the gum The results also showed that there were no significant differences in signs and symptoms of withdrawal between placebo gum and 2 mg nicotine gum The second study involved a comparison of signs and symptoms of withdrawal from placebo, 2, and 4 mg gum, and a comparison of these findings to those obtained in studies of tobacco cigarette withdrawal We also examined whether the dose of gum or severity of withdrawal subjects experienced following abstinence from gum use was a determinant of whether subjects continued to use the gum or relapsed to cigarette smoking Subjects were withdrawn from cigarettes for four days during which previously validated signs and symptom of withdrawal were measured Subjects were then randomly assigned to either placebo, 2 or 4 mg nicotine gum in a double-blind manner for a period of one month They were then withdrawn from the gum and signs and symptoms of withdrawal were measured again over the course of four days Gum was made available to subjects if they chose to continue use of gum, and follow-up was conducted at one, three and six months to determine smoking and gum use status Thus far, the results indicate that subjects experienced more severe withdrawal symptoms during cigarette deprivation that nicotine gum deprivation Interestingly, there were no differences in severity of withdrawal between those subjects who were prescribed placebo, 2 and 4 mg gum with exception of a measure of craving for tobacco No differences were found in spite the fact that we asked all subjects to chew at least six pieces of gum per day Preliminary results also showed that the dose of the gum did not predispose further use of the gum Data regarding relapse to smoking is pending In summary, the results show that among subjects who quit smoking, there is a relatively high prevalence of persistence of gum use However, this continued use may not be a simple function of avoiding signs and symptoms of withdrawal from nicotine gum or dose of the gum

OPTIMAL COMBINATIONS OF NICOTINE DOSAGE FORM AND BEHAVIORAL INTERVENTION John Grabowski, Ph D Tufts University

Tobacco dependence constitutes a prototypic form of drug dependence but also represents well the most complex form of biobehavioral and behavioral medicine disorder There is ample evidence from the behavioral pharmacology laboratory and clinic that the use of nicotine polarcrilex, gum, can effectively produce the pharmacological effects that are also obtained when tobacco cigarettes are smoked Behavioral and physiological abstinence symptoms can be reversed by readministration of nicotine in this form Maintenance of tobacco cessation can thus be assisted with this pharmacological adjunct Behavioral intervention techniques have been implemented to reduce tobacco use As in the case of nicotine polarcrilex, some advantage emerges in the maintenance of smoking cessation, even when nicotine replacement is also maintained In combination, behavioral and pharmacological strategies have proven variably effective at reducing smoking The results to date suggest that there is a need to reexamine the basic behavioral-pharmacological models and common strategies in treatment and to determine whether improved combinations of pharmacological adjuncts and behavioral intervention strategies will improve success rates A three-stage model of cessation is proposed Consideration is given to the natural history of acquisition of tobacco use, duration of treatment, optimal behavioral strategies and optimal dosage preparation forms of pharmacological adjuncts

PROBLEMS AND CHALLENGES FOR NICOTINE REPLACEMENT John D Slade, M D University of Medicine and Dentistry of New Jersey St Peters Medical Center

The basis for our knowledge of the clinical utility of nicotine replacement has depended upon studies of volunteers participating in controlled trials These settings sometimes differ from typical clinical settings in a number of ways which may have important effects on the efficacy of the nicotine replacement in clinical practice The level of motivation and expectations about therapy are obvious patient variables which may be different The interest level, understanding and support of the provider has both positive and negative influences upon the probability of achieving a stable abstinence, and these are expecteed to vary in important ways as well These issues can be specifically addressed in post-marketing surveillance programs and focused studies which consider problems such as the following Most people who try to quit fail What factors improve the chances of their making further quit attempts? Is failure after nicotine replacement more likely to lead to postponing the next quit attempt than failure after other therapies? Consideration of the over-the-counter (OTC) availability of nicotine raises additional questions about efficacy and safety, including possible increase in the use of nicotine gum by people who continue to smoke Might pharmacist prescription of nicotine provide better results than either physician prescription or OTC availability because of convenience and better follow-up? Pharmacist prescription could also form the basis of sound post-marketing surveillance, while this would be difficult with OTC marketing Other challenges for nicotine replacement include questions about nicotine maintenance versus nicotine withdrawal, and the general policy question of nicotine's regulatory status, and the possible implications of regulatory status of nicotine replacement modalities for therapeutic intervention

PUBLIC POLICY ISSUES ASSOCIATED WITH NICOTINE Gregory N Connolly, D M D , M P H Division of Dental Health, Massachusetts Department of Public Health

This presentation will discuss public policy issues associated with the promotion and sale of three types of non-smoked nicotine replacement products that have been recently developed The products include low-nicotine containing pouches of moist snuff, nicotine vapor inhalers (smokeless cigarettes or nicotine tubes), and nicotine polacrilex (gum) All of these products have been recently developed and have been marketed in different ways as nicotine replacement devices Marketing practices including product design, distribution, promotion and advertising will be reviewed, and comparisons made among the products The target audiences for the devices will also be described, and, to the extent that data are available, user demographics will be discussed Based on industry marketing strategies and trends in product use, it appears that the pouches of moist snuff have become popular among young males and serve as initiating devices into nicotine use by persons with no previ-

ous history of cigarette smoking The nicotine tube has been marketed as a nicotine delivery system that allows smokers to obtain nicotine from the tube in settings where smoking is prohibited The manufacturer makes no health claims about the product Its use may remove environmental pressures to quit smoking and help maintain tobacco dependence The effectiveness of the tube in delivering nicotine to the body has been questioned Nicotine gum has been marketing as a therapeutic device to aid nicotine dependent users in abstaining from tobacco cigarettes The gum is dispensed only through the prescription of a physician, although its acceptance by the medical community has not met initial expectations of some The proliferation of nicotine delivering devices has raised a number of public policy issues Recent state and federal actions that regulate the devices or their marketing will be discussed as well as future policy trends

