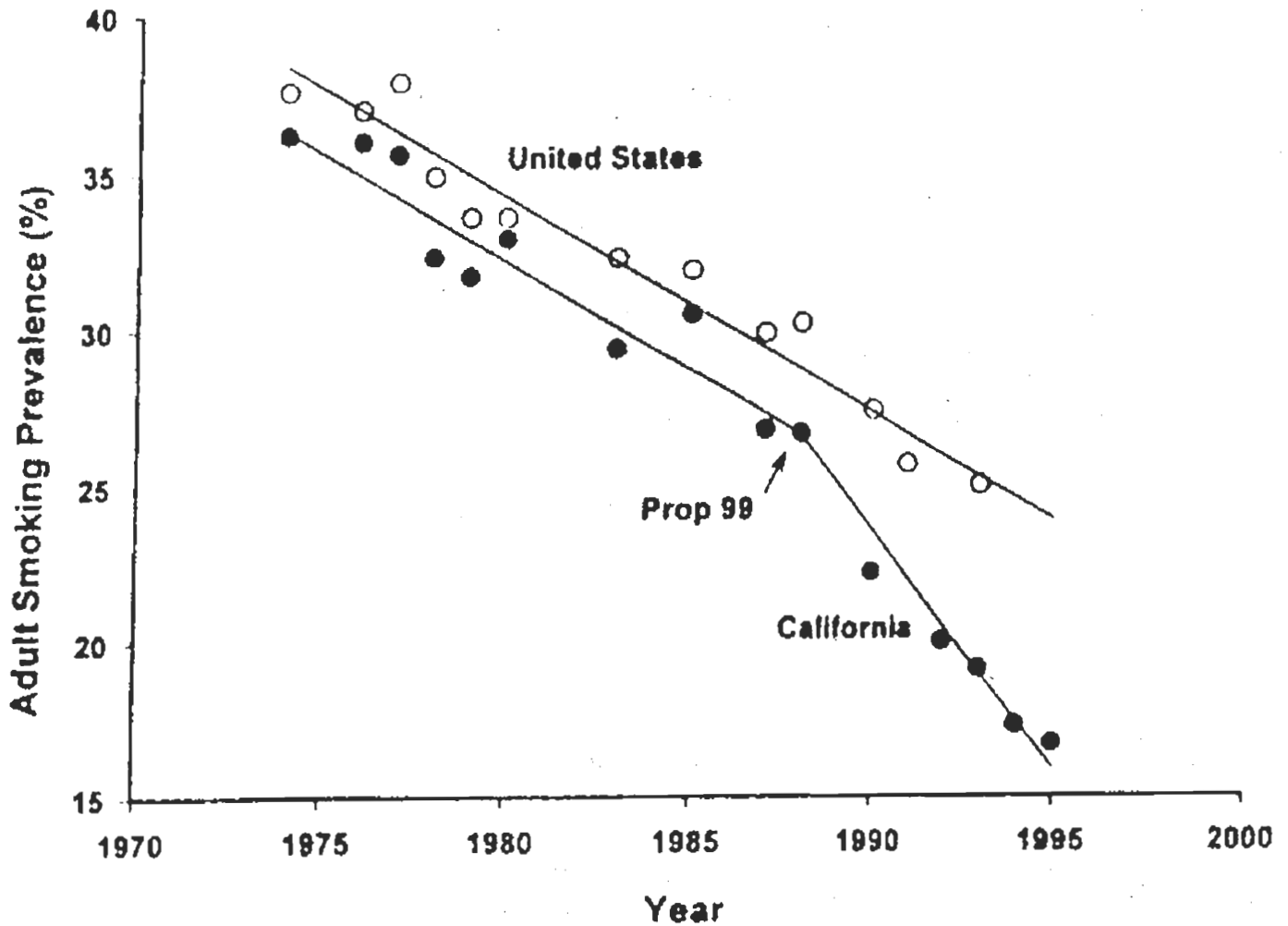
Figure 4



Estimated decline in RR for AMI (A; ●, male; ○, female) and stroke (B) over time after smoking cessation.

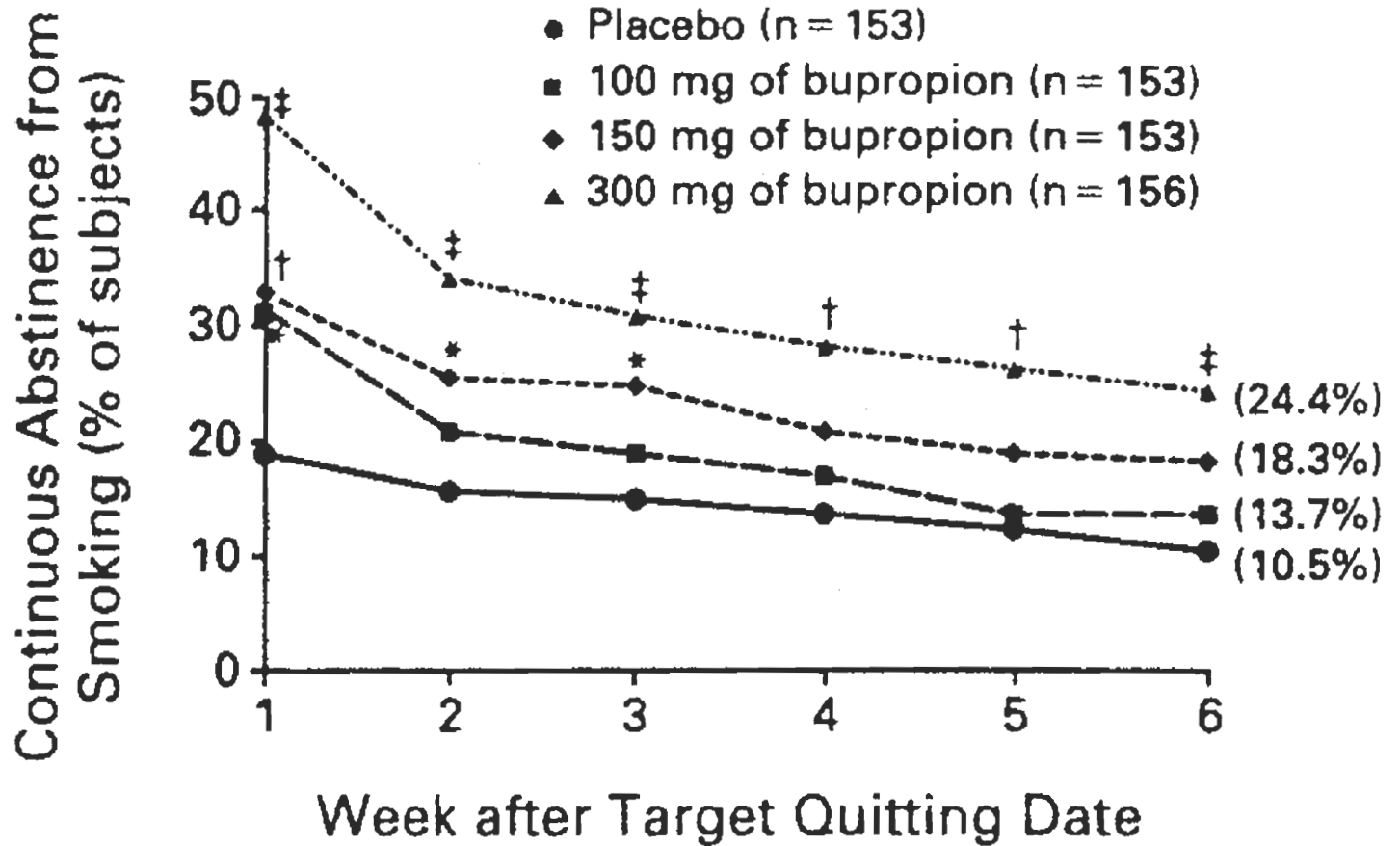
Figure 5

Adult Smoking Prevalence



Proposition 99 accelerated the historical decline in smoking prevalence in California by $\approx 1\%$ per year. Data source: California Department of Health Services.

Figure 6

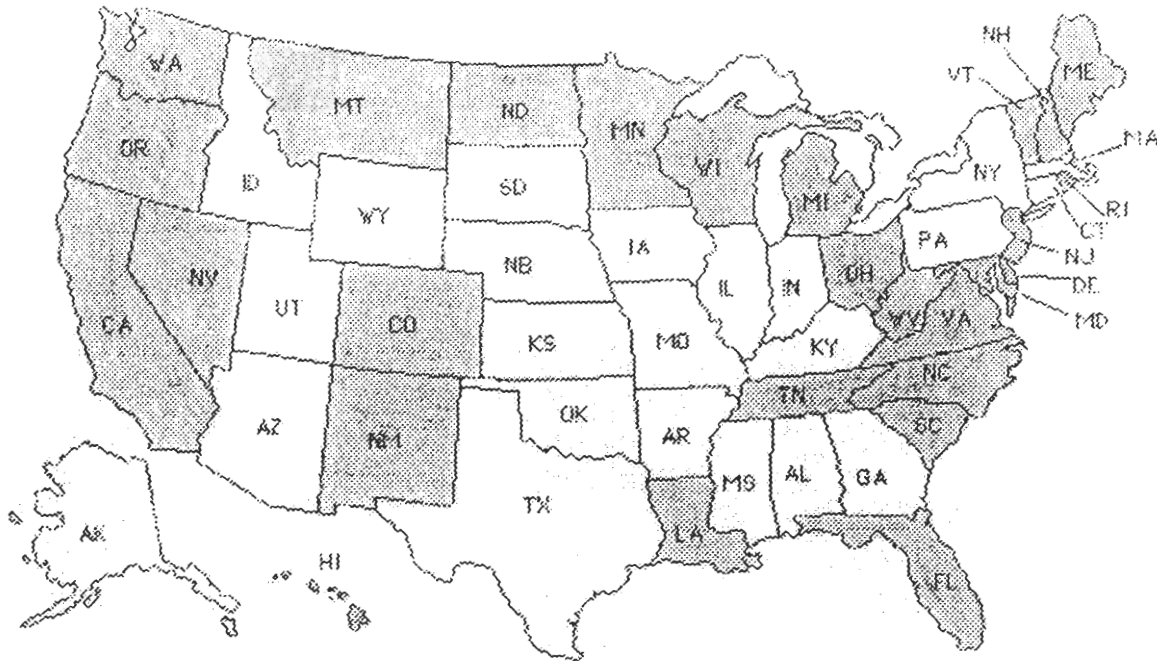


Rates of Confirmed Continuous Abstinence from the Target Quitting Date through the End of Treatment.

Self-reported abstinence was confirmed by a finding of an expired carbon monoxide concentration of 10 ppm or less. The asterisks ($0.01 < P \leq 0.05$), daggers ($0.001 < P \leq 0.01$), and double daggers ($P \leq 0.001$) indicate significant differences from placebo. All subjects are included at all time points.

Figure 7

States which provide Zyban™ to Medicaid recipients
(from HCFA state drug utilization data, 6/99)



- | | | |
|----------------------|----------------|---------------|
| Colorado | California | Delaware |
| District of Columbia | Florida | Hawaii |
| Louisiana | Maine | Maryland |
| Michigan | Minnesota | Montana |
| Nevada | New Hampshire | New Jersey |
| New Mexico | North Carolina | North Dakota |
| Ohio | Oregon | Rhode Island |
| South Carolina | Tennessee | Vermont |
| Virginia | Washington | West Virginia |
| Wisconsin | | |