SYMPOSIUM

The Impact of Diet on Mood States

Monday August 31, 1987 • 2 00 p m –2 50 p m
Marriott Marquis Hotel • Empire/Hudson/Chelsey Room

Chair *Larry Christensen*, Texas A&M University

THE BIPHASIC EFFECT OF CALCIUM ON MOOD AND EMOTIONAL BEHAVIOR Kamyar Arasteh, Texas A&M University

Mood and emotion have been shown to be attenuated by biochemical changes The therapeutic use of pharmacological agents in the therapy of depression, for example, is an instance of the general susceptibility of emotion to physiological change Dietary substances represent a major source of the transient biochemical make-up of an organism and as such they should influence behavior, cognition, and emotion Calcium, as one of the essential minerals in the diet of humans, plays an important role in the celullar processes including neuronal transmition, and neurotransmitter secretion Moreover, because alterations in emotion have been shown to be associated with changes in the neurotransmitter function, calcium might prove influential in the emotional process In one experiment intended to assess this proposed effect, rats were maintained on a high calcium water solution and tested in a learned helplessness paradigm The high-calcium rats showed significantly longer escape latencies than their control counterparts Also, biochemical assays revealed that, in contrast to the control group, high-calcium rats had a significantly lower level of activity of the neurotransmitter 5-hydroxytryptamine, a finding associated with depression In another experiment, human participants were given a much lower dose of calcium and were then administered several scales designed to assess changes in mood and cognition The calcium group, when compared to the placebo group, showed a significant enhancement of mood It is, therefore, proposed that calcium influences mood and emotional behavior, and that this influence is exerted in a dose-dependent and biphasic fashion More specifically, small increases in the level of calcium are suggested to enhance mood, while large increases are thought to exacerbate the same

PRESENTING SYMPTOMS AND PSYCHOLOGICAL CHARACTERISTICS OF DIET INDUCED MOOD-DISTURBANCE Kelly Krietsch, Texas A&M University

Caffeine is a dietary substance that has typically been thought of as a psychoactive drug which has the effect of increasing alertness and decreasing drowsiness Since the late 1970's a number of studies have appeared which have challenged this general assumption and have revealed that caffeine seems to be related to a variety of mood states such as depression, anxiety, and irritability However, caffeine's effect is very idiosyncratic affecting different individuals in different ways Additionally, caffeine is not a substance affecting all individuals who are experiencing depression or anxiety Sucrose is another substance which seems to have a similar idiosyncratic influence on individuals Although the literature on sucrose is contradictory, evidence exists indicating that this dietary substance does have an effect on certain individuals although these individuals are definitely not those with Attention Deficit Disorder The literature is very consistent in demonstrating that the effect of sucrose, if any, is to benefit this disorder However, another body of literature indicates that sucrose seems to have the effect of increasing fatigue, reducing vigor and increasing depression But sucrose is not related to all individuals with such symptoms Therefore, several studies were conducted which attempted to identify the presenting symptoms and the psychological characteristics of individuals who possessed symptoms induced by dietary caffeine and dietary sucrose In order to identify these presenting symptoms and psychological characteristics it was necessary to identify a group of individuals who were responsive to each of these substances and then focus on the characteristics and symptoms which differentiated these two groups Double-blind challenges with dietary caffeine or sucrose were used to identify those individuals whose symptoms were totally or partially due to ingestion of caffeine and/or sucrose Analysis of the presenting symptoms revealed that the subjects responsive to these substances presented with a specific set of symptoms but they did not reveal a set of psychological characteristics which would differentiate them from those who did not respond to dietary caffeine and/or sucrose

A PSYCHOMETRIC TEST FOR IDENTIFYING A DIETARY INDUCED MOOD DISTURBANCE Larry Christensen, Texas A&M University

Within the past decade a number of studies have appeared in the literature documenting the fact that various dietary substances can have an impact on behavior Caffeine, for example, has been demonstrated to have an impact on anxiety, depression, restlessness, and irritability Sucrose has been demonstrated to have a variety of effects such as inducing sleepiness, drowsiness, and confusion, and reducing vigor The difficulty with applying this knowledge is that the affects of these dietary substances are idiosyncratic Caffeine, for example, will produce insomnia and nervousness in some people and increased alertness and a feeling of contentedness in others Similarly, sucrose has been demonstrated to produce drowsiness and confusion in some individuals but have no negative impact on other individuals such as hyperactive children In fact some evidence indicates that sucrose may be of benefit to hyperactive children Consequently, some mechanism is needed that will be able to identify those individuals that are experiencing a negative impact from the dietary substances caffeine and sucrose For the past several years we have been developing a psychometric instrument explicitly for the purpose of identifying individuals with a dietary induced mood disturbance